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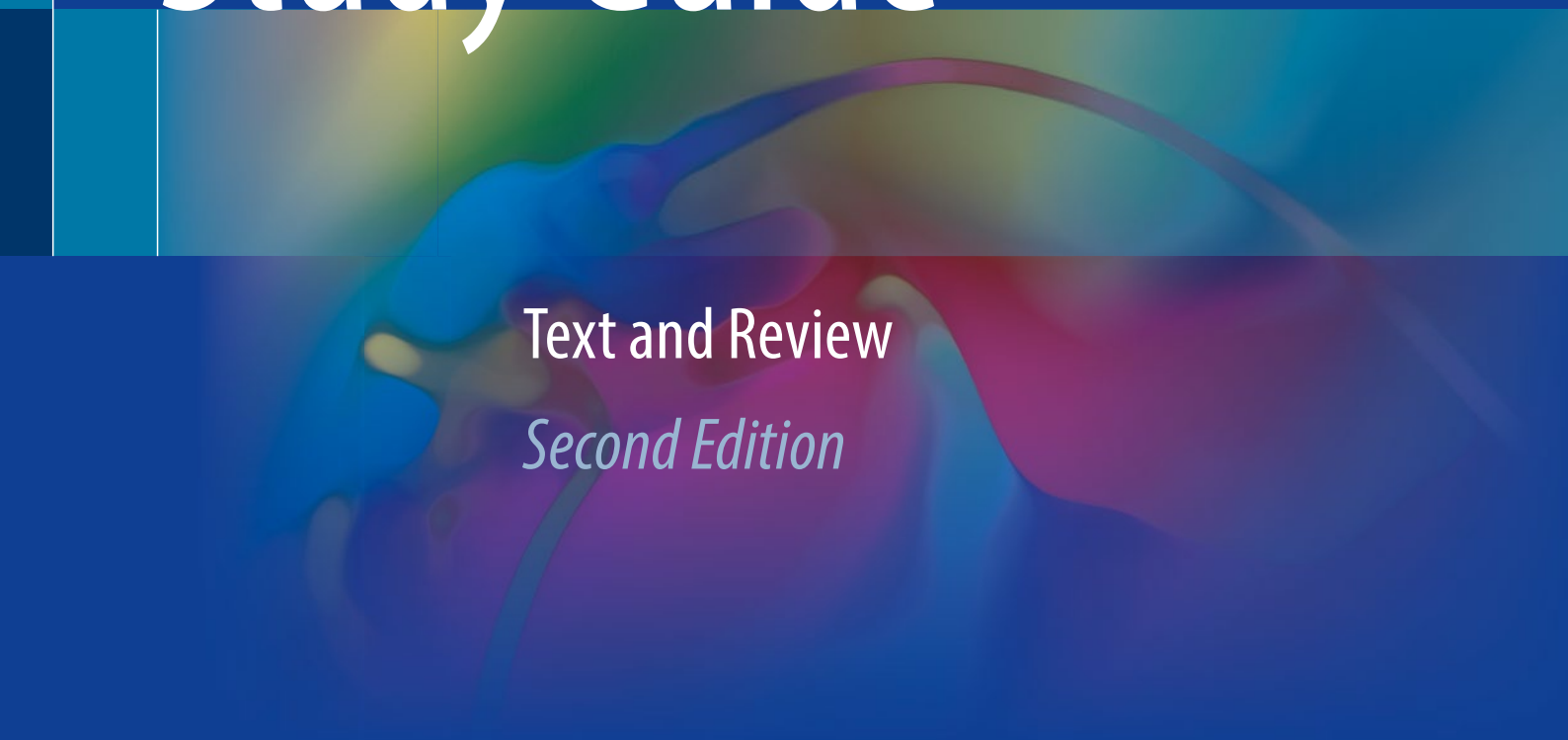
Editors

Clinical Informatics Study Guide



Text and Review

Second Edition

Springer

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Foreword

Information is not just necessary for delivering care; information arguably *IS* care. Although some clinicians, such as surgeons or physical therapists, do a lot with their hands, most clinicians work with their heads, spending practically all of their time collecting, managing, processing, and communicating information. Simply put: maximizing health for individuals and populations requires managing those factors that impact their health, and there is no management without the right information delivered to the right people at the right time in the right way to make the right decisions.

In the 1960s, there was a well-known catchphrase that "the medium is the message." First introduced in *Understanding Media: The Extensions of Man* by Marshall McLuhan, the notion was that the medium in which a message is conveyed has as much impact on individuals and society as its content. This is most evident in health care, where managing patient care requires as much or more information from patients' health records as from patients directly. The electronic health record (EHR) is the medium in which clinicians work and deeply impacts that work.

Most undergraduate medical education does not appreciate this. Medical students spend more time memorizing Krebs' tricarboxylic acid cycle (and promptly forgetting it after the test) than being trained to find, manage, and make sense of patient information and medical knowledge. They spend more time memorizing the names of the foramina in the skull than learning how to identify their patients' problems and track their management. Heretofore, clinical information management was a skill students picked up indirectly by observing others and toiling haphazardly through whatever chart or EHR system was available. Fifty years of research and development has yielded a lot of data about the potential capabilities and benefits of EHRs, yet realizing these benefits has been elusive. Although EHRs are now ubiquitous in hospitals and outpatient practices, thanks to the billions of dollars of financial incentives provided by the HITECH Act, most EHRs are optimized to manage health system logistics and billing more than clinicians' caring for patients. Consequently, EHRs have become a major source of frustration and career dissatisfaction for clinicians.

As with any major infrastructure or cultural change, hiccoughs were likely to occur with the rapid transition from paper to electronic health care records. Workflows optimized using paper-based records became dysfunctional with EHRs. Transitioning health care information management from paper to electronic media has required rethinking clinical workflow, which, in turn, has required a new generation of health care providers who understand both medicine and health care delivery as well as health information technology and its capabilities and foibles. In response to this need for people who work at the interface between the technicians who develop EHRs and other health information technology and the clinicians who use them, the American Board of Medical Specialties established clinical informatics as a formal physician subspecialty in 2011.

To be effective, clinical informaticists must be generalists with broad knowledge and experience in medicine and informatics. They must have a good basic understanding of how medicine is practiced across a broad range of specialties in both inpatient and outpatient practice venues. They must understand how work flows, or could flow, in these various venues and how

to use the information to optimize health care decision-making in the face of messy clinical data that are frequently contradictory, missing, or even plain wrong. They must realize that practically every data point is surrounded by a cloud of uncertainty that health care providers must tolerate and manage for each decision made and each action taken. Similarly, clinical informaticists must understand how health data are generated, stored, transmitted, and processed to yield useful information. They should have sufficient technical knowledge to help health system leaders make decisions about purchasing and implementing EHRs and other health information technologies. Finally, clinical informaticists must understand organizational behavior and management to leverage health data and meta-data to improve health care quality, safety, and efficiency.

Fifty years of rapidly—yet chaotically—evolving health information and its underlying technology has characterized the field of clinical informatics. The editors and authors of this textbook have collated and organized experiences and lessons from the field into a useful, comprehensive compendium that informs budding clinical informaticists while defining the knowledge gaps that need filling. The content dives deeply into data science, data models, and health information technology architectures and the interactions between health information systems and clinical medicine that must be managed if technology is to realize its promise to benefit patients, and the clinicians who serve them, as well as to enhance patient and community health. This book represents a journey into a still young and exciting field where change is constant, and an uncertain path lies before us. Today's and tomorrow's clinical informaticists will certainly be "sailing the ship while building it." Still, the knowledge and wisdom in this book will light the way by illuminating the shoulders that current and future clinical informaticists will stand on to give our patients, country, and planet the high-value health systems they want, need, and deserve.

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Preface

Although the need to manage data and information in medicine is centuries old, the medical subspecialty of clinical informatics has officially existed for only a decade. While becoming a clinical subspecialty and during the years following recognition by the American Board of Medical Subspecialties, we repeatedly discussed the need for a foundational text to support the preparation of clinical informatics leaders. As we taught this content to our graduate students, we struggled to find a single, comprehensive text that sufficiently covered the core content. We, therefore, embarked upon a journey to create the first edition of this text with the intent that it would be a valuable resource for trainees in clinical informatics fellowships, clinicians who desire to prepare for the board exam independently, as well as those ineligible for the physician board exam but are seeking to understand or advance in the field of clinical informatics.

We are delighted with the positive feedback from students, colleagues, and other readers over the past six years. This guide indeed filled a gap, helping many individuals prepare for the clinical informatics board exam and learn about the field in their classes. Yet, the book was outdated just a couple of years post-publication with any text in a technology-heavy field. In 2019, we, therefore, started to work in earnest on expanding and updating the text. First, we sought to ensure that the book covered the revised and expanded core content published by the American Medical Informatics Association (AMIA), making its way into the board exam. Second, we sought to add depth to many topics and update material relevant to modern practices in clinical informatics. Finally, we added content on the heels of the COVID-19 pandemic, which delayed the book's development but highlighted the critical role that informatics plays in medicine and public health. This edition represents an updated and expanded volume of comprehensive, modern, and relevant practice to support the training of the next generation of clinical informatics leaders.

Now more than ever, training in clinical informatics is essential for the future of the nation's health system and the populations it serves. The health system is challenged by commercial electronic medical record systems that use analytics to drive regulated health care delivery processes that frustrate clinicians and patients. Hospitals were quickly overrun with patients during the COVID-19 pandemic, and resource management for things like ventilators, personal protective equipment, and vaccines was challenged by weak information systems and manual workarounds that don't work. Moreover, health systems are now under attack daily by cybercriminals that seek to extort money while shutting down critical health services. As a science and profession, clinical informatics is at the center of these challenges and has tools and methods to address them. When properly designed for efficiency and effectiveness, clinical IT systems can support human-centered patient care and clinical workflow. With a robust informatics team, a health system can deploy dashboards, workflows, and integrations that enable the management of patients, staff, and resources management during a pandemic. And with a vigilant, adaptive cybersecurity strategy, health systems can ward off would-be attackers without shutting down mission-critical devices or IT systems. We hope that the theories, approaches, and practices detailed in this text help train clinical informatics leaders to confront the challenges of today and the future.

We are pleased to have assembled the group of authors represented on these pages. Each of them has contributed significantly to the advancement of clinical informatics practice as a

teacher, researcher, informaticist, advocate, or policymaker. Many are Fellows of AMIA or the American College of Medical Informatics, distinctions that indicate their leadership in practice or research. They dedicated many hours preparing and revising the content in this book, and we are honored to serve as editors for their content. We could not have created this text without their assistance in this journey.

How to Use This Book

The book is written to support the formal training required to become certified in clinical informatics. The content is structured to define or introduce key concepts with examples drawn from real-world experiences to impress upon the reader core content in the discipline. The book is not intended to provide comprehensive details on specific informatics systems or components. It goes into considerable detail concerning foundational, theoretical concepts drawn from the sciences underlying informatics (e.g., computer science, information science, cognitive science). The authors were instructed to guide our readers through the core content in clinical informatics, referencing or directing the reader to additional materials that will provide greater depth. All the while providing a roadmap for faculty who wish to go deeper in courses designed for physician fellows or graduate students in various clinically oriented informatics disciplines (e.g., nursing, pharmacy, radiology, public health). The book can also serve as a reference for those seeking to independently study for a certifying examination or periodically reference while in practice. The content is relevant to certification in both the American Board of Medical Specialties (ABMS) subspecialty certification in Clinical Informatics and the AMIA Health Informatics Certification (AHIC).

Structure of the Book

The book is divided into sections that group related chapters based on the primary foci of the core content: (1) health care and computing fundamentals; (2) clinical decision-making and care delivery; (3) enterprise health information systems and data; (4) leadership and managing change; and (5) professionalism. The chapters do not need to be read or taught in order.

Clinical informatics focuses on applying computers and information systems to the delivery of patient care and population health. We, therefore, begin the book with an overview of clinical informatics as a specialty within the larger field of medicine. Chapter 1 defines and describes the history of clinical informatics as a medical subspecialty. It further describes typical roles for informaticians in a variety of clinical settings. The disciplines of computer and information sciences heavily influence the theory, methods, and applications of clinical informatics. Therefore, this edition of the book added Chap. 2, which provides a detailed introduction to these two critical disciplines. Increasingly clinical informaticists need to understand and guide real computing system challenges in their organizations. Understanding how computers work (not think) and structure information are critical to designing solutions to problems faced in modern health care. In Chap. 3, the reader will find an overview of the U.S. health policy context, emphasizing laws and regulations that pertain to health care system data and information. Clinical informaticians need to understand federal and state laws surrounding health information in addition to the technologies that manage them. This is followed in Chap. 4 by an overview of the U.S. health care system. Understanding how health care is organized and delivered is fundamental to those in charge of capturing, storing, and making information accessible to the many clinical and allied health professionals that work in fragmented organizations and facilities throughout the health system.

The next section of the book focuses on clinical decision-making and the informatics tools, algorithms, and systems that support decision-making in clinical contexts. In 2008, Charles Friedman postulated a "fundamental theorem" of biomedical informatics; that "a person

working in partnership with an information resource is 'better' than that same person unassisted." The theorem succinctly asserts two important themes found across numerous landmark articles: (1) humans are incapable of storing and processing all of the data and information necessary to deliver high-quality care in all contexts and (2) computers should not replace human decision-making. Chapter 5 reviews how evidence-based knowledge is discovered and transformed into guidance for practicing clinicians. Next, Chap. 6 reviews the complex process of making clinical decisions. To design effective electronic health record systems, one must understand how clinicians make decisions. Chapter 7 discusses how clinical decision support (CDS) systems apply evidence-based knowledge and guidelines to support clinical decision-making processes. Decision-making processes occur in the context of complex clinical workflows. Therefore, in Chap. 8, we review tools and models for analyzing and modifying clinical workflow. This is followed by Chap. 9, which examines the theories and practices of human factors engineering and human–computer interaction. These disciplines contribute significantly to the design and function of clinical information systems that support decision-making and workflows.

In the third section, we examine the data and information systems found in health care settings. Chapter 10 reviews the technical foundations upon which health information systems are built. Informatics leaders will need to make decisions about which systems support clinical decision-making and how systems should be organized, connected, and supported. This chapter will arm clinical informatics leaders with the knowledge and tools necessary for making these kinds of decisions. In Chap. 11, readers will find an overview of various information systems they will likely encounter and manage in their careers. Chapter 12 describes information system life cycles and the governance and ongoing maintenance necessary to keep systems operational. Chapter 13 focuses on standards, technical building blocks that enable interoperability between systems. Supporting and selecting standards is essential for informatics leaders because otherwise, the clinical information systems implemented will be silos of data unable to support the range of clinicians caring for patients. Next, Chap. 14 examines the state of interoperability across the enterprise and external to health care organizations. Currently, the U.S. federal government is Promoting Interoperability across the health system, so this chapter explores the drivers and barriers to health information exchange and interoperability.

The third section of the book ends with chapters that explore fundamental and modern clinical informatics practices. Chapter 15 examines data and information governance, critical operational procedures that ensure data are fit for use and available to authorized users who need them to perform their role as clinicians, administrators, or researchers. Chapter 16 examines the exciting world of analytics. Large volumes of clinical data are now integrated across enterprises (thanks to standards and interoperability) and can be rapidly mined for evidence to inform care delivery. This section also examines cybersecurity (Chap. 17), a fast-growing, critical skill set for clinical informaticists who must not only keep systems operational but defend them from would-be attackers on the other side of the globe. Finally, this section ends with another incredibly fast-growing area of informatics, telehealth. The COVID-19 pandemic shifted a significant volume of ambulatory care into the virtual world, where patients connect with their physicians on mobile applications or via text. Chapter 18 examines the state of telehealth and explores its potential a future in which policy, reimbursement, and technologies will likely evolve telehealth into a routine, common way of care delivery.

In the fourth section of the book, we focus on a critical aspect of clinical informatics: leadership. Clinical informaticists will be looked to within their organizations as leaders, be it team leads to implement information systems or as a Chief Medical Informatics Officer (CMIO). In Chap. 19, we provide a review of various leadership models and guidance on the dimensions of leadership. Chapter 20 covers a wide range of strategies for managing people, teams, and meetings. Chapter 21 focuses on the strategic and financial planning necessary for informatics leaders, especially CMIOs or Directors of informatics departments with a budget. Then in Chap. 22, we focus on the management of change because inevitably, the introduction of an

information system, or the upgrade of a system, requires organizational or personal change. Research in informatics has repeatedly shown that effective management of this change is a critical determinant of the system's success. In Chap. 23, we discuss the principles of project management, which include the tools and theories behind successfully driving both small and large system implementations and informatics performance improvement.

In the final section of the book, we go beyond the core domains of clinical informatics. The chapters in this section focus on related, "sister" branches of the larger field of biomedical informatics. Understanding these aspects of biomedical informatics is vital for clinical leaders because (1) clinical informaticists will likely interact with specialists in these areas in their daily activities and (2) these areas are increasingly interconnected to the practice of clinical informatics. Chapter 24 focuses on consumer health informatics which supports the increasingly important function of patient engagement. New technologies and tools are available to put patient data and information into the hands of patients and their caregivers. Collaboratively, clinicians and patients can improve health and well-being while supporting patients' preferences in their care plans. Then in Chap. 25, we explore public health informatics. Population health is booming, and public health agencies have decades of experience analyzing population-level data and implementing interventions to improve the health of populations. Understanding the systems, methods, and challenges in public health agencies informs clinical informaticians' work while identifying community partners who can collaborate on improvements to health care delivery and outcomes. Moreover, public health informatics is in the spotlight following COVID-19 as its critical role in the health system, and its many informatics challenges were highlighted during the pandemic. Finally, in Chap. 26, we examine the newer area of Precision Health Informatics, which is helping to achieve the vision set forth by the National Institutes of Health PM initiative.

Structure of Each Chapter

Within each chapter, the reader will find several sections designed to support understanding of the core content in clinical informatics. Nearly all chapters begin with a clinical vignette or story that illustrates at least one key lesson. The vignettes add context and depth and are drawn from the real-world experiences of the authors. In addition to vignettes, we pushed authors to include illustrative figures, tables, and boxes to reinforce the main content of the chapter. Each chapter further highlights the core content covered in the chapter to demonstrate which sections of the board exam are contained. Finally, chapters include discussion questions aimed at sparking dialogue in formal courses or fellowship programs.

Statement from the Editors

The world needs you. Individuals who understand the principles and best practices in clinical informatics are necessary to fix the flaws in modern electronic health record systems, design better health information systems, and develop advanced technologies to improve patient outcomes and care delivery. It will take hundreds of clinical informatics specialists and many thousands of informatics-savvy clinicians to design, develop, implement, and use information systems to improve care and patient and population health outcomes around the world. We hope this book plays a role in making that vision a reality.

Indianapolis, IN — John T. Finnell, MD, MSc
Indianapolis, IN — Brian E. Dixon, MPA, PhD

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Part I

Fundamentals

The Discipline of Clinical Informatics: Maturation of a New Profession

1

Don E. Detmer, Benson S. Munger, Elaine B. Steen, and Edward H. Shortliffe

Learning Objectives

After reading this chapter, the learner will be able to

- Describe the evolution of clinical informatics as a profession;
- Provide an overview of how the clinical informatics subspecialty was created; and
- Discuss the roles clinical informaticians play in health care systems and settings.

Practice Domains: Tasks, Knowledge, and Skills

- K001. The discipline of informatics (e.g., definitions, history, careers, professional organizations)

Introduction

The roots of the applied informatics discipline date to the 1960s, when hospitals and other health-related entities first began to adopt the data processing capabilities that were taking hold in other aspects of business and science. Since the funds required to adopt such methods were substantial—this was the era of expensive mainframe computers before time-sharing or personal computers had been introduced—it is not surprising that the principal uses of computers were in large hospitals and that the applications were motivated either by clinical care or business operations. Thus, the beginnings of clinical informatics can be identified some 60 years ago, and the expertise in the area has had over a half-century to evolve and mature. During this period, the emerging discipline has been tracking the remarkable changes in computer science and communications technology, the underlying health sciences, and the delivery and financing of health care.

As growing numbers of individuals began to work at the intersection of computing and medicine, sometimes obtaining formal training in both areas, it became clear that a new profession was emerging—one that focused less on research per se and more on the effective practice of applied clinical computing and information management. Many questions regarding such individuals arose and were vigorously discussed early in the new century's first decade. How might mid-career individuals get training in the area? Was it really necessary for them to go back to graduate school full-time? Was there a role for informatics as an area of subspecialty training for physicians who wanted to devote significant portions of their careers to work in the area? How do other health professionals, such as nurses, pharmacists, and dentists, approach this set of challenges and opportunities? How could an individual demonstrate to employers (typically health systems, hospitals, other health-related entities, and public and private payers) that they were qualified for a formal position in clinical computing, focused on practice, strategic planning, and implementation rather than on research? Might there be a suitable way to get certified in the area without needing to return to school to get a formal graduate degree?

Although these questions were asked by individuals from a range of health professional backgrounds, they became especially pertinent for physician informaticians who saw chief medical information officer (CMIO) positions emerging within a culture of recognized medical specialties. In this chapter, we summarize what happened to address these questions, culminating in the creation of a formal subspecialty for board-certified physicians through the American Board of

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Medical Specialties (ABMS), the emergence of and growth in the Accreditation Council for Graduate Medical Education (ACGME) accredited clinical informatics fellowship programs, efforts by the American Medical Informatics Association (AMIA) to establish an AMIA Health Informatics Certification (AHIC) for applied informatics professionals who are not eligible for the clinical informatics subspecialty (CIS), as well as emerging issues as the specialty matures.

This volume is intended to help individuals preparing for their clinical informatics board examinations or who wish to refresh their knowledge of the field from time to time after they have been certified. Accordingly, readers will notice references to the clinical informatics subspecialty for physicians throughout the volume. There are, however, many other kinds of professionals who work in clinical informatics, and the book will be valuable for them as well. As described below, there is considerable similarity between the body of knowledge for the clinical informatics subspecialty for physicians (CIS) and the AMIA health informatics certification (AHIC). Thus, individuals preparing for either examination may find benefit from this book. Further, while this volume is intended for practitioners and does not prepare individuals to become researchers in clinical informatics, it conveys a body of knowledge and experience useful to researchers in the field.

Clinical informatics is an applied sub-discipline of the field of *biomedical and health informatics*, which AMIA has defined as "the interdisciplinary field that studies and pursues the effective uses of biomedical data, information, and knowledge for scientific inquiry, problem-solving, and decision making, motivated by efforts to improve human health" [1]. The term *clinical informatics* refers to the practice in health care settings where informatics concepts are applied to the care of both individuals and populations. With the advent of widespread use of electronic health records (EHRs), it is now possible to manage populations of patients routinely, thus bridging a gap between personal and population health that has existed for over a century. This is one of the transformative aspects of clinical informatics as a discipline. Since there has traditionally been a chasm in the United States between care of individuals and care of populations, clinical informatics offers the best opportunity for America to heal this regrettable historic oversight since excellence in *both* the care of individuals and populations is essential for a first-rank healthcare system.

In 2009, AMIA published two key papers that introduced the notion of a clinical subspecialty for informatics physicians and were pivotal to establishing the new subspecialty [2, 3]. They emphasized that clinical informaticians use their knowledge of patient care, combined with their understanding of informatics concepts, methods, and tools:

- To assess information and knowledge needs of health care professionals and patients;
- To characterize, evaluate, and refine clinical processes;
- To develop, implement, and refine clinical decision support systems;
- To lead or participate in the procurement, customization, development, implementation, management evaluation, and continuous improvement of clinical information systems.

Once the CIS was established, the *Core Content for the Subspecialty of Clinical Informatics* [2] became the foundation of the CIS certification examination. It informed fellowship program curricula, board review materials, and maintenance of certification programming.

Ten years later, in recognition of changes in CIS practice and the need to support the development of competencies on which fellows could be assessed, AMIA collaborated with the American Board of Preventive Medicine (ABPM) to update the CIS core content. That effort (described later in this chapter) resulted in the CIS Delineation of Practice (DOP) [4] which is now the basis for the CIS examination. This volume introduces and summarizes the concepts, methods, and tools included in the CIS DOP and provides case studies and illustrations of both effective approaches and those that have limited the success of the field to date.

History and Development of Clinical Informatics as a Medical Subspecialty

Clinical informatics developed over decades as computing and computer systems entered hospitals and clinics—primarily for billing purposes and laboratory results reporting and management. In a somewhat parallel fashion, radiology sought to digitize and store its images for analysis and retrieval, using communications technologies to deliver them wherever needed. A first-generation of clinicians emerged who were sufficiently interested in computing and computer science that they undertook formal study in these disciplines and then worked as researchers or practitioners at the intersection of computing and clinical care. By the early 1970s, the U.S. National Library of Medicine had begun to fund research and researchers' training in the emerging discipline. National meetings engaging those sharing these interests emerged during the late 1960s and 1970s. The introduction of an annual Symposium on Computer Applications in Medical Care (SCAMC), beginning in 1977, served as a particularly important catalyst to the creation of a national community that, in time, became known as the *medical informatics* community. By 1984, the American College of Medical Informatics (ACMI) was formed as an honorific society in which peers elected future members based upon

their contributions to the field. Building on a smaller professional society known as the American Association for Medical Systems and Informatics (AAMSI), AMIA was formed in the late 1980s through a formal merger of ACMI, AAMSI, and SCAMC, each of which had been formed as a separate corporate entity. AMIA quickly became the professional home where both senior and junior informaticians, including those focused on clinical care, could present their work and find out what was current in the field. Such informatics specialists were not necessarily physicians, however. Indeed, nursing informatics began educational programming on a broader scope and scale than medicine. From the beginning, AMIA welcomed all health professionals and other scientists (e.g., computer scientists, decision scientists, cognitive scientists, sociologists) interested in the application of computing and communications technology in health and health care. This integrative dimension of the field is one of its defining characteristics set within a healthcare landscape noteworthy for its 'siloes' of both knowledge and practice. While other groups did exist, they tended to be narrower in scope, and none was as large or influential as AMIA.

The term *informatics* was still new in the 1980s. Early informatics professionals in applied settings such as hospitals often referred to what they did as "health information technology" (HIT or health IT). While the use of the HIT and *health IT* designations by informaticians is less common today, there is still confusion regarding the relationships between clinical informatics and HIT. There was also confusion at the international level. Most other countries came to refer to HIT as HICT or health ICT, explicitly including "communications" and "information" in their acronym. Forty years later, with the digital revolution and the widespread implementation of EHRs, *clinical informatics* is being used in many job descriptions that do not always align with the CIS definition of practice (DOP). This has introduced a new source of confusion about the relationship between informatics professionals and those in related roles such as HIT or health information management (HIM). Furthermore, the emergence of data science is complicating the broad understanding of the clinical informatics discipline.

Today the U.S. HIT community has a large trade organization known as the Health Information Management Systems Society (HIMSS), whose annual conventions often attract clinical informaticians who want to interact with colleagues and track the newest technologies and products. With its annual informatics meeting, AMIA has complemented and cooperated with HIMSS while attracting a more knowledge-driven and scholarly audience, including researchers and professionals who look beyond the technology to educational needs and the conceptual underpinnings of knowledge and information management in health care settings. Since 2014, AMIA has organized the Clinical Informatics Conference that focuses on applied-informatics practice. In 2021, over 650 attended its virtual conference.

Today, while AMIA has formally identified individuals engaged in clinical informatics as informaticians, many prefer to identify themselves as informaticists. Only time will tell which term will dominate in the future. Suffice it to say that they are essentially synonyms in terms of common usage despite the use of clinical informaticians in this chapter.

Defining the Characteristics of the Profession

Following the release of a professional code for informaticians in 2004 [5], AMIA held a Town Hall meeting during its annual symposium to discuss the matter of formal training and certification in clinical informatics, regardless of one's area of clinical expertise or even one's previous health professional training, if any. The goal was to approach clinical informatics as an integrative health care discipline and as one practice domain within the larger 'house' of biomedical and health informatics. The AMIA Board decided to focus its initial efforts to establish informatics certification on one health profession rather than mounting a certification effort across all disciplines at the same time and engage all other clinical informaticians in the healthcare team as soon as feasible.

AMIA first pursued certification for physicians. Then, with insights and lessons from that effort, it pursued certification for other clinical informatics experts (see the discussion of this topic later in this chapter). It made sense to start with MDs because many existing clinical informatics subspecialists were also physicians, board-certified in one of the major clinical specialties (e.g., internal medicine, surgery, pediatrics, radiology) and because the notions of specialist and subspecialist, and the processes for their certification, were familiar and well defined. A subspecialty, in this context, is a field of narrower concentration for someone who is already certified as a specialist. For example, cardiology is a subspecialty of internal medicine. As was successfully argued, clinical informatics can be viewed as a relevant subspecialty for physicians trained and certified in any standard specialty—i.e., they may appropriately work in clinical informatics regardless of their primary training and practice.

Any new discipline within the medical profession seeking to obtain support for formal specialty or subspecialty status must first convince other medical specialists and subspecialists that the discipline is worthy of such designation. Thus, three critical sets of players were involved in addressing the challenge that faced AMIA:

1. Clinical informatics needed to be viewed formally as a separate discipline by other medical specialty groups. Such recognition is evident when a nationally recognized

organization representing the rising discipline is elected to formal membership in an organization such as the American Medical Association (AMA) or the Council of Medical Specialty Societies (CMSS). CMSS is an organization whose purpose is to provide a forum for collaboration among medical specialty organizations to influence policy, medical education, and accreditation from a broad, cross-specialty perspective.

2. The subspecialty needed to be recognized by the American Board of Medical Specialties (ABMS). ABMS is an umbrella organization for the certifying boards in all the various specialties and subspecialties of medicine; it formally recognizes specialties and subspecialties and, through its constituent boards, creates and maintains the certification examinations that attest to the competence of medical subspecialists.
3. The Accreditation Council for Graduate Medical Education (ACGME) must be engaged since the ACGME exists largely to review and accredit training programs capable of preparing candidates to sit eventually for the certification examinations of the constituent boards of the ABMS.

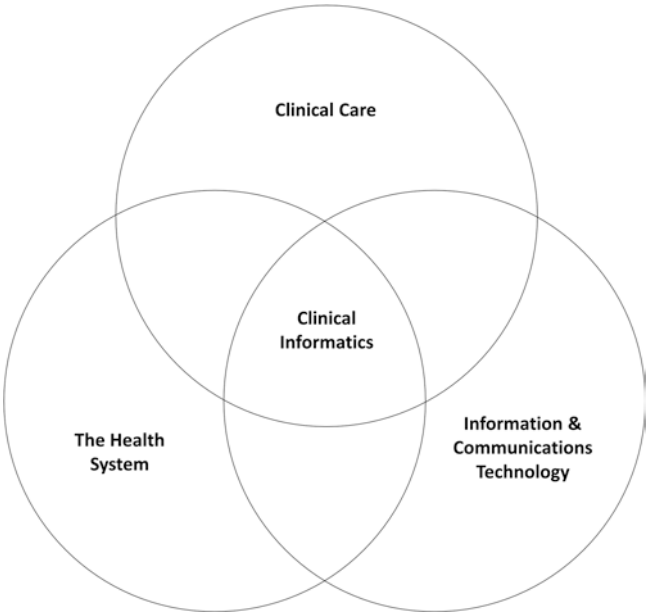

Fig. 1.1 Domains of clinical informatics (reproduced from reference [2] with permission from the American Medical Informatics Association and the Journal of the American Medical Informatics Association)

In mid-2006, John Lumpkin, Vice-President of the Robert Wood Johnson Foundation (RWJF) and AMIA President and CEO Don Detmer, met informally with the presidents of several medical specialty societies to discuss a new clinical informatics subspecialty. The result of this meeting was an expression of genuine enthusiasm accompanied by recognition that the formal process for establishing a new subspecialty would require considerable effort and time. To continue building the case for the new subspecialty, AMIA sought and achieved membership in CMSS in 2007.

In the same timeframe, RWJF awarded AMIA a grant to develop two key documents essential for formally approaching ABMS to consider a new subspecialty. Through that grant, AMIA engaged Benson Munger, a former executive director of the American Board of Emergency Medicine, to help to guide the process. Separate task forces were appointed to develop the core content of the field [2] and recommended fellowship training requirements [3]. After approval by the AMIA Board of Directors, these documents, along with a descriptive piece by Detmer and Lumpkin [5], were published in the *Journal of the American Medical Informatics Association* (JAMIA) in 2009.

Several key concepts were critical at this early development stage. As noted earlier, clinical informatics is intrinsically an integrative discipline. This was acknowledged by appointing non-physician clinical informaticians to each AMIA task force, where they functioned as full members. There was representation from nursing, pharmacy, and dentistry. The groups also emphasized the concept of a learning healthcare system committed to the principles outlined in the IOM reports, *Crossing the Quality Chasm* (2001) and *Health Professions Education: A Bridge to Quality* (2003) [6, 7]. Equally important, the role of a clinical informatician was to take both a clinical and a system view, emphasizing that qualified subspecialists should be capable of leading organizations strategically and tactically with respect to all major aspects of integrating information and communications technology with information needs as they might evolve. A key visual was created to represent this perspective (Fig. 1.1). This remains as a core set of insights and responsibilities for practicing the discipline of clinical informatics. Since then, an enlarging focus on both person- and population-based perspectives has emerged.

Seeking Approval for the Clinical Subspecialty

The next step in the process was to identify one or more ABMS boards that would agree to propose the formal creation of the CIS. Although many Boards were supportive and expressed an interest, the American Board of Preventive Medicine (ABPM) was most interested in submitting a formal proposal and becoming the administrative board. Detmer and his successor as AMIA President/CEO, Edward Shortliffe, committed to working with the ABPM to develop the application to ABMS for the new subspecialty. Verbal support from other boards was helpful in reassuring ABPM that there was enthusiasm within ABMS for the creation of the new subspecialty, and AMIA gathered data to demonstrate the potential demand for such a certifying exam.

In mid-2009, a senior leader from ACGME met with informatics program directors who, up until then, were most familiar with requirements for graduate (MS and Ph.D.) education and generally had less familiarity with formal fellowships that would need to be accredited if trainees were to become board-eligible within the ABMS certification model. The interactions at that meeting were crucial, not only because informatics educators began to understand the ACGME accreditation model but because ACGME leaders began to realize that if they were involved in accrediting informatics fellowships, they would encounter many issues that had not arisen previously. There were, for example, questions of whether masters' degrees would be required or optionally offered to clinical informatics fellows in training and how or whether ACGME would assess that option. Most fellowships have clinical and research requirements, but what was "clinical time" for a clinical informatics fellowship? Perhaps it could be a service component that affected clinical programs at the affiliated medical institution? Unlike most fellowships, it was unclear what a "direct patient care" component would be. Since fellows could come from various clinical backgrounds and specialties, it was not reasonable to expect the informatics fellowship formally to provide a panoply of direct patient-care opportunities in every specialty. ACGME began to realize that creating a clinical informatics subspecialty would require them to rethink the definition of the term "clinical". Shortly after the Colorado meeting, ACGME leaders began a discussion of this question, leading to the formal adoption of a new, expanded definition that was approved by their board and placed on the ACGME website in 2009 [8]:

> The word "clinical" refers to the practice of medicine in which physicians assess patients (in person or virtually) or populations in order to diagnose, treat, and prevent disease using their expert judgment. It also refers to physicians who contribute to the care of patients by providing clinical decision support and information systems, laboratory, imaging, or related studies.

This new definition became an extremely important factor in the subsequent discussions with ABMS as the subspecialty proposal was being considered. As discussed below, this remains a critical issue today since entities like the Centers for Medicare and Medicaid Services (CMS) have yet to develop appropriate payment mechanisms for both practice and education consistent with this definition.

By the autumn of 2009, the leadership of the ABPM had approved a plan to propose the new subspecialty to ABMS. As is customary for new subspecialties, there was a 5-year practice application period during which active clinical informaticians who were also ABMS-certified physicians could apply to be deemed board eligible and sit for the examination. After that, a formal fellowship in clinical informatics would be required to achieve board eligibility. As is the case for all residencies and fellowships, those fellowships would need to be accredited by the ACGME. In 2017, ABMS approved ABPM's application to extend the initial 5 year practice track through the 2022 exam cycle. The extension was predicated on the argument that an insufficient number of ACGME accredited informatics fellowship programs had been established, even though many had been implemented or were planned.

The initial ABMS approval process involved a year-long review. All the other boards in ABMS reviewed and then had to approve the notion of a new subspecialty certification. Shortliffe and AMIA staff worked with ABPM to prepare and submit the formal proposal and were delighted when it garnered support from the other boards. With unanimous support from their constituent boards, ABMS leadership agreed in late 2010 to initiate internal review of the proposal. Their Committee on Certification (COCERT) met twice to review and discuss the proposal before forwarding their positive recommendation to the full ABMS board.

The COCERT meetings in 2011 were crucial elements in the approval process because the committee was charged with determining whether there was adequate justification for treating the proposed subspecialty as a separate discipline. They also wanted to assure themselves that the field is a suitable area of specialization for practicing physicians. Shortliffe accompanied ABPM's executive director to those meetings in Chicago to support the proposal and answer questions about the discipline and the community of physicians who were likely to pursue certification if a board examination were offered. A key question that arose and debated at both committee meetings was whether clinical informatics was sufficiently "clinical" since some viewed the work as technology-oriented and not involved with direct patient care. Arguing that many other subspecialties have limited direct interaction with patients and that all clinical informaticians would also be board certified in an established patient-care specialty, Shortliffe also directed the COCERT members to the ACGME definition of "clinical", which by that time had already been approved by the ACGME board and posted on their web site. The updated definition, reproduced above, helped to allay concerns and, by the end of the summer of 2011, the ABPM's proposal had been approved by COCERT and was forwarded to the ABMS board for a final decision. The approval came in September 2011, capping a long study period and preparation by AMIA, RWJF, and the ABPM. The clinical informatics community was jubilant!

The Clinical Informatics Subspecialty in the Context of ABMS Evolution

The subspecialty of clinical informatics occupies an interesting space within ABMS. In 1972, ABMS initiated the process of approving new subspecialties [9]. American medicine

was early in the process of practice differentiation. Except for the surgical specialties, graduate medical education beyond a 1-year rotating internship was uncommon. The American Boards of Pathology, Internal Medicine, and Pediatrics had begun to develop subspecialties, and nine were created. These subspecialties directly related to one primary board (e.g., cardiology, gastroenterology, forensic pathology, hematology). The certificates were each issued by their primary board. In total, the decade of the 1970s saw 19 subspecialties approved by the ABMS.

During the 1980s, ABMS approved 21 new subspecialty certificates. This decade also brought the first discussions among ABMS boards about a subspecialty that might cross primary specialties and therefore require a different approach to examination development and administration. An example of this new approach was geriatric medicine. Both the American Board of Internal Medicine (ABIM) and the American Board of Family Medicine (ABFM) issue subspecialty certification in geriatric medicine. Both boards participate in the development of the examination, but ABIM takes responsibility for formal examination administration.

This cross-discipline subspecialty also created a challenge for ACGME's program accreditation process. It envisioned training programs sponsored by departments of multiple primary specialties and could theoretically accept fellows from more than one primary specialty. It also assumed that the training programs would have a common set of core training requirements, as the graduates of those programs would be taking a common certification examination. This period brought several other subspecialties that had were either in the same content areas or had shared training and certification across two or more primary boards. Examples would include critical care, sports medicine, and undersea and hyperbaric medicine.

During the 1990s ABMS approved certificates in 32 subspecialties. This period gave rise to discussions within ABMS about another new concept. As subspecialties involving multiple boards were developed, the diplomates of boards not directly involved in issuing certification in that joint subspecialty indicated an interest in accessing that training and certification. In many cases, the number of diplomates from other boards would not justify the direct co-sponsorship of their primary board. These discussions led to the concept of a co-sponsor allowing a diplomate of another board to access their training programs and certification system. This concept significantly expanded the scope of certification in some subspecialties.

Between 2000 and 2009, ABMS approved 34 subspecialty certificates. This number was significantly influenced by two new subspecialties, (a) hospice and palliative medicine and (b) sleep medicine. Hospice and palliative medicine has ten co-sponsors; sleep medicine has six.

The first 3 years of the 2010 decade saw ABMS approve 12 new subspecialty certificates and among them was clinical informatics. As we have described, this subspeciality certificate is officially sponsored by ABPM, which functions as the administrative board. Before the subspecialty received final approval by ABMS, the American Board of Pathology (ABPath) also chose to co-sponsor the new subspecialty. Furthermore, because of clinical informatics' unique nature, there was significant interest in training and certification by diplomates from a wide variety of ABMS boards. The result is that clinical informatics was the first subspecialty in medicine that allows training and certification from all 24 of the current primary boards. It is not surprising that this first occurred with clinical informatics since the clinical interactions and applications of the subspecialty apply to all specialties in medicine and the other health professions.

Creating and Offering the Board Examination

Once the subspecialty had been approved, ABPM moved quickly to create and offer the first subspecialty board exam. Because the ABPM did not have the internal content expertise to create the formal examination, they asked AMIA for nominees to sit on the question-development committee. As mentioned, the ABPath had submitted a request to ABMS and had been approved to be a co-sponsor of the subspecialty. Thus, both AMIA and ABPath forwarded proposed exam committee members to ABPM, and the committee was formed. ABPM ran the process and, in light of their long history of offering preventive medicine specialty boards and several subspecialty examinations, had ample internal expertise regarding the steps to be taken, including providing access to psychometric specialists who could guide the development of exam questions.

Initial Development of Fellowship Programs

Once ABMS approved ABPM to issue sub-certification in clinical informatics, the process moved to ACGME. As was mentioned earlier, ACGME is the organization responsible, in the United States, for the accreditation of graduate medical education programs in all medical specialties and subspecialties. AMIA leaders maintained contact with ACGME while the proposal was proceeding through the ABMS.

In 2011, ACGME appointed a Residency Review Committee (RRC) group to develop the new program requirements and recommend them to the ACGME Board. The committee was composed of graduate medical education experts in clinical informatics. The review committee began with the Draft Training Requirements developed and published by AMIA [2, 3]. The review committee also

requested feedback from the clinical informatics community and, based on that feedback, developed a recommendation that was submitted to the ACGME Board and approved in February 2014. As a parallel process, the ACGME staff began constructing the Program Information Form (PIF) to be used by programs to apply for ACGME accreditation. This PIF was made available to potential applicant programs in May 2014.

Although ABPM is the primary administrative board within the ABMS structure, with ABPath as co-sponsor, the fellowship training process is intended to avoid limiting sponsorship of fellowship programs exclusively to preventive medicine or pathology departments. It was always envisioned that many other primary specialties would be interested in sponsoring fellowship programs. Therefore, local medical schools and teaching hospital departments from various specialties would submit applications to ACGME.

When the original Program Requirements were approved and distributed, the list of primary specialties that could sponsor an ACGME fellowship program was limited. Ultimately, program requirements for clinical informatics approved in 2014 allowed for sponsorship by departments of nine primary specialties (anesthesiology, diagnostic radiology, emergency medicine, family medicine, internal medicine, medical genetics, pathology, pediatrics, and preventive medicine).

Concern about the lack of clinical informatics expertise among RRC members was mitigated by the presence of the Clinical Informatics Review Committee (CIRC) that the ACGME had approved and appointed. The CIRC provided a structure through which applications from clinical informatics fellowship programs could be pre-reviewed by a panel of experts with a recommendation provided to the relevant RRC responsible for the decision. The relevant Residency Review Committees have primarily absorbed the responsibility for reviewing and approving Clinical Informatics programs.

The ABPM application to ABMS contained a list of existing fellowship programs (many of which offered graduate degrees and had trained post-residency physicians) and a projection of programs that would likely emerge following the creation of the clinical informatics sub-certification. That list was a combination of fellowship programs that looked somewhat like the proposed ACGME fellowships and others with many years of experience and funding but were blends of degree and certificate programs. Many of the programs on the list were located in medical schools or had existing faculty relationships with one. Many were also funded by the National Library of Medicine and had been in operation for many years. One of the assumptions in the subspecialty application was that a significant number of the existing programs would move to create a parallel program that would train physicians using the ACGME program requirements.

In 2014 the first applications were submitted to the ACGME, reviewed by CIRC, and forwarded to the appropriate Resident Review Committees (RRCs). In late 2014 ACGME accredited the first set of clinical informatics fellowship programs [10, 11]. By 2021, the number and distribution of ACGME accredited programs have expanded significantly, with 48 currently accredited across 22 states. The largest number of programs can be found in California (7) and New York (6).

Updating the CIS Core Content

By 2018, a decade had passed since the CIS core content was first developed. During this time, CIS practice had evolved due to changes in health care generally, wider use of clinical/health information systems, and advances in informatics practice gained in part through extensive experience in incorporating EHRs into clinical processes. Other factors that shaped CIS practice included: evolving clinician and patient expectations for how they interact with information systems and applications; increased attention to and capabilities for analyzing data from the nearly ubiquitous EHRs for population health management, precision health, and research; burgeoning emerging data such as phenomic characteristics and patient-generated health data with the potential to be leveraged for clinical decision-making; and growing emphasis on value-based health care. As a result of these changes, the 2009 core content, which was the basis for the CIS certification exam, was inconsistent with current needs and practice. Also, during this period, clinical informatics fellowship programs were grappling with using the CIS core content to develop competencies on which fellows could be assessed and recognized that they needed more than a knowledge outline for this task.

In light of these factors, in 2018, AMIA and ABPM agreed to update the CIS core content and organized a formal practice analysis methodology for the revision [4]. Thirty-seven CIS diplomates participated in drafting and reviewing a description, or delineation, of CIS practice in terms of domains, tasks, and knowledge and skills required to perform those tasks. All CIS diplomates (nearly 1700) were invited to review the draft CIS Delineation of Practice (DOP) via survey. Over 300 diplomates completed the survey. Their responses were used to finalize the DOP published in 2019 that now serves as the basis for the CIS certification examination co-sponsored by the ABPM and the American Board of Pathology and administered by the ABPM.

The CIS DOP comprises five major domains of practice, 42 task statements, and 142 knowledge statements. There is considerable consistency between the 2009 CIS core content and the 2019 CIS DOP, but several differences exist. In terms of content, the increased use of health data from EHRs and

other electronic sources is reflected in an entire domain on data governance and analytics, and dimensions of quality and performance improvement are identified in greater detail (e.g., measures, safety standards, benchmarks). In terms of structure, the tasks provide context for the knowledge statements by highlighting how CIS diplomates use that knowledge in practice. In addition to informing the content and structure of the clinical informatics examination, the CIS DOP supports the development of clinical informatics fellowship curricula and updates to ACGME's Clinical Informatics Fellowship Program Training Requirements and national clinical informatics milestones for fellows. Further, the task statements may inform future job descriptions and help employers understand what constitutes informatics practice. The CIS delineation of practice will need to be updated regularly to reflect changes in clinical informatics practice.

Career Options for Clinical Informaticians

The 2019 CIS practice analysis survey provided the first glimpse of the CIS diplomate workforce. Over 80% of respondents to the 2019 CIS practice analysis survey reported working in healthcare delivery organizations or other healthcare providers. Other specified work settings included: universities, public health agencies, industry, and consultant firms. These respondents had an average of 16.2 years of experience and spent 62% of their time in activities directly related to clinical informatics [4].

As previously noted, a common title for an experienced clinical informatician is *Chief Medical Information Officer* (CMIO), sometimes called *Chief Clinical Informatics Officer* (CCIO) [12] or in the case of the U.S. Department of Veterans Affairs the *Chief Health Informatics Officer* (CHIO). This position in a healthcare organization is at a senior level within the executive structure and typically reports to the chief executive officer (CEO) or the chief medical officer (CMO). The role enjoys close interactions with the chief information officer (CIO) and the rest of the senior management team. Principal responsibilities relate to serving as the primary point of contact between the medical staff and the institution's clinical information systems, e.g., EHRs, data exchanges, data repositories, and systems to address clinical performance, such as quality and safety. When the CMIO role was first introduced the positions tended to report to the Chief Financial Officer (CFO) or the CIO and focused on information technology as infrastructure rather than as a strategic asset. With its new reporting structure, the role has evolved to be a strategic and operational position. Although the trend today is for the CMIO to report to the CEO or CMO, there is substantial variation. Furthermore, based upon one's attributes, experience, and aspirations, some clinical informaticians are beginning to find themselves pursued for CIO, CMO, or even CEO roles. Looking forward, it is likely that clinical data analytics, with an emphasis on clinician performance, quality, safety, and external reporting relating to these matters, will play a larger role in the CMIO job description. For example, the COVID-19 pandemic highlighted the need for better coordination between clinical and public health data, e.g., a seamless connection needs to exist between numerator (individual patient) and denominator (population) data.

As the numbers of trained clinical informaticians increase in the future, it is also possible that all major departments and units in major healthcare delivery systems may have a "Chief Surgical IO", a "Chief Pediatric IO", and other such individuals who work across the major departments and also link to other health professionals such as nurses, pharmacists, etc. Chief Nursing Information Officers (CNIOs) are already becoming common in larger health systems, as are Chief Research Information Officers (CRIOs). The Veterans Health Administration includes Chief Health Informatics Officers (CHIOs) within many of its medical centers, who represent various clinical backgrounds. The role of such individuals is to serve as members of a clinical informatics team whose job is to assure that HIT systems meet growing strategic goals—supporting clinical operations and research while engaging patients, community resources, and other relevant entities. A recent movement among several state departments of health is to create an equivalent position of CMIO to offer strategic advice and to provide oversight of public health considerations, linking with other health data experts in the state (including CMIOs in healthcare delivery systems).

Today, the CMIO role (under a variety of names) has various permutations within the Departments of Defense and Homeland Security, the Public Health Service, and the Veterans Health Administration, with a span of responsibilities that may involve hospitals as well as other types of care facilities and outpatient settings. Roles and responsibilities may involve planning, evaluation, or consultation depending on needs. Within the Department of Health and Human Services (DHHS), those departments that relate to health care payment, research, health policy, quality, and safety, such as the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Agency for Healthcare Quality and Research (AHRQ), also offer opportunities. A few positions also become available as staff to Congressional representatives, health committees in Congress, or the White House for those interested in health policy. Today, these opportunities may best be described as emerging. Still, adventuresome clinical informaticians should not dismiss potential opportunities where their imagination and an entrepreneurial attitude may create positions of major value to society.

Opportunities also exist in the corporate world in those industries that have a large workforce. Many such companies already have CMOs who help address employee or customer health issues. Still, increasingly they also need someone whose skills reflect both strategic and management issues related to the HIT needs of the organization. Insurers and health system consultancies also come to mind. Finally, EHR vendors are beginning to hire such individuals to serve both internally and externally facing positions, both for ongoing relationship management, product development, and, in some instances, marketing.

Current Challenges for Clinical Informatics

As of June 2021, there were 2104 clinical informatics diplomates certified by the ABPM. Of these, 145 had completed an ACGME-accredited Clinical Informatics fellowship. The remaining diplomates applied through the ABMS approved practice track. As mentioned above, this practice track was originally scheduled to terminate in 2017 but was extended by ABMS through the exam administration in 2022. We expect a significant reduction in the number of clinical informatics subspecialists certified yearly when the practice track terminates in 2022.

Early experiences in creating fellowships suggest that some will arise from within specific specialty units or clinical departments within hospitals or medical centers. As was discussed earlier, those programs will need to be sponsored by or partner with one of the nine primary specialty programs approved by the ACGME. Complex relationships and partnerships may need to be created if the fellowship "home" is not in one of the nine specialties. Furthermore, there are questions about whether and how the RRCs will standardize how they evaluate the clinical informatics fellowships. Will there be uniformity in expectations across the specialties? As this volume emphasizes, clinical informatics is viewed as a broad and integrative discipline. Those completing fellowships need to have a broad knowledge of the field, regardless of their primary specialty or the "partnering" specialty responsible for the ACGME accreditation of their training program.

Perhaps the greatest hurdle for new and developing fellowship programs has been funding the fellowship positions that they offer [13, 14]. Interesting models have already been seen (e.g., funding of positions by a company through a grants program, by the hospital itself, by the physicians' group in the host department, or by existing informatics training grants that have been adapted to emphasize fellowship training for a few of their positions). Not all institutions can self-fund incremental fellowship positions, and it is politically difficult to reprogram existing fellowship training funds from another subspecialty to support clinical informatics fellowship slots. While many observers hope there will be new federal funding to support such training positions, health systems and training programs need to be innovative in funding clinical informatics fellows.

As with most fellowships, the program director for a clinical informatics fellowship is expected to be board-certified in the subspecialty. This created start-up challenges for institutions that did not have such expertise in-house. Furthermore, the fellowships require additional faculty who can define the curriculum, offer it to trainees, serve as mentors, and oversee projects. Thus, there has been a substantial need for new faculty at many institutions seeking fellowships. Accreditation of their program will require that they have the required local expertise. Given the potential shortage of board-certified subspecialists, especially after 2022, this is likely to continue to be a great challenge as the discipline seeks to increase the available fellowship training opportunities.

As organizations and institutions seek to find qualified individuals, they are faced with a confusing array of credentials. There are multiple organizations in the informatics certification field. These credentials cover a wide range, including basic certificates, degrees from academic entities, and training and certification based on accredited programs [15]. Employers looking at this landscape have difficulty identifying the training and skill base represented by each option. ABMS certification in clinical informatics is, of course, intended to help with this problem. By establishing an official subspecialty, ABMS and ABPM offer a credible reference certificate to employers who seek to engage physicians in their clinical informatics processes. But, as with any certificate, ABMS certification in clinical informatics cannot address every employer's needs, especially in the short term. The implementation and output of the ACGME-accredited training programs will continue to take several years, and physicians holding that certificate will not fill every position.

In addition to the "supply" concern just outlined, there are demand questions. Physicians in the informatics community have been decrying the lack of informatics content in the medical school curriculum for years [16, 17]. Until recently, there have been very few role models for medical students who might develop an interest in clinical informatics, and there is accordingly hope that the creation of the formal ABMS subspecialty, plus the introduction of fellows and faculty who have expertise in the area, will increase the credibility of this training option and draw more physicians into the discipline. The challenge, of course, will be to match the supply and demand so that there are not only applicants to fill the available fellowship positions (which does not currently seem to be a problem) but also enough positions to match an increasing number of residents who wish to pursue subspecialty training in clinical informatics.

Another dimension of importance concerning board certification is the issue of maintenance of certification (MOC).

This aspect of the current specialty certification landscape is particularly rocky at present, with rising concerns from specialists and others about several issues relating to MOC, including costs, relevance to actual competence on the job, and current professional practice profiles, among others. There is a movement in medical education to transition from "time in seat" to competency-based education wherein the criteria for professional performance are explicit, and learners can advance at their own pace, as evaluated by both written exams and observed demonstrations of knowledge and skills. Many hope that MOC will also eventually adopt this approach, both for clinical informatics and more broadly. However, major pedagogical, administrative, and political aspects will need to be accommodated before such new approaches will be adopted. Since clinical informatics is a relatively new entrant to formal recognition as a subspecialty and information management is its core capability, it is ideally positioned to offer leadership in transitioning from examinations 'at a distance' to an online review of current practice behaviors, processes, and outcomes. The field could offer a 'hands-off' yet valid, timely evaluation of current activities and competencies for those activities.

Complementary Developments

New Professional Recognition Opportunities

Beyond recognizing an individual's professional competence, there is now a way for CI diplomates to demonstrate their commitment to the discipline of clinical informatics. In 2018, AMIA launched "Fellows of AMIA" (FAMIA) to recognize members, with an applied focus to their informatics work, who have demonstrated professional achievement, leadership in the field, and sustained commitment to AMIA. By 2021, 435 individuals had been inducted as FAMIA.

Further, clinical informatics is also recognized internationally as a profession of note. Beginning in 2017, an International Academy of Health Sciences Informatics (IAHSI) was created through the auspices of the International Medical Informatics Association (IMIA). Individuals worldwide are elected to Fellowship based on prior performance in the broader discipline of health sciences informatics, but many members emphasize clinical informatics [18]. The IASHI seeks to disseminate knowledge and best practices, foster new ideas, and encourage global collaboration around expertise and resources.

The Faculty of Clinical Informatics of the United Kingdom is a multidisciplinary group that supports professional competency standards for informatics practice [19]. From a core group of 107 Founding Members in 2017, a robust organization has developed that now has a multidisciplinary faculty of hundreds of fellows, associates, and international fellows. The Faculty offers consultancy services to the NHS Digital (the public body responsible for developing and operating the National Health Service health information technology and data services) and fosters educational developments and scientific conferences.

Health Informatics Certification

After ABPM launched the new subspecialty, AMIA began working to establish certification for applied informatics professionals who are not eligible for CIS [20, 21]. In 2019, AMIA completed a practice analysis (similar to the one conducted for the CIS) to inform eligibility criteria and the examination blueprint for the new certification program [22]. In 2021, AMIA announced the eligibility criteria for AMIA Health Informatics Certification (AHIC). AHIC is intended for applied health informatics professionals who are in or seek senior roles. It is open to informatics professionals who come from a range of education and training pathways, including but not limited to dentistry, medicine, nursing, pharmacy, public health, health informatics, and computer science. The first AHIC examination was offered in autumn 2021.

AHIC constitutes an important development for the field of applied informatics. Now all members of the informatics team have a means of demonstrating their competence. This is particularly important in an environment where *informatics* in job titles has become quite common, even if the role does not align with the descriptions of informatics practice that emerged from the CIS and health informatics practice analyses. Of note, the CIS and health informatics delineations of practice have considerable overlap in terms of the knowledge statements and tasks [23]. These results reinforce our understanding of the shared knowledge base that informaticians bring to the various roles they fill.

Looking to the Future

Over the past decade, the clinical informatics discipline has made progress towards fulfilling the potential of health information technology to enable more effective health care delivery systems, a happier, more productive workforce, and enhanced, more equitable patient care, with improved outcomes for both individuals and populations. Yet, serious work remains so that emerging EHRs remove burdensome documentation requirements, accommodate emerging data, and create seamless data flows needed for both care and system management and improvement. As a result, the discipline will increasingly incorporate data sciences, data analytics, precision medicine, applications of artificial intelligence, and automated ways to capture patient clinical experiences accurately both for care documentation and to meet financial imperatives for payment. We also anticipate opportunities for clinical informaticians to contribute to the advancement of citizen

science and the development of informatics-enabled tools designed to address health inequities [24].

Transitioning from systems built upon thinking and practices that predate computer and information technology to those that take full advantage of the emerging power of today's interactive communication abilities, so that improved work design can direct greater attention to the patient-clinician interaction is both a research and applied challenge. Certainly, there is interest and a renewed commitment to making the technology aspects of the discipline less intrusive [25]. The ultimate aim is to capture all relevant information while doing so 'behind the screen'.

Despite biomedical informatics' relative youth as a scientific discipline, it is difficult to imagine an applied career for aspiring young health professionals that offers brighter prospects. Clinical informatics resides within a vortex of rapid changes in technology, scientific discovery, health-related information and communications applications, and rising expectations for improvements in health and healthcare. At the same time, legacies from the past continue to create inertia against desired changes. Thus, there is a need for well-educated and energetic informatics talent committed to moving health and healthcare forward. People who can span boundaries by combining specialized and general knowledge and skills will remain essential for continuing "sense-making" in environments where timely access to the right information at the right time can prove life-sustaining.

The details regarding the creation of the clinical informatics subspecialty are arguably less important than the larger lesson. Despite a 50-year history, clinical informatics is young and only now coming into its own as a broadly recognized professional discipline. The steps required to advance the cause were time-consuming, arduous, and met by setbacks along the way. But the dominating logic of recognizing the importance of informatics to our health and health care systems has inspired persistence on the part of the prime movers in the process and influenced the reception that the field has garnered as more people learn about its substance and strategic importance. Its broad interdisciplinary nature, coupled with a commitment to interprofessional training and exchange, is a model for others to follow as many people in health and medicine strive to break down traditional silos and to promote the inclusiveness and openness that are essential for the health of our people and the future of our world.

Questions for Discussion

1. What distinguishes the clinical informatics subspecialty from other medical subspecialties?
2. How does the emergence of the clinical informatics subspecialty reflect the evolution in understanding of what constitutes the practice of medicine?
3. How does clinical informatics enable achievement of this broader understanding of medical practice?
4. How might one characterize the clinical and public health (as opposed to technical or administrative) content of the field of clinical informatics?
5. If a healthcare institution lacks clinical informatics expertise, how would you convincingly explain to its leaders the rationale for recruiting a suitably trained expert to join their team?
6. How have the challenges facing clinical informaticians changed over the past decade and what challenges do you expect to see in the next decade?
7. What do you consider to be the biggest challenge facing the clinical informatics discipline?

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Fundamentals of Computer Science

2

Eric Puster

Learning Objectives
In this chapter, you will learn about:

- The basic science of computers
- Common vocabulary used by computer programmers
- The building blocks of computer code
- The general approach to solving a problem using a program, computational thinking
- Programming best practices to be used in generating code
- The framework for preparing software for use
- How to read code made by others and identify common problems

Practice Domains: Tasks, Knowledge, and Skills

– K006. Computer programming fundamentals and computational thinking

Case Vignette
Complaints from clinicians and nurses about numerous preventative health maintenance alerts have risen to the top of the health system. A clinical informaticist is instructed to integrate them into a single workflow addressed by population health nurses. The plan, as devised, involves creating a list that shows the patients with the most alerts at the top, along with contact information and barriers to care. When the patient's needs have been addressed, their name drops off the list to allow the next patient to rise to the top. The informaticist meets with the lead programmer for an early design meeting and is told that this system cannot be created. When asked why, the programmer cites privacy concerns, database structure limitations, and processing capacity; what technical challenges might prevent such a system from being created? What practical constraints will such a system be forced to obey? Why hasn't a system like this already been deployed everywhere in the United States?

Introduction

Long, long ago, automatic weaving looms were created to make the patterned fabric to replace armies of poorly paid weavers. At first, a good deal of human help was needed to reconfigure the machine for each new pattern, but humans were far from perfect for this process. To prevent waste, the loom operators began using punched cards to instruct their looms which weaving pattern to use when creating each bolt of fabric. The common elements of the various patterns were broken down to a binary code, as each position on a card was either punched or not punched.

Hematologists took hold of this idea in 1952 and began using punched cards to represent patient cases. They then used these cards to create cross-references for certain disease characteristics, enabling more accurate differential diagnoses based on those characteristics. At first, humans compared the cards, but in 1961, a computer began to be used for the purpose. This was the beginning of computers in medicine [1]. Before long, computers were used to store data about individual patients, predict diagnosis based on clinical observations, and send orders electronically. The electronic health record system was born.

Configuring those systems is one of the most challenging tasks in the world of computing. Not only can a slight mistake mean life or death, but the designers of software must contend with government policy, hospital politics, inadequate funding, changing standards of care, and the need for the software to communicate with a host of outside systems.

Fortunately, since the invention of the discipline of computer science, quality assurance techniques have developed. The definition of **Software Quality** has reached a mature international standard. The process of **Computational**

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Thinking for breaking down a real-world problem into programmable steps has been thoroughly studied. And **Coding Best Practices**, an informal set of guidelines to achieve the quality standard, are widely available.

Unfortunately, however, programmers are not trained in medicine. Even those with a long experience in **Health Information Technology** (HIT) are not kept abreast of the latest changes and generally know little of how medicine is truly practiced. For this reason, they must confer with clinicians who have a foot in both worlds, who speak both languages. If clinicians and researchers can communicate their world-changing ideas to HIT professionals, the world will change.

Programming and Computational Thinking

Generally speaking, for a computer to perform any task, even the most banal, we must boldly depart from the familiar shores of standard human thinking and step into a world of pure logic. This does not mean "smarter logic." One common misconception is that a computer is "smart" because of how well it can complete various tasks. In reality, computers are quite the opposite, blindly following every instruction given with no thought to the consequences unless taught exactly what to look for. The task of a **computer programmer** is to instruct a computer to perform a task correctly, covering every possible contingency in a reasonable amount of time, using limited computing resources.

There are exceptions to this micromanaging approach. Artificial Intelligence aims to task the computer to build its own logic and does not follow the rules set forth here. This topic is covered in Chap. 16.

Computer Primer

Before we can delve into the wonderful world of computers, we need to develop a shared understanding of some important terms. As in every profession, programmers have developed their lexicon to facilitate their work. Only a portion of these terms will be included here, but they should be sufficient to at least discuss computer science concepts.

The Von Neumann Model

Von Neumann was an early pioneer in electronic computing, and his simple model [2] for the parts of a computer still holds mostly true today. The names of these parts will be used liberally throughout this chapter.

Input: Information from the external world. Obtained from devices like keyboards and mice.

Memory: Stores data for use by the computer. This includes Random Access Memory (RAM) and Solid-State Drives (SSD). The reason for different types of memory is that the closer they are to the heart of the machine, the faster they are, but the smaller in capacity.

Central Processing Unit (CPU) Control Unit: Follows instructions to move data, tell the logic unit what to do with it, and deal with input and output data. Modern high-powered computers may have more than one.

CPU Logic Unit: Carries out operations on the data from inputs and memory. The speed of a CPU clock (3 GHz) refers to the maximum number of commands this unit can perform each second (3 GHz = 3 billion commands/second). Modern computers usually have several.

Output: Information sent outside the computer. Monitors and printers are common devices that use computer output.

Programming Terms

Although different programming languages vary widely, some concepts are common between them.

Variable Just like in Algebra, a **variable** represents a piece of data that is determined and re-determined as the process goes on. The variable is created with a specific line of code called a **declaration**. This line of code is a command that names the variable, may give it a starting value and type, and instructs the computer to reserve a little space in memory for it. If the value is ever changed during the program, the computer overwrites the value in memory with the new value.

There are many variable types, but a few important ones are the integer (such as 10, abbreviated **int**), the floating-point number (such as 10.263, abbreviated **float**), and the boolean (TRUE or 1, and FALSE or 0, abbreviated **bool**).

Function A **function** is a specific group of commands that a program may need to perform many times. A common function is the "=" on the keypad of a calculator. When the user presses this function button, a **function call** is initiated. The calculator takes whatever is on the screen, the operator such as + or –, and whatever the user enters afterward, combines these inputs and **returns** the result to the calculator screen.

A function in a computer program may be a single line or a million lines, but they all take inputs, called **arguments**, and return a result. A function is also **declared**, just as a variable is, and stored in memory. In the C programming language (a very popular language), functions are declared like this: **return function(arguments)**. An example of a function in C is **sqrt()**, which calculates the square root of a number. The function call for the square root of 4 would be written **x**

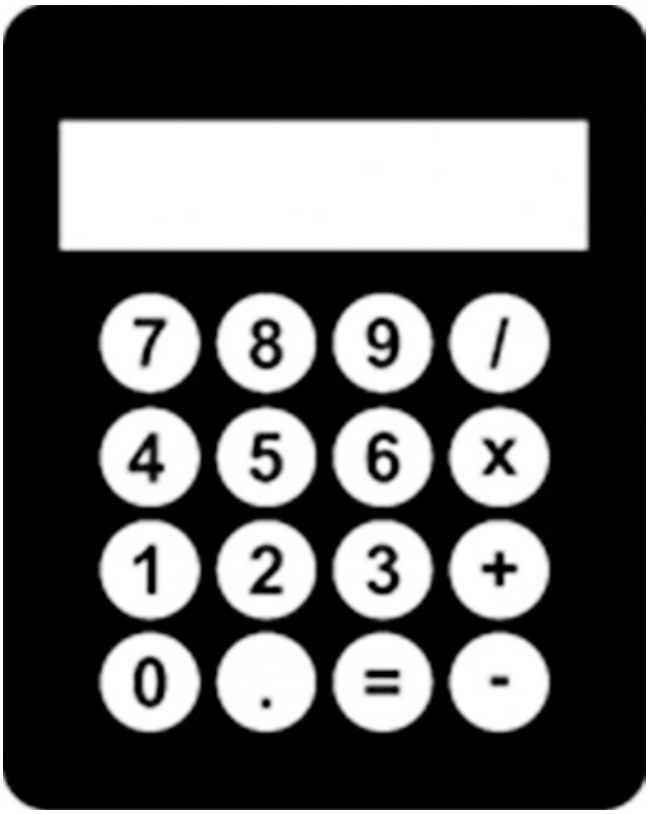

Fig. 2.1 An example calculator

= sqrt(4), where the answer, 2, would be returned into the variable **x** (Fig. 2.1).

Array An **array** represents a series of variables or values in a specific order. For instance, the line at the ice cream shop might be "Frank" then "Jane" then "Lucy", or **hungry_patrons = ["Frank", "Jane", "Lucy"]** written programming style. To look at a specific person in line, square brackets are used. So **hungry_patrons[0]** would be "Frank" and **hungry_patrons[1]** would be "Jane". Most languages have a prewritten function for finding the number of elements in an array. In C, it is called **size()** and is a function built into how an array works. So, for our example array, **hungry_patrons.size()** would be 3. The dot between **hungry_patrons** and **size()** shows that the **size()** function is a built-in function for arrays rather than a separate one.

String A **string** is a specific type of array made up of single characters. For instance, **"Ice Cream Shop"** is an array of 14 characters (even the space has a character code). Since **hungry_patrons** is an array of strings, and a string is a type of array, **hungry_patrons** is an array of three arrays and could be written **[["F", "r", "a", "n", "k"], ["J", "a", "n", "e"], ["L", "u", "c", "y"]]**. Strings are usually identified by being in single- or double quotes.

```
your_car = {
    type: "car",
    year: 2016,
    color: "teal"
}
```

Key

Value

Fig. 2.2 An example JavaScript object

Object Many languages use **objects**, which are variables that contain key/value pairs, functions, and even other variables. **Key/value pairs** in an object are in no particular order, so they cannot be accessed in the same way as an array. For instance, **your_car.type** or **your_car[type]** might be "sedan", while **your_car[1]** would make no sense to the computer, just as **hungry_patrons[type]** would also have no meaning. The curly brackets in the example tell the computer that everything inside the **{}** is part of **your_car**. A note: for compactness, a JavaScript object is used here, rather than C (Fig. 2.2).

Computer Language

Now that we have discussed some words for talking *about* computers, we need to discuss some words for talking *to* computers. Before a computer can execute even a single task, it must understand what it is asked to do. And because a computer makes no assumptions, everything must be spelled out to the finest detail. This is done, line by line, by laying out instructions much like a recipe. The computer reads the recipe from start to finish, performing each step. These recipes are computer **programs**. In modern programming, part of the work of programming is done by humans and part by algorithms. Before we can talk about computer instructions, however, we need to look at the alphabet used by a computer.

Binary

English has 26 individual characters to represent its spoken language, and many more if we include mathematical and scientific language. In contrast, there are just two characters in the language of computers, the base 2 number system 0 and 1. The language of the computer is built from only these two characters, and each 0 or 1 is called a "bit." The bit itself arises from an electrical impulse (but how this happens is beyond the scope of this chapter.)

A word about words: A **word** in the computer sense is a sequence of bits, not a word as in the English language sense. Bits combine to form a number, which may represent that integer exactly, or perhaps a floating-point number, or even a letter from the English alphabet. A computer will use a translation table to understand what the combination of bits represents. The most common translation table in modern applications is **Unicode** [3], so-called because it attempts to unify all possible symbols, including Asian logographic languages. In Unicode, "Hello" would be represented by the integer sequence 1032 1541 1548 1548 1551.

Fig. 2.3 A Jacquard Loom

Four bits make a nibble, eight bits make a byte, and sixteen bits make a word. In early computers, a nibble or a byte (depending on the system) comprised a single "instruction" or "number" or "idea." Complexity has grown since then, and in modern computers, the basic unit of communication is arguably the **quadword**, which comprises a sequence of 64 0's and 1's. This is the 64-bit system in commercially available machines.

Machine Code

The punched cards of the weaving loom mentioned at the beginning of the chapter could be thought of as a **machine code** to create a recipe or **program** to weave the fabric. Humans imprinted a binary code on a card ("hole" or "no hole"), which was then read by the loom to produce each successive row in a piece of fabric. It is referred to as a "code" because the card is not written in normal human language (Fig. 2.3).

Modern programmers do not generally look at machine code. This is because programs written for computers today are so complex compared with the simplicity of marking lines of fabric. The algorithms for reducing the program to the smallest size are so advanced that the code becomes difficult to translate back into a human-readable form. Translating machine code is time-consuming and expensive and contemplated only for very specific purposes, such as catching cybercriminals.

The smallest units of **machine code** refer to a single, basic **instruction**, such as fetching a number from memory, performing a logic function on two numbers, or storing a number in memory. To make things more complicated, every processor brand might have its own set of instruction codes or **Instruction Set Architecture** (ISA). For humans to work on a program, something more abstract would be helpful.

In one popular machine code [4], instructions for adding two numbers together might look like this (depending on variants and hardware).

```
00000000000100000000000010000011000000000010000000000000100000011
00000000000100010000000111000011
```

Assembly Language

The next step in simplification or abstraction uses readable human language to represent each step in a process. This level is at least understandable, even though we still need many lines of **assembly language** to perform even simple programs. To translate assembly language into machine code, programmers utilize a software tool called an **Assembler**. **Assemblers** use information about the instruction set and the machine's architecture to convert each instruction to binary.

Assembly also allows for other clever tricks, such as comments (small notes that help the programmer remember what part of the program does), some error checking, and allowing "labels" to name variables something memorable, such as "ans" for the answer to the addition problem. At one point in time, this was the level at which most programmers operated, but the need to produce more code more quickly and more reliably pushed the field to the next level.

The same instructions for adding two numbers together as above, but in Assembly language, might look something like this:

```
LD t1 0x00000001 ;Load Memory location 1 into t1
LD t2 0x00000002 ;Load Memory location 2 into t2
ADD ans, t2, t1 ;Add t1 to t2, store the answer in ans
```

For those curious, LD is the command "Load Doubleword" that loads data from memory. "0x" means hexadecimal notation, which can be thought of as a shorthand for binary. In assembly, comments start with a semi-colon; everything on the line afterward is ignored by the computer. In C, "//" denotes a comment.

Compiled Language

The next level of abstraction involved moving toward commands that are easier to read and contain more than one Assembly instruction within them using a **compiler**. What earned the compiler its name is how it converts the **compiled language** into machine code using multiple optimizers and error-checkers in various sequences, compiling the changes on top of each other. Each line of code is read into the compiler, and these statements are, in turn, broken down, analyzed, optimized, broken down further, checked for errors, etc., and finally written into machine code. The result is that complex functions can be represented in very compact statements understandable to humans.

Adding two numbers together in C looks something like this:

```
ans = t2 + t1;
```

This example is much easier to understand and removes many spots where a human might make an error.

Operators: C-like languages use several symbols for logical and arithmetic operations. Some important ones to know are shown here (Table 2.1).

As in math, there is an order of operations in computer programs. Note the difference between "=" and "==". A computer will not figure out which was meant by the programmer, which is a frequent source of bugs.

Table 2.1 Common operators in the C programming language

x + y	Return the sum of x and y	x – y	Return the difference of x and y
x * y	Return the product x and y	x / y	Return the result of x divided by y
x = y	Store a copy of y in x	x % y	Divide x by y, return the remainder
x || y	If x OR y is TRUE, return TRUE	x == y	If x and y are the same, TRUE
x && y	If x AND y are TRUE, return TRUE	x > y	If x is larger than y, TRUE
x >= y	If x is larger than or equal to y, TRUE	x != y	If x and y are not the same, TRUE
!x	If x is TRUE, return FALSE; otherwise, return TRUE (or "1")	x++	Store x+1 in x
x[y]	Return the yth value in x	x << y	Multiply x by 2 to the yth power

Table 2.2 TRUE vs. FALSE examples

Variable value	Is there something there?
0	FALSE
–1	TRUE
["Frank", "Jane", "Lucy"]	TRUE
"False"	TRUE
4 – 4 (the result of 4 minus 4)	FALSE

Compiled language also enables **code libraries** using **linkers**, which allows the user to call on common and very well-tested pre-written code to perform complicated functions. For example, to find a certain string of characters in a document of any size:

```
index = strstr(document, "you found me")
```

After this executes, the variable **index** will hold the numbered position in the string **document** where the string "you found me" first occurs. And because the code library has been reviewed and optimized many times over, the programmer does not need to worry (much) about hidden bugs. They are ready to move on to build the next part of their program. How could we possibly do any better?

What is TRUE? This brings up the side topic of what is TRUE and FALSE. These boolean logic ideas show up frequently in programming and depend somewhat on what programming language is used. Generally speaking, FALSE is equal to "0" and any value that is not FALSE is TRUE. Another way to phrase the question is, "Is there something in the variable?" This leads to some confusion for humans but makes perfect sense to the computer (Table 2.2).

Interpretive Language

Compiling a program takes time, and any given compiled program is almost 100% guaranteed to have at least one bug, meaning it will need to be changed and compiled again. Eventually, this time adds up. Some programmers thought it would be nice to run code without having to compile it. This idea led to the creation of **interpreted languages**. **Interpreted languages** use "just-in-time" compiling to run each instruction right when needed, without waiting for the compiler. This allows for quick adjustments to the program, **dynamic typing** (meaning the interpreter will figure out the type of a variable without being told), as well as the ability to "emulate" the software, meaning the ability to show what the result will look like to a user after each change in the code is made.

The most popular languages in use today are only interpreted, such as JavaScript and Python, or are compiled with an option for an interpreter, such as Java and C. There are many commonalities between these different languages. In this text, we will represent concepts with C-like structures unless otherwise specified.

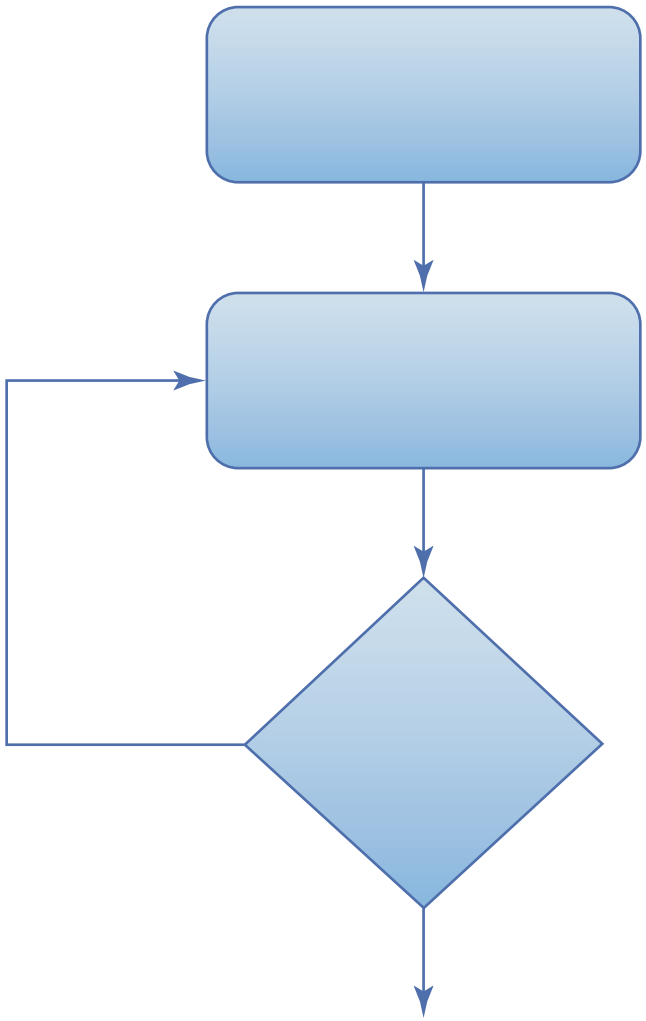

Fig. 2.4 An example flowchart with sequential, conditional and iterative elements

Control Structures

In a process flow diagram or "decision flow," each step in the process has a little box describing what it does. Working very much like those blocks, the building blocks of a program are called **Control Structures**. In programming, a control structure may also include other blocks inside of itself to break down the process further. These structures take one of four general forms: sequential blocks, conditional blocks, iterative blocks, and recursive blocks (Fig. 2.4).

Sequential

A sequential block executes a series of specific instructions in order. This is the default mode for most programming languages.

```
get_in_line();
buy_ice_cream();
eat_ice_cream();
```

After each step completes, the program marches on to the next instruction. In C-like programs, a semi-colon notes the end of an instruction.

Conditional (If/Else, Switch)

A conditional block executes several possible sets of instructions depending on the answer to a TRUE/FALSE question.

```
if ( have_flavor("chocolate") ) {
  buy_ice_cream("chocolate");
} else {
  buy_ice_cream("vanilla");
}
```

In this example, if h**ave_flavor("chocolate")** returns **TRUE,** then we will call b**uy_ice_cream("chocolate")**. If **have_flavor("chocolate")** returns **FALSE**, then we will call **buy_ice_cream("vanilla")**. A second common conditional control structure is the "switch." A "switch" command goes beyond just TRUE and FALSE, checking the value of a variable called "flavor" and deciding on a response.

One other important kind of conditional structure is the **exception**. In some languages, an exception is **thrown** if some section of code has an error. A separate section of code

```
switch (flavor) {
  case "vanilla":            // If flavor ==
"vanilla", start here
    eat_ice_cream();
    break;                 // This skips the
other cases
  case "chocolate":          // If flavor ==
"chocolate", start here
    savor_ice_cream();
    break;
  case "mint":               // If flavor ==
"mint", start here
    make_ugly_face();      // No offense to
mint-lovers
    break;
}
```

called an **exception handler** can take that exception and do something about it. For example, for the above code, consider the case that there is no ice cream. Then, "flavor" is not valid, and an exception is thrown, which might trigger an attempt to get ice cream and try again, or else call the **make_ugly_face()** function.

Iterative (While, for)

Consider the problem of looking through a list of ice cream flavors to see if the shop has chocolate. We do not know how many flavors there might be, so it is hard to write a sequence of conditional blocks to check through it. Instead, we can use an **iterative structure** to repeat the same sequence of instructions repeatedly until we conclude.

The **while loop** executes a series of instructions, then asks a question to see if it can stop:

```
while (are_we_there_yet == FALSE) {// "Are
we there yet?" "Nope"
  drive();                          // Drive
down the road a bit
  eat_chips();                        // Eat
some chips
  fiddle_with_AC();                 // Try to
get temp right
}                                  // Time to
ask again . . .
```

This loop will not stop, ever, until the condition a**re_we_there_yet == TRUE**. So, setting this loop aside and going back to our ice cream example, we could create a **while loop** that scans each group of characters to see if it is "Chocolate". If there is a match, we set a variable **are_we_there_yet** to **TRUE** to tell the loop to stop, and another variable, such as **found_it**, to **TRUE** to show we found it. If we hit the end of the sign without finding chocolate, we also set a**re_we_there_yet** to **TRUE** but in this case, set **found_it** to **FALSE**. If we are not done, we move to the next entry and check again.

A **for loop** is much like a while statement, except that some of this work is right in the first line. Consider the following:

```
found_it = FALSE;
for (int position = 0; position < ice_cream_
sign.size();
position++) {
       if    (ice_cream_sign[position]    ==
"Chocolate") {
    found_it = TRUE;
    position = ice_cream_sign.size();
  }
}
```

The first thing we do is assert we have not yet found chocolate and set **found_it** to **FALSE**. Next, we start the for loop, which has three parts separated by semicolons. The first part is the **initialize** step, which sets the variable **position** equal to 0. The for loop then makes a **test**: "Is **position** less than the size of the **ice_cream_sign** array?" If so, we continue. The last part is the **update** which tells the computer what to do after each iteration finishes. In our case, the variable **position** is increased by one to check the next spot in **ice_cream_sign**. In this way, we iterate over each position in the **ice_cream_sign** array, one at a time.

During each iteration, we check the **positionth** spot in **ice_cream_sign** to see if "Chocolate" is there. If that check returns **TRUE**, we set **found_it** to **TRUE** to mark our success, and we set **position** to a value which will ensure that the loop does not run again.

Where do we start? An important note is that if we did want to start at the beginning of a document and run through to the end, in C-like languages, the first character would be at position "0", not position "1". The reason for this is beyond the scope of this book. Starting with "0" is called "zero-indexing" and is another frequent bug-maker. The position "1" in "Hello" is "e", not "H", as might seem more natural.

Loops can present serious problems in code and are one of the most frequent sources of bugs. This will be discussed more in-depth near the end of this chapter. For now, let us consider the question of the **nested loop**. Consider this code,

meant to change every entry in **myarray** into all lowercase "z", character by character.

```
myarray = ["Car", "Red", "2016"]
// Start by iterating through each element,
like "Car"
for (int word = 0; word < myarray.size();
word++) {

  // Inner loop based on the length of the
element, so 3 for
"Car"
   for (int letter = 0; letter < myarray[
word ].size();
letter++) {

     // Set the "letter"th position of the
"word"th element to
"z"
    myarray[ word[ letter ] ] = "z";
  }
}
```

The nested structure allows the loop to cycle through each word in the array and then through each letter of each word and replace each with "z", no matter how many words or how long they are. This structure is very powerful, but the more layers, the harder it is to understand and fix if it is not working correctly.

Recursion

Recursion is not always considered a control structure, but it can do tasks that no combination of the other mentioned control structures could. In essence, a recursive process calls itself, sometimes many times, to reach an answer. An easy-to-understand (though gratuitous) example is that of the factorial from mathematics.

```
int factorial(int x) {
  if (x == 1) {return x;}
  else {return x * factorial(x - 1);}
}
```

Let us step through this, calling **factorial(3)**. The function checks to see if 3 == 1. It does not, so instead, it tries to return 3 multiplied by a function call. At this point, the program puts **factorial(3)** on the bench and calls **factorial(3 - 1)**. This function starts by checking to see if 2 == 1. It does not. So instead, the program calculates 2 multiplied by **factorial(1),** which requires putting **factorial(2)** on the bench in memory to wait for the result of **factorial(1)**. Finally, **factorial(1)** sees that **x** does equal 1 and returns 1. **Factorial(2)** comes off the bench and returns 2 times 1 a.k.a. 2, and **factorial(3)** then returns 3 times 2 a.k.a. 6.

However, keep in mind that each function call waiting to return consumes a piece of memory (this has to do with the programming stack, which is beyond the scope of this chapter). Calculating **factorial(1000)** this way may gradually choke the processor as the program stores each successive function call on a slower, more distant memory. There are other processes, like searching an organization chart for a particular person, where recursion is, by far, the most elegant approach.

To present this process, we need to introduce another data structure commonly used in programming: the "tree." In a tree, there are a series of entries linked together through parent-child relationships. A parent entry contains information about itself and an array of links to all its children. The start of a tree is the highest entry—the one that has no parent. In the diagram, you can see a tree with the highest entry named "Alice." Our recursive function will have the task of finding the entry named "Charlie" and will do so in a "depth-first" fashion, meaning that it will check if it has found the answer, and if not, will call itself on each of the children.

Call #1 examines the highest entry where it finds Alice is not Charlie and calls itself on the first link in Alice, the one pointing down to Bob. This function call is set aside in memory while function call #2 takes the stage. This call sees that Bob is not Charlie either and calls itself on the first child of Bob, Dan. This function, call #3, sees that Dan is not Charlie and that Dan has no children. It returns FALSE, meaning it finished without finding Charlie (Fig. 2.5).

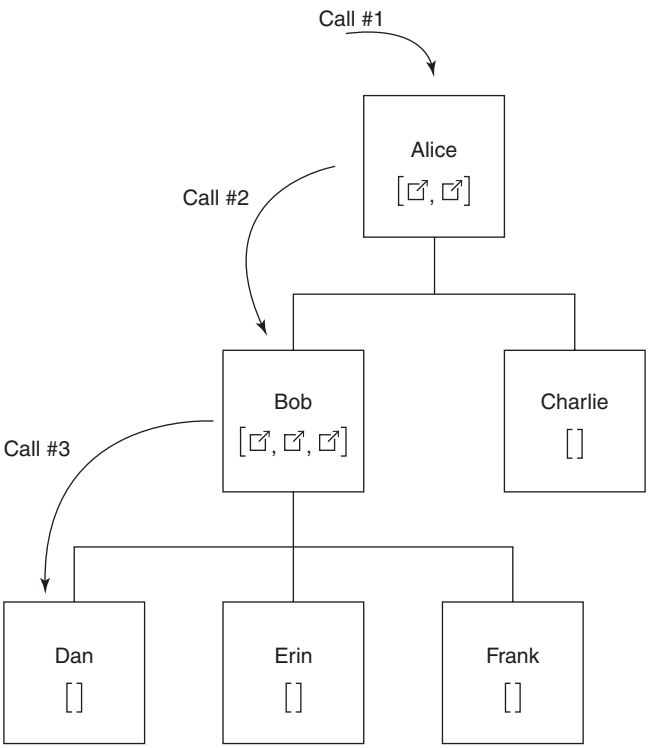

Fig. 2.5 Recursive function calls in a data tree

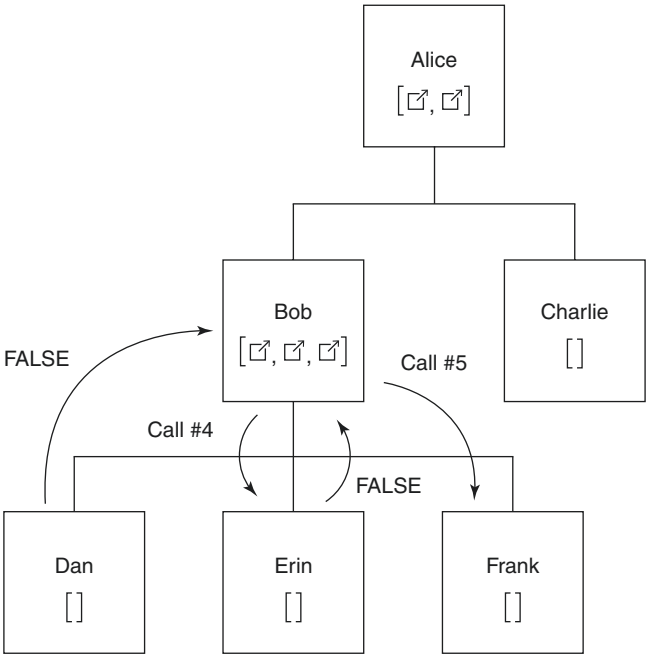

Fig. 2.6 Checking each of the children

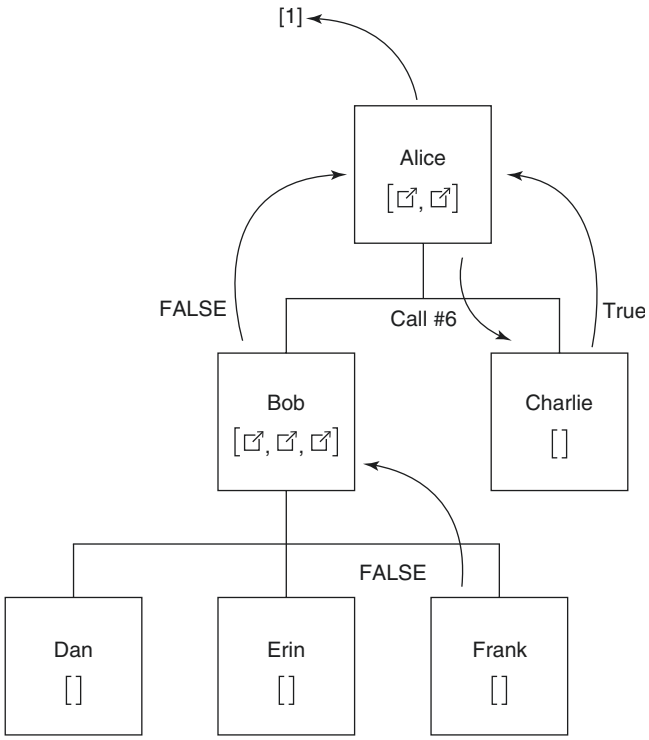

Fig. 2.7 Returning the result

At this point, a normal function would be stuck. There is no link back to Bob inside Dan. But a recursive function can overcome this because function call #2 is still sitting inside the Bob entry, waiting to continue. Function call #2 wakes back up to get the FALSE return signal from call #3, sees that there is another child of Bob, and calls #4 on Erin. This also returns FALSE, so call #5 is made on Frank. This again returns FALSE (Fig. 2.6).

At this point, call #2 gives up and returns FALSE back to call #1. Call #1 sees that Alice has another child, and so calls #6 on Charlie. Call #6 quickly finds it has found Charlie and returns TRUE. Call #1 knows that when one of its calls returns TRUE, it should send back the index in the array of children; in this case, 1 (0 was Bob). Since there was only one step, an array with a single entry [1] is the final return value for the function. If the function was searching for "Frank," it would have returned [0,2] to show the path: the first link in Alice (remember 0 is the first one!), then the third link in Bob (Fig. 2.7).

Computational Thinking

We have examined some of the common tools used to make things happen in programs, and we have also seen that solving a problem using a program can be challenging and error-prone. Experience over the decades has produced a few common approaches to reach the end goal of **Software Quality**, defined by the International Standards Organization (ISO) as [5]:

1. Functional Suitability: Gets the right result.
2. Performance Efficiency: Gets there in a reasonable time using few resources.
3. Compatibility: Friendly towards other software.
4. Usability: Minimizes user frustration.
5. Reliability: Does not crash the computer or light things on fire.
6. Security: Cannot be misused by bad actors or unwise users.
7. Maintainability: Can be understood/updated by the next programmer (especially oneself.)
8. Portability: Can be moved or replaced easily.

Computational Thinking focuses on the first part: getting the right result. But it also considers many of the other factors in software quality. Denning [6] defines computational thinking as "the mental skills and practices for designing computations that get computers to do jobs for us, and explaining and interpreting the world as a complex of information processes." We will discuss a few techniques along these lines, thinking about a system designed to irrigate a garden.

Specification

The first step in programming involves no computer code, and strictly speaking, it is outside the box of Computational Thinking. We must first identify precisely is the question we are going to answer. This includes mechanical questions, such as the size of the garden, and computational ones, such

as how to decide if watering is needed and how much. Answering these questions upfront will save time by creating a solution that covers what is needed and no more. We will address the subject of specification more in-depth later in the chapter. Here is the start of our specification.

Aims:
- Primary: To encourage the growth of corn in a garden plot using irrigation.
  - Secondary: To minimize water waste.
  - Tertiary: To minimize user interaction.

Unanswered Questions:
- How do we decide how much water is needed?
  - How does the system dispense the water?

Decomposition

To accomplish our aims, we need to break them down into some specific, solvable problems. This process is called **decomposition**. As the program solves each of the problems, it returns the result to the main program. When all results are in, the aims are reached. Turning our attention to irrigation, there are a few tasks that make up the overall aims:

1. Calculate total water needed per day.
2. Calculate total water supplied by other means today.
3. Calculate how far to open the tap to spread that water flow over 24 h.
4. Open the valve.

The reader may have noticed an assumption: we are meant to spread the water flow over 24 h. Assumptions are the bane of programmers—do not assume anything if possible. Whenever feasible, nail down every fact in the specification. Some assumptions can be unavoidable: we might assume that the water supply has water, that the hoses are connected and not leaking, that the valve opener has power connected, etc. In these cases, we still want to identify each assumption to build exception handlers or other systems to reach the best end we can (perhaps by sending a message to the user or using a backup system).

The reader may also have noticed that each of these steps requires more decomposition, especially how we will figure out how to calculate the total of other sources of water. Here is the first attempt in pseudocode.

1. Access a weather internet site.
2. Find information about weather prediction for today.
3. Scan for rainfall prediction.
4. Read rainfall prediction for the day into a variable.

Pseudocode

Pseudocode is not another programming language. It is like an author outlining their book before they begin writing it. To make pseudocode, a programmer describes roughly what they want to accomplish with each code section to complete the solution.

Another critical assumption was just made: the system will have access to the internet. This will need to be added to the specification, or another way to predict the rainfall will need to be used.

Abstraction

There may be other water sources, such as animal life, sprinklers not intended to hit the garden, pipe leakage, the sudden eruption of an artesian well, or simply a poor prediction from the meteorologist. However, these are not important enough or easy enough to predict to be worth the trouble. The problem can be simplified to:

"How much water do I need today."

- "How much will fall from the sky today."

"Total water to dispense today."

This is an **abstraction**. It simplifies a problem from an unanswerable question to an answerable one.

Whether or not to use an **abstraction** is often a matter of art, estimating the likely effect to decide whether it should be included in the model. This is not specific to the world of computing, being common to physics, statistics, and informatics.

A **function** is another form of abstraction. For instance, in **C**, **sqrt()** is a function that calculates the square root of a number. The programmer does not need to understand Newton's method for square roots to find one, they just call the function, and the correct answer is delivered to them.

This function is part of the **C** code **library**, a group of widely used functions that have been written and thoroughly tested.

Pattern Recognition

Recognizing patterns in a problem allows us to create an abstraction (such as a function or a loop) to handle the issue every time it appears, rather than typing the code all over again. In our irrigation example, we assigned 24 h to the irrigation. Why? Consider the pattern of updates on meteorological estimates. At least once per day, a new prediction is made. The closer we are to the period of time being predicted, the more accurate our calculation is.

Recognizing this pattern makes our solution more likely to give us the right answer. After all, we might simply spread the yearly average rainfall over 9 months. But then we would be farther off the mark every day during the 9 months.

Also, each of the steps of calculation needs to be solved multiple times. As such, they should be in functions or loops that can be run over and over, rather than a single million-line program that repeats almost character for character at the start of each new day during the 9 months.

Parallel Processing

In years past, the computer had a single processor that needed to execute each command in order. If a command had to wait for half a second for information to be fetched from the hard drive, everything would come to a standstill for the full half-second, even if the next command did not require that data yet. Since that time, hardware and software designers have enabled a way to overcome this obstacle through parallel processing.

Think about a racetrack where runners all run on a single lane. Each racer must finish before the next can begin. Adding parallel tracks makes the race much more exciting (and takes less time) as all the racers can compete simultaneously. Software optimizers or programmers identify sections of code that can run simultaneously without interfering with each other and mark them. The computer then turns these sections of code into a series of executable statements called **threads**. Then, while thread #1 waits for the slow hard drive to respond, thread #2 can run its commands. Increasing the number of **cores** or **processors** in a single computer allows for more and more threads to run simultaneously.

This kind of computing is also often called **asynchronous**. It increases performance, but this parallel competition also makes a new type of bug possible called a **race condition** if the threads are not truly independent. One example might be a news website that wants a user to pay before they see an article. Two threads are started: one to check to see if the user is a paying customer, the other thread to load the content. The race is on! If the programmer is not careful, the "content loading" thread might show the article before the "paying customer check" thread finishes, letting the user get the article for free.

Parallel vs. Asynchronous: These two terms are often interchanged but are not the same. "Parallel" refers to two threads executing simultaneously without waiting for the other to finish. "Asynchronous" also refers to threads running simultaneously without waiting but more specifically refers to the two threads not having to work according to the same rhythm. For example, if a laptop with a slow processor is playing a game on a website, and the website server is preparing the next level of the game using a faster processor, the laptop and the server are working together, but each to a different rhythm.

In our irrigation example, finding the prediction for daily rainfall and calculating the total water needed are separate, isolated calculations. The order in which they occur does not matter. They both access one piece of data (the date), but they do not change it, so running these two commands in parallel (or asynchronously) works well. However, both need to finish before calculating the amount of water to dispense; otherwise, we will cause a race condition and undesirable results. (In the worst case, an error that causes the program to stop completely or dispense an infinite amount of water, or at best, the same amount of water each day despite what the prediction is).

Algorithm Design

The word **algorithm** is often used to describe parts of programs, but they are not the same. An algorithm is a set of instructions to complete a calculation, such as determining how much water to dispense. But the program as a whole must also operate a valve and perform other functions. In this way, an algorithm is a part of a program and requires its own consideration.

In our garden irrigation system, the algorithm appears simple, but we could consider plenty of modifications that would introduce more subtleties. For instance, we might average the predictions from several websites or use a weighted historical average using the usual rainfall in past years. We might want to consider the price of water at different times of the day or measure the user's habits to predict the likelihood that the water flow will cause problems with water pressure (i.e., someone showering in the house.) We could also consider the time of day, watering more at night than when the sun is up. The program could even take minute-by-minute rainfall measures to predict how much water will be needed for the rest of the day.

Each of these could bring benefits to our aims but could also subvert them. For example, determining when the user will need water for other things might mean more user interaction, which we do not want. On the other hand, averaging the predictions of multiple websites would help a great deal if one of the websites were to go down. We also need to consider the available inputs and outputs, the computing resources at hand, and the end goal in mind. A garden irrigation algorithm that is 100% accurate but requires a small university's computing resources is not useful.

Coding Best Practice

It is important to discuss the right way to cement these principles in code along these same lines. Even if the code reaches the end goal of giving us the right answer, there are right ways to code, and there are wrong ways to code. A quote attributed to Tom Cargill of Bell Labs [7]: "The first 90% of the code accounts for the first 90% of the development time. The remaining 10% of the code accounts for the other 90% of the development time." Coding projects may require 180% of the expected time due to code being written the wrong way, leading to rewrites and workarounds. Following best practices can make the difference between a software project being on headlines or headstones. Unfortunately, **coding best practice** is not outlined step-by-step in a position paper; rather, it is an informal set of rules generally followed by successful programmers. Here are some of the more prominent ones:

Commenting Almost all languages allow for commenting. This is the text written into a program that is ignored by the interpreter/compiler/assembler and is exclusively for the programmer's use. They should be written liberally. There are two reasons for commenting gratuitously: (1) writing down a chain of thought might reveal errors, and (2) code is awfully difficult to understand without it, even for the programmer who wrote it. Verbose comments are encouraged as a best practice.

Keep It Simple Eventually, the code will need to be reviewed, maybe even by the original programmer. If the code is understandable, it increases the chances of being updated or reused rather than scrapped. A more efficient way to solve a problem is not always better; others need to understand how it works.

Naming Conventions Along with the above, ensure that variables and functions are all named something meaningful. For example, **predicted_rainfall** is generally better than **pr**. Going further, it helps to have variables, and functions differentiated by differing use of underscores and capitals, such as lowercase and underscores for variables (i.e., **predicted_rainfall**) and specific capitalization and no underscores for functions (i.e., **dailyRainfallReader**()). The reader may also have noticed that there are no spaces in the names. Almost always, the compiler or interpreter has no way to know whether a space is intended to start a new piece of code or is another part of a name. There can be no ambiguity or assumptions in programming; the space represents the move to a new command or part of a command.

Modular Design When we decompose a problem into individual parts, we can then write solutions to those parts. These are modules. It is very important to segment these modules from each other because the inevitable bugs become much easier to deal with if we can isolate the module that causes them. This also allows for reusability, as a module that performs a task can be used repeatedly by different parts of a program. This saves the time of writing it again and prevents the new bugs that that would create.

Handle Garbage Gracefully A function must be written to handle any input from the user gracefully and without crashing. If invalid input is given (such as **"Golf"** or **-1** for rainfall in a day), the program must respond benignly. The best response points out the issue, such as **"Invalid input to calcVolume(): 'Golf'"** but anything other than crashing or causing other unpredictable behavior is preferred. This is also called **Programming Defensively** as if the programmer imagines that users and other programmers are going out of their way to cause trouble.

There are many, many more opinions and ideas about what constitutes coding best practice. See the sources at the end of the chapter for more information.

Operating System

Once a program is written, it needs a place to run. Many applications are now written to run on an internet browser, but all must eventually run on some kind of operating system. Windows is an example. The operating system is itself an abstraction. The full understanding of what an operating system is and what it does is beyond the scope of this text, but the simplified version is given here for context.

A computer is made of hardware: chips, capacitors, fans, etc. A tiny kernel runs inside the processor, directing the processing of instructions. On top of this runs the BIOS, which allows the processor to interact with the memory, the keyboard, and other basic devices. On top of the BIOS runs the Operating System, which provides a means for software to make hardware requests, send information to the internet, show graphics on the monitor, or load data from memory. It also ensures that processor time is shared fairly among all the applications and that all the applications behave well and

do not interfere. When a piece of software runs, processor time is supplied. All the particulars of how that happens are hidden from view.

Application

An application is a program, and it runs on the operating system, making requests of the hardware repeatedly, usually at the behest of the user. There are many popular examples of applications, from iTunes by Apple to Microsoft Teams. The most familiar applications are those that we install and show windows for us to interact with when we run them.

Background Applications Some applications are running even though there is no window showing on the screen. These are called "Background Applications" and include things such as the Notification app for Facebook. They may or may not announce their presence, and many background applications never interact with a user at all. **Push**-style background applications wait to be triggered (pushed) by other applications, while the **pull**-style pulls information automatically to know when to trigger (such as the time of day). Operating systems generally use dozens of such applications to perform their tasks. It is common for large applications to load most of themselves into faster memory in the background using a launcher application. When the user clicks to activate them, they can load more quickly.

Web Applications Some applications run on top of other applications. This is true of web applications, which do not run on the Operating System itself but rather on the internet browser (such as Safari or Chrome). Without the browser, the software cannot run. These applications require a different programming language because they make requests of another application rather than the Operating System, which brings up the subject of the API.

Application Programming Interface (API) Applications cannot tell each other what to do unless they specifically open them to communication. The specific commands and procedures for one program to communicate with another one constitute an API. In this way, applications can work together to accomplish something. Google Authentication has an API. Facebook and other applications use this when the user clicks on "Sign in Using Google." The application sends some information to Google's API to tell it who is trying to authenticate. Google asks for the password, checks it, and sends a success or failure message back to the application. If successful, the application logs the user in without ever seeing the password. Interoperability like this is crucial in medicine and is covered more in-depth in Chap. 13.

Beyond the Application

Many years ago, the environment for using a program consisted only of the user, the computer, and maybe some machinery operated directly by the computer, such as a printer. With the advent of computer networks and the internet, there came incredible opportunities for sharing data and information between computers. Modern programming employs what is often called the **client-server model**. In this model, the client computer interacts with the user, showing information and presenting buttons to push and fields to fill. The client also interacts with a server, asking for data and submitting the client's user's data. To organize this data, the server uses a database. In this way, when a client asks for data, the server can find the correct information quickly and supply it.

A simple example is the checkout of any web store. The checkout screen is part of a web application running on the user's computer or phone, presenting buttons and a display. The user enters a request to make a purchase of $100 using their credit card. The application then interacts with a server computer at the credit card company headquarters, asking if the user is authorized to make a payment and $100 available. The server performs two database queries, one to check out the credit card number, PIN, expiration date, etc., and the other to see if $100 is available. If both are valid, the server tells the database to credit $100 to the seller and replies to the web application that the request was successful. Finally, the web application shows the user that the transaction was successful.

Full-Stack Sometimes an individual describes themselves as a "full-stack" developer. This stack is distinct from the system stack mentioned earlier. What a full-stack developer is advertising is the ability to develop programs for serving users (client-side programming), serving applications (server-side programming), and serving data (database programming). They might say they do a particular kind of stack, such as a LAMP stack. This refers to a particular group of programming languages and development platforms. The LAMP stack is JavaScript (an interpretive language), **L**inux (an operating system), **A**pache (a server platform), **M**ySQL (a database platform), and **P**HP (a scripting language for websites). A full-stack application has a client, server, and database portion.

Databases Data is the bread and butter of informatics and is found most often in a database. Greater focus is placed on databases in other chapters of this text, so it will not belabor the subject here, only to say that databases use **declarative** programming languages. Structured Query Language (SQL) is an example and differs from the languages we have discussed up until now, because its lines of code are interpreted by the software running the database, not the CPU, to deter-

mine what action to take. Think about what happens when you use a search website. You declare what you are searching for, and the website returns the results. But every site makes its list of results differently because of its programming. Much the same way, declarative code makes a generic request, and the database code decides how to process it.

Preparing the Code for Use

Whether or not code is successful in use depends on how good it is, but it also depends on whether it fully addresses the problem it set out to solve. It also depends on the ability to be updated and fixed as the inevitable bugs begin to surface.

Specifications

Knowing what the code is supposed to do before the programmers get to work is crucial to success. There is no single standard method in which to prepare a software specification, but there are some common elements (Table 2.3):

Many of these elements are common to project design, which are covered in detail in Part IV of the book. Suffice it to say that without a specification, the software cannot be tested to conform to a specification, and therefore it is impossible to know if it is done or even safe for use.

Unit Testing

When each module is conceived, the method for testing it should also be considered before coding begins. Code architects create a test for each aspect of the program, referred to as a **unit test**, and the programmers write simple code to pass each test. This is called "Test-Driven Development" and has proven very effective in bringing a specification to life with as few assumptions as possible, especially in bigger projects [8]. The tools for this process are discussed in Chap. 12.

Table 2.3 Common elements in software program development

Authoring information	Who wrote the spec, and when they wrote this version
Aims	What the software is supposed to do from the perspective of the user.
Methods	What tools will be used, such as the programming language, the database platform, and the operating system?
Stakeholders	Who cares about whether the project succeeds or fails and those that influence the specifications?
Testing	How will we test that the program works and will continue to work in real-world settings?
Work Estimate	How much work will it take to get to the finish line?
Unanswered Questions	Project questions that need an answer, even those that involve no actual coding

Reading Other People's Code

Code does not read like a novel. It is designed to be understood by a computer, with no room for assumptions. In places, it will appear to be excessively lengthy, with many logic checks that seem unnecessary. In other places, a complicated step in the process may be obscured by a poorly named function that leaves the reader without any clue to the intended result. Comments may be present, but even these can be unreliable at times. As a result, reading code written by someone else is a daunting process.

The author knows no rigorous, well-studied process for reviewing code, despite being asked to do it many times. There are two main techniques to get started trying to understand a piece of code. The first involves writing in commands called **breakpoints** or using an interpreter to see exactly what the program is thinking at a given point in the process. For example, for the irrigation system, a programmer might insert a command to print the values of all the variables right before the code finishes. That command is just for debugging and forms a breakpoint. This should show how much rain is predicted to fall, the garden area, the website is used to get the information, etc.

If the code cannot be run, then the second technique is needed. First, look for something in the code with a known intent—for example, the command to read a rainfall prediction from a website, recognizable by the URL. Otherwise, there may be a particularly helpful comment or a function call to a well-known library function.

Starting from that well-understood line of code, work backward towards the beginning of the code section, and once everything from the beginning makes sense, work forward until the end of the code section. It may be helpful to add or update comments along the way as a reminder for those coming after.

Reading Other People's Code for Errors

Even more challenging is looking for errors in the code of others, especially if the program cannot be run. First, find out what the code is meant to do and how it failed. It may be valuable for the programmer to think about how they would approach the end goal of the code, as the error might be apparent by comparison.

With loops, it is useful to start to write out the value of the variables at the end of each iteration. This can reveal the pattern of advancement, and give an impression of what the data might look like 10 or 1000 iterations in (Table 2.4).

We need proceed no further to know where this will wind up.

Table 2.4 Working a loop by hand

	a	i	j

str a = "astronaut";
for (int i = 0; i < 1000; i++)
{
for (int j = 0; j < 5; j++) {
a = a + a[j];
}
a = a + " ";
}
	astronauta	0	0

	astronautas	0	1
	astronautast	0	2
	astronautastr	0	3
	astronautastro	0	4
	astronautastro a	1	0

Here are some of the most common errors, some of which have been mentioned before.

Off-by-One Zero-indexing throws humans for a loop. Consider the following code:

```
// Calculate the mean
array grades = [86, 72, 95, 100, 65, 92];
int sum = 0;
for (int i = 1; i <= grades.size(); i++) {
  sum = sum + grades[i]; // Add each grade
to the sum
}
int mean = sum / grades.size();
```

It may seem straightforward, but this code has two common errors, both relating to zero-indexing. It is in how the **for loop** is started: the variable **i** starts with a value of 1, so the first loop will add **grades[1]** to the sum. But **grades[0]** is the first number in the array, not **grades[1]**. The second error is left to the chapter exercises, which are available as an electronic download.

Unit Conversion Imperial/Metric conversion contributed to the crash of at least one space probe [9]. Consider this code:

```
// Calculate the right medicine dose
float weight = getPatientWeight();  // Prompt
nurse to enter
patient weight
// Access online database
float recDosePerWt = getRecDosePerWt("acetam
inophen");
return weight / recDosePerWt;
```

It first calls **getPatientWeight()** and stores the result in **weight**, then gets the dosing for acetaminophen by weight, and then returns the weight-adjusted dosing for a patient. This code appears innocuous, but it has a serious flaw. Will the nurse enter kg or lbs.? And what about the online source? Does it use kg or lbs.? There can be no assumptions in the code. Modern dose databases will provide the units along with the dose information, and this should be compared against the units entered by the nurse to ensure that they align, and if not, make the conversion. Finally, the units must be part of the returned value to avoid passing bad data back up the chain.

Infinite Loop Consider the following code:

```
// Count the appointments on my calendar
for the week
int day = 0;
int total_appts = 0;
int daily = 0;
while (day < 7) { // Stop when we reach the
7th day

  // Grab the number of appointments for the
day
  daily = getDayAppointments(day);
  total_appts = total_appts + daily; // Add
to the total
}
```

We start by setting some things to zero. Then we start our loop. We first fetch the number of appointments for the day, then add it to **total_appts** before going on to the next day. But we are missing a statement. The variable **day** is never actually changed, so we keep adding appointments from day 0 to **total_appts** over and over again into infinity. This loop will attempt to continue forever, consuming all computer resources in its quest for completion. This kind of bug is what usually causes the dreaded "freezing screen." There are times that an infinite loop is intentional, such as the loop to run the irrigation system every day until the end of time. But in that case, it would be instructed to wait until the next day before continuing.

Syntax Error This is a trivial error for a computer to detect but may be very challenging for a programmer. Consider the following:

Good, helpful comments describing the exact thought process are useless to identify the problem in this case. The line that declares the array "**array sieve = . . .**" does not have a semi-colon. That may seem like an innocuous issue, but the

```
// Check a number to see if prime under 100
int checkPrime(int num) {

   // if less than zero or more than 100,
return an error
  if (num < 1 || num > 100) {return -1;}

   // If not prime, one of these must be a
factor
  array sieve = [2, 3, 5, 7]

   for (int i = 0; i < 4; i++) { // Cycle
through each number in
sieve

// If the result is an integer, it can't be
prime
if (isInt(num / sieve[i])) {return FALSE;}
  }

   // If none of the numbers was a factor,
num is prime
  return TRUE;
}
```

result is that the computer sees a reserved token "for" for the **for loop** in the same line as the array declaration, and it does not know what to do. This will crash the program. Since the syntax is different in different kinds of code, the only hope when reviewing someone else's code is to look for patterns in variable declarations or line endings and try to see one that is not like the others.

Out-of-Bounds Anytime there is a logic check, make sure it is possible for the check to result TRUE or FALSE depending on what goes in. Consider the following:

```
// Eat a sandwich only if it is lunchtime
string meal = getCurrentMeal();
if (meal = "lunch") {eatSandwich();}
```

In this case, we get the name of the current meal and then run a logic check, which, if **TRUE**, results in eating a sandwich. But the logic check is not what it appears. To check if **meal** equals "**lunch**", we must use **meal == "lunch"**. The code shows the value of **meal** to **"lunch"** then checks to see if **meal** is **TRUE**. There is a string in the **meal** variable, so the result of the check is **TRUE,** and we **eatSandwich**(), no matter the time of day. Sometimes **out-of-bounds** occurs when an object or array is used instead of the intended attribute or property. For instance, **array < 5** might always return FALSE, while **array.size() < 5** will return TRUE if the array is small enough.

Another way to be **out-of-bounds** is called a **buffer overflow**. It was mentioned previously that variables have a specific place in memory, which is true of strings. Consider this code for reading the first ten characters of a string:

But what happens if **string** is less than ten characters

```
for (int i = 0; i < 10; i++) {
  // printf prints string[i] to the screen
  printf("%c", string[i])
}
```

long? This will cause the loop to start reading out what is in memory outside of **string**. As expected, this is undesirable and can be catastrophic if the program is not just reading but writing to those out-of-bounds memory locations that could contain other parts of the program.

Dirty Data When code provides for a user to enter something, it bears remembering that they may enter *anything* (mentioned above in "Handle Garbage Gracefully"). They may write "Cheese" for the year, or write programming code in the Chief Complaint (see "code injection" in another text), or even accidentally add whitespace to the beginning or end of their name. "Whitespace" here refers to characters in a string that do not appear on the printed page. The space itself is the most common example, but others the line feed, the carriage return (both for starting a new line), the tab, and the non-breaking space. These invisible characters must always be accounted for when using strings provided by a user.

Imagine a database for storing patient names. Suppose a careless assistant added a space at the end of a name. When the database is later searched for the patient's exact name (without the space at the end), the search will come up empty. The common way to prevent such problems is to **scrub** or **sanitize** the data to ensure that whatever the user enters, your program can clean it up enough to make sense of it and not crash. One slightly unusual emoji is sometimes enough to bring a massive database to its knees.

Recommended Resources/Tools

In this section, the author notes several external resources for further developing one's programming skills. The author has no financial interest in any of the resources.

Learning a Programming Language In the author's opinion, the best way to learn how to program is to find a problem the budding programmer cares about, then find a simple tool that does part of the work and builds on it. There are many free resources to learn about any given language. Some prominent ones are:

- www.learn-c.org: A member of a group of websites for learning C, JavaScript, Python, SQL, and others.
- www.cppreference.com: A reference for C/C++.
- www.w3schools.com: A reference for web development.
- https://checkio.org: Gamified code tutorials for python.
- https://stackoverflow.com: A forum where programmers discuss programming problems. Any problem you are running into has likely been seen (and solved) before.

Programming Best Practices In the opinion of the author, the best way to learn the informal rules of programming is to adapt the tools of other programmers for one's use. This will teach the way code is currently written and how to make code more useful to others. Here are some sources:

- https://opensource.com
- https://alternativeto.net: Find an open-source version of software you use, look at the code yourself.
- https://curc.readthedocs.io
- "Hints for Computer System Design" by Lampson [10]

Two sources that deserve mention for widely covering code architecture are Code Complete [11] for classical techniques and Clean Code [12] for covering the more modern Agile methods for coding.

Emerging Trends

There are many potential developments for Health Information Technology in the near future. All of them carry implications for programmers, clinicians, and ethicists alike. As advancements in this category overlap substantially with other chapters in this text, only the issues most closely tied to programming and computer systems are presented.

Cloud-Based Computing Cloud-based computing means that rather than running software locally on the user's computer (or a computer owned by the user's company) and sending requests to the server in the cloud as needed, part or all of the application is run on the server itself. This allows for more flexibility in software crashes, greater ease in updating the software, potentially better protection of corporate secrets, and makes it much easier to roll out the software to new users. All the user needs is an internet browser. New computer languages (Dart/Flutter) and development platforms (AngularJS) have been constructed to enable this structure. The principal drawback is in the speed of the application since the data must move over the internet to be used and becomes dependent on shared hardware that many users might be trying to use simultaneously. A secondary issue is security, as more organizations are involved in storing and transporting data.

Best-in-Class vs. All-in-One This conflict refers to choosing between a collection of the best-specialized application for each task (such as one app for surgery scheduling and a different one for prescription transmission) or a suite of applications from a single company that covers all needs. As expected, best-in-class applications outperform in their main task but typically struggle to communicate with systems designed by others. In the medical industry, best-in-class applications dominated initially, mostly because few organizations could afford applications for all purposes. Eventually, all-in-ones began to take the lead as communication problems proved to be too harmful. Now, as better standards proliferate (e.g., SMART on FHIR) [13], and withholding connectivity becomes illegal (e.g., information blocking) [14], best-in-class alternatives that communicate seamlessly may become much more common.

Open-Source Software Open-Source refers to the practice of sharing all information freely [15]. In the case of software, it means making all code available for anyone to view, use and change for free (usually as long as credit is given to the author.) Linux, an operating system on which both Android and iOS are based, is open-source. Most servers running web pages use Linux or one of its derivatives. The VistA project is an open-source medical record system once used by the Veterans Health Administration in the United States. It continues to be used by many clinics around the world. GNU Health is another open-source suite of interconnected applications for health management focusing on social medicine. OpenMRS and OpenHIE, developed by the Regenstrief Institute, are open-source medical records systems used in several places worldwide and excel in record-sharing capabilities. And because the code is truly open, anyone with a desire to help can adopt part of the project and become a programmer or subject matter expert shaping the next version of the software.

Distributed Computing The current model used by most electronic health record systems is to have all the patient records stored in a single database (with some backups nearby and far away) that all users contact to search for information. This arrangement is highly susceptible to accidental or malicious failures and requires occasional complete blackouts to update the system. One solution is to move to **distributed computing**, where patient records and other information are scattered throughout numerous computers and copied many times over. This would make an accident or even an attack much less likely to do significant damage to the system but poses its own challenges. One has to do with establishing how to ensure there are enough copies of a given record to be accessed easily, but not so many that all device hard drives are full. Another challenge is making sure the data is safe on all the devices it has been scattered to.

Alternate Computing Methods The way we make computers is rapidly reaching a dead-end due to the laws of physics. Increasing the speed of a computer relies on making its parts smaller. But, if they become much smaller, the vibration of a single atom could have disastrous consequences. Some alternatives have been suggested that would use completely different computational models. The quantum computer accepts a series of coefficients for physics equations, runs them until they reach a steady-state, and then produces an answer in the form of quantum bits [16, 17]. A DNA computer could theoretically store data extremely compactly and perform its functions by splicing DNA strands [18, 19]. These systems require a very different approach to the one presented here, and none has yet proven that it can truly replace our current model.

Summary

Many of the problems we face in medicine can be addressed with technology. That technology will inevitably rely on code. But the programmer is not trained in medicine, anatomy, pathology or even the sciences medicine depends on. To communicate to design solutions, clinicians must speak the language of programmers and understand some of the constraints imposed by computers. By discussing program design in the language of programmers, clinicians have a better chance of implementing the tools that patients and society require. Without that communication, the process for maintaining the health of our communities will inevitably suffer from bugs.

Here is a brief recap of the themes from this chapter:

- Computers are not smart. They only do exactly what they are told.
- Computers are powerful. They can shorten a task of a lifetime to mere seconds.
- Computers must be instructed carefully, or bad things will happen.
- Control structures are the programmer's tools and include sequential blocks, iterative blocks, conditional blocks, and recursion.

Most problems can be broken down into solvable steps using decomposition, abstraction, and pattern recognition. Keep these principles in mind when developing new or troubleshooting existing programs:

- Quality software works efficiently but can also be understood and replaced easily.
- Specifications are required to understand if a program is finished and safe.
- Verbose comments are helpful to those who come after you.
- Checking the code of others is difficult. Working it out by hand is a helpful tool but using a computer to do it is better.

Questions for Discussion

1. Returning to the question at the end of the vignette, consider the following questions:
   (a) What are the parts of such a system?
   (b) What tasks must such a system perform, and which consumes the most resources?
   (c) How might the system tasks conflict with the tasks of other users of the database? (e.g., nurses, doctors, administrators)
   (d) Are any of the tasks illegal?
2. What value does a clinical informaticist provide that even an experienced health information programmer cannot?
3. Must a clinical informaticist also be a programmer? How much programming should an informaticist know?
4. Complete the specification for the water irrigation system or another programming problem of your choice.
5. Write pseudocode to solve the problem mentioned in the vignette. Consider at least two regular preventative maintenance items related to your specialty and one barrier to care.
   (a) What parts of the solution can run in parallel?

(b) What pieces of data are needed to be stored in a database?
(c) Consider the problem as a client-server model. What parts would run on the client? Which would run on the server?

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Clinical Informatics Policy and Regulations

3

Matthew A. Eisenberg

Learning Objectives
At the end of the chapter, the reader should be able to:

- Describe the process for developing health IT policies.
- Identify and list major legislation that provides the legal and regulatory framework for health IT.
- Discuss the tension that exists between Federal, State, and Local regulations.
- List and describe some of the key policy challenges we face today and can expect in the future.
- Discuss how clinical informaticists can influence the creation and implementation of new health IT policy.

Practice Domains: Tasks, Knowledge, and Skills

- K024. Policy and regulatory frameworks related to the healthcare system
- K035. Definitions of measures (e.g. quality performance, regulatory, pay for performance, public health surveillance)
- K041. Quality standards and measures promulgated by quality organizations (e.g. National Quality Forum [NQF], Centers for Medicare and Medicaid Services [CMS], National Committee for Quality Assurance [NCQA])
- K042. Facility accreditation quality and safety standards (e.g. The Joint Commission Clinical Laboratory Improvement Amendments [CLIA])
- K043. Clinical quality standards (...)
- K044. Reporting requirements

Case Vignette: FHIR APIS and Apple Health App!
You want to download your electronic health information to your iPhone using Apple's Health application as you go between your many care providers. It's essential since they all work at different clinics and use different electronic medical record systems. Your primary care provider, who also works in Medical Informatics, mentioned that you could do that as well as importing information from other providers and have a "personal health record" on your phone. You'll need to have a patient portal account to authorize the data exchange and determine what updates will be sent automatically in the future. The type of information you can access, the software technology that supports it, and the rules that require health care providers to share this information are regulated by the Federal government, with additional rules coming from your state capital.

Introduction

This chapter provides an overview of the regulatory landscape for clinical informatics. The chapter further describes how clinical informaticists can influence healthcare and health IT policy.

Why should clinical informaticists be concerned with healthcare policy and regulations? Healthcare regulations, and the federal rulemaking processes, govern how hospitals and providers get reimbursed for the important services they deliver, and they dictate the terms under which medicine is delivered in a variety of contexts. This includes the digital health space. Clinical informaticists must be aware of the policies and regulations that govern how their organization operates so they can optimize health IT systems to support care delivery and patient outcomes. Furthermore, informaticists must be aware of special regulations that govern the use of electronic health record (EHR) systems, their components, and the growing array of consumer-facing IT applications that interface with the EHR. Policy and regulation further guides interoperability as well as data exchange with

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other hospitals and clinics. Thus, knowledge and awareness of health IT policies and regulations are a must for the savvy clinical informaticist working in healthcare in the twenty-first century.

Fundamentals of Policy and Historical Regulations

Healthcare regulations are intended to protect the public interest, provide access to care, support affordability, and set targets for quality and outcomes. Starting in the late nineteenth century, the US government attempted to regulate and improve public health and reduce the spread of disease. Today, the federal government is focused on drug safety, food supply safety, disease prevention, including immunizations and pandemic preparedness and response, medical research funding, health insurance industry reform, and cost containment for the increasing portion of federal spending (not just out of pocket costs) that taxpayers fund for health care. In 2020, the US spent about 18% of the gross domestic product on health care [1].

The Hill-Burton Act of 1946 established non-profit hospitals in the US in exchange for a promise to deliver uncompensated care to the needy. This exists today in the Community Benefits programs that many hospitals provide to support tax-exempt, non-profit status [2].

In 1965, the Social Security Act Amendments created Medicare and Medicaid. Medicare is a national health insurance program that is split into component parts for reimbursement. Part A covers hospital, hospice, post-acute, and home care reimbursement. Part B provides reimbursement for beneficiaries for services, including outpatient office visits, procedures, preventive care, and medical supplies. Parts A and B constitute "Original Medicare". In 1972, Medicare was expanded to cover the disabled, patients with end-stage renal disease (ESRD) requiring dialysis or transplant, and people 65 and older that enroll in the Medicare program. Part C created managed care programs for beneficiaries, and Part D, a prescription drug benefits program, was added in 2003 as part of the Medicare Prescription Drug Improvement, and Modernization Act (MMA) [3] provides prescription drug coverage.

It is important to note that the legislation passed by the US Congress, either with the Executive Branch signature or by congressional override, sets the direction of the federal government policy. However, through a highly scripted and legally mandated regulatory process, Federal agencies draft, release, and finalize the regulations and sub-regulatory guidelines that specify the details of regulatory requirements and direct operational execution. For health information technology (IT) policy junkies, we are familiar with the rulemaking process and spend hours reviewing that language found in the Federal Register. Hence, we often reference specific language in the Code of Federal Register (CFR) like CFR 170 and 171—the specific regulatory language outlining information blocking resulting from the 21st Century Cures Act passed in 2016. Several regulations directly link to the CMS health insurance programs and are released in a routine cadence every year. You can simply follow the release of these regulations online at regulations.gov [4] and get detailed updates from the CMS regulatory website [5].

Organization of the Federal Government and Agencies with Oversight for Health Care and Health Information Technology

The Congressional Branch

The US Congress consists of the Senate and the House of Representatives. The best way to learn about the process of how a bill becomes law may still be the School House Rock version of "I'm just a bill" [6].

Several key committees have oversight over health care, summarized in Table 3.1.

Government and Trade Associations like the Government Accountability Office, the Institute of Medicine, the Congressional Research Service, the American Medical Association, the American Hospital Association, the American Medical Informatics Association (AMIA), Health Information Management Systems Society (HIMSS), and the College of Health Information Management Executives (CHIME) all provide background and advice on health policy matters.

Here are two good resource to access information on health IT policy:

Table 3.1 Key Congressional Committees

Senate Committees	House Committees
Health, Education, Labor and Pensions (HELP) [7] • Jurisdiction over Public Health including Medicare, Medicaid, and the Children's Health Insurance Program (CHIP)	Ways and Means [8] • Jurisdiction over revenue-related aspects of the Social Security system, Medicare, and social service programs
Finance	Energy and Commerce
Appropriations • Jurisdiction over agencies in the Department of Health and Human Services	Appropriations

1. HIMSS Public Policy Center (https://www.himss.org/what-we-do-public-policy-advocacy/policy-center) This site allows users to look up information on recent health IT policy decisions as well as engage with lawmakers in their district to influence public policy debates and decisions.
2. AMIA Public Policy website (https://amia.org/public-policy) AMIA has a weekly newsletter it sends to members with the latest on what is happening with federal and state policies that impact health IT. The website publishes statements from AMIA in response to federal requests for information or comment on draft regulations.

Most healthcare organizations have employed Government and Community Relations staff who work with healthcare advocacy groups like the American Hospital Association to lobby congressional members and staff on various bills as they work their way through the legislative process. Many health systems also contract with lobbying groups to follow and advocate for various changes to legislation at the state and federal levels and have direct contact with State and Local government offices.

Engaging with local and federal government is important, because their decisions are influenced by the voices that speak up when a law is proposed, or regulations are drafted for comment. If informaticists do not speak up on behalf of their organization or their personal opinions shaped by their practice, then our community does not have a voice at the table. Work with the government relations officer at your organization to engage in the process and weigh in on regulations that impact your practice.

The Executive Branch

The Executive Branch, headed by the President of the United States, consists of 15 Cabinet Level departments, including the Health and Human Services Department, with oversight over health care. Within HHS, there are eight key agencies and many "offices" [9].

- *Agency for Healthcare Research and Quality (AHRQ)*
- *Centers for Disease Control and Prevention (CDC)*
- *Centers for Medicare and Medicaid Services (CMS)*
- *Food and Drug Administration (FDA)*
- *Health Resources and Services Administration (HRSA)—Safety net and FQHCs*
- *Indian Health Service (IHS)*
- *National Institutes of Health (NIH)*
- *Substance Abuse and Mental Health Services Administration (SAMHSA)*
- *Office of the National Coordinator for Health IT (ONC)*
- *Office of Civil Rights (OCR)*

Other agencies outside of HHS also play an important role in health policy. These include federal health delivery systems like the Veterans' Health Administration (VHA) which is part of the US Department of Veterans Affairs (VA). This is the single largest health delivery system in the United States, with over 1200 sites and 171 VA Medical Centers serving some nine million enrolled Veterans [10]. At the same time, the VHA focus on Veterans, the Department of Defense (DoD) Military Health System, and the Defense Health Agency (DHA) provides care for active military and their dependents.

In 2015, the DoD awarded Cerner Corporation, Leidos, and Accenture a contract for the newly branded MHS Genesis EHR. This new EHR would replace both health systems' homegrown electronic record systems (Vista-CPRS and AHLTA = Armed Forces Health Longitudinal Technology Application) with a commercial EHR product created by Cerner Corporation to support full interoperability. This ongoing transition is expected to take more than 10–15 years and 15 billion dollars.

Apart from the DoD health delivery systems, other agencies Federal agencies play an important role in developing and implementing health IT policy. The National Institute for Standards and Technology (NIST) is part of the Department of Commerce, was created in 1901, and is one of the oldest physical science laboratories in the nation. The mission of this Standards Development Organization (SDO) is "to promote US innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life" [11]. NIST is involved in nationwide interoperability efforts, including the development of tools that allow EHR vendors to validate their products work successfully against the criteria specified in Meaningful Use regulations.

The President's Council of Advisors on Science and Technology (PCAST) also offers advice to the Executive Branch on matters involving science, technology, education, and innovation policy. Created by executive order in 2019, members include distinguished individuals from sectors outside the Federal Government with diverse perspectives and expertise [12].

The Federal Trade Commission was created by Congress in 1914 as part of the Federal Trade Commission Act and signed into law by President Woodrow Wilson. The FTC is a bipartisan federal agency with a unique dual mission to protect consumers and promote competition. The Federal Trade Commission's job as a law enforcer is to stop firms from engaging in anticompeti-

tive conduct that harms consumers. The agency also guides market participants—including physicians and other health professionals, hospitals and other institutional providers, pharmaceutical companies and other sellers of health care products, and insurers—to help them comply with the nation's antitrust laws. In 2010, the Federal Trade Commission (FTC) began enforcing its Health Breach Notification Rule for web-based businesses, NOT HIPAA-covered entities [13].

The Role of the Private Sector Including Standards Development Organizations (SDO) and Healthcare Industry Trade Associations and Lobbying Groups

The HITECH Act of 2009 established two new Federal Advisory Councils, one on policy and one on standards, to advise the Office of the National Coordinator for Health Information Technology (ONC). The 21st Century Cures Act of 2016 modified these primary federal advisory councils forming a single Health Information Technology Advisory Committee (HITAC) [14].

The National Committee on Vital and Health Statistics (NCVHS) serves as a statutory advisory body to the Secretary of HHS providing statistical support and reporting. The National Academy of Sciences founded the Institute of Medicine in 1970 to provide independent advice to the government. on issues of health and science policy.

The Patient-Centered Outcomes Research Institute (PCORI) is a private, non-profit organization created by the Affordable Care Act to fund comparative effectiveness research (CER), similar to the NHS Care Excellence (NICE) in the UK [15].

Key Health Care lobbying and professional groups involved in policy and regulations include the American Hospital Association [16] (AHA and state-based affiliates), the American Medical Association [17] (AMA and state base affiliates), the American College of Physicians (ACP) [18], the American Academy of Pediatrics (AAP) [19] and the Association of American Medical Colleges (AAMC—171 accredited programs in the US and Canada) [20]. Informatics and trade association groups also support regulatory work and policy development, including AMIA [21], HIMSS [22], WEDI [23], and the HIMSS sponsored Electronic Health Record Association (EHRA) [24].

Additional non-profit advocacy and industry groups include the National Committee for Quality Assessment [25], the Joint Commission [26] , which outlines the National Patient Safety Goals, the Institute for Healthcare Improvement [27], the Sequoia Project [28], a non-profit advocacy group focused on promoting interoperability, and the Workgroup for Electronic Data Exchange [29] (WEDI) focused largely on payer sponsored transactional standards and interoperability just to name a few.

What Every Clinical Informaticist Needs to Know About Health IT Policy: The Basics

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 established national standards for electronic payments or transactions and created national identifiers for providers (NPI), insurance plans, and employers.

This legislation and subsequent rules obligated health care "covered entities" to protect the privacy of individually identifiable personal health information (PHI) and facilitate an individual's rights. It supports the disclosure of PHI only for "treatment, payment, and operations" and requires that all other disclosures can only be done with the individual's signed authorization and consent. Sharing of PHI is subject to the "minimally necessary" limitation, so only that information needed for the given purpose is to be shared and nothing more. All patients must be provided with a notice of privacy practices, and the legislation defines the need to establish "business associate" agreements for those entities that work with health care delivery systems to "perform or assist in the performance of" any function or activity involving the use or disclosure of PHI.

Oversight for HIPAA resides in the Department of Justice Office of Civil Rights [30]. The website includes samples for the Notice of Privacy Practices (NPP) and Business Associates Agreements for health organizations to use. Most health systems now post their NPP on their external websites and may capture signatures digitally.

The HIPAA Privacy Rule states explicitly what personal health information (PHI) must remain private without health consumer authorization. Under HIPAA rules, a limited data set cannot contain any of the following personal health information elements [31]:

- Names
- Street addresses or postal address information except for town/city, state, and zip code
- Phone/Fax numbers
- E-mail addresses
- Social Security numbers
- Medical records numbers
- Health plan beneficiary numbers
- Other account numbers
- Certificate and license numbers
- Vehicle identifiers and serial numbers, including license plates
- Device identifiers and serial numbers
- URLs and IP addresses
- Biometric identifiers such as fingerprints, retinal scans, and voiceprints
- Full face photos and comparable images

Health systems and health information management programs can use several methods to de-identify health records such that the information cannot re-identify any given individual. These include the Expert Determination and Safe Harbor methods outlined in guidance provided by ONC [32]. Briefly, these methods can be explained as follows:

- **Expert Determination** An expert (could be a CMIO) with knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable; apply those methods; and documents the methods used.
- **Safe Harbor** Removal of the 18 identifiers listed above to ensure documents are de-identified.

The Security Rule establishes standards to protect an individual's electronic protected health information or e-PHI. This is separate from the more recent 21st Century Cures related ONC regulation that defines electronic health information (EHI) as "electronic protected health information as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set." Psychotherapy notes as defined in HIPAA or information compiled in reasonable anticipation of, or use in, a civil, criminal, or administrative action or proceeding are excluded [33]. The ONC regulations on information blocking initially set the United States Core Data Set for Interoperability (USCDI) version 1.0 as the minimum data set required for any exchange.

At the time of this writing, the OCR has already released proposed rules updating HIPAA regulations, and we await final regulatory updates [34].

American Recovery and Reinvestment Act and the Health Information Technology for Economic and Clinical Health Act of 2009 (ARRA and HITECH Act)

The American Recovery and Reinvestment Act (ARRA) was an enormous federal stimulus program enacted to help the United States recover from the "Great Recession" of 2008. Building on the recommendations of the Bush administration made initially in 2004, the government-supported funding to "computerize health records" through the Meaningful Use incentive program. This program was created through the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, a component of the overall ARRA stimulus program. Eligible providers and eligible hospitals could either recoup previously spent funds or help offset new project costs by implementing electronic medical records and proving that these were implemented to support "meaningful use" of the tools.

Historically, the program consisted of three stages. Stage 1 set the foundation by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information. Stage 2 expanded upon the Stage 1 criteria with a focus on advancing clinical processes and ensuring that the meaningful use of EHRs supported the aims and priorities of the National Quality Strategy. Stage 2 criteria encouraged the use of Certified Electronic Health Record Technologies (CEHRT) for continuous quality improvement at the point of care and the exchange of information in the most structured format possible. In October 2015, CMS released a final rule that established Stage 3 in 2017 and beyond, which focused on using CEHRT to improve health outcomes. In addition, this rule modified Stage 2 to ease reporting requirements and align with other CMS programs.

Since the onset of the Meaningful Use incentive program, CMS has continued to update the program annually, often changing the program's name to focus on the latest regulatory objectives. The program was briefly renamed Advancing Care Improvement but currently is referred to as the Promoting Interoperability program.

HITECH Changes to HIPAA

HITECH updated and expanded the existing Health Insurance Portability and Accountability Act (HIPAA) of 1996 in several ways. A major change included setting the minimum number of patients affected by a data breach to 500, which previously was variable and determined by state law. Here is a brief summary of selected major changes to HIPAA made by HITECH regulations:

- The definition of a covered entity expanded to include health information exchanges as well as regional health information organizations, e-prescribing vendors, and subcontractors.
- Business associates were now considered covered entities.
- Penalties for data breaches expanded up to $50,000 per violation.
- Sale of protected health information prohibited except under narrow conditions.
- Required patients to receive copies of their health records, electronic format preferred.
- Definition of electronic media expanded to include anything on the Internet as well as voice over IP technologies.

An Evolving Meaningful Use Program

ONC is the part of HHS responsible for certifying electronic health information technology like electronic health records (i.e., CEHRT). Only certified software can be used as part of the CMS performance programs. The requirement regarding interoperability also comes from the ONC. It has progressed from the Common Clinical Data Set (CCDS) outlined in Stage 3 of the meaningful use program to most recently the United States Clinical Data Set for Interoperability (or

USCDI). As of this writing, by October of 2023, all CEHRT must support complete interoperability of all "electronic health information" as outlined in regulation and defined by each health system.

Today Meaningful Use lives on as the Promoting Interoperability Program. Since October 2015, when CMS released the final rule establishing Stage 3 of Meaningful Use for 2017 and beyond, we continue to track routine regulatory releases like the annual Medicare Hospital Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and Long-term Care Hospital Prospective Payment proposed and final regulations [35]. Most hospital Quality departments access and submit data for the various CMS Quality Programs through their Quality Net [36] portal.

Patient Protection and Affordable Care Act (ACA) of 2010

This comprehensive health care and health insurance reform law enacted in 2010 is often referred to as the ACA or, more simply, "Obamacare" as it was passed during President Obama's first term. One of the main goals was to expand access to affordable health insurance coverage for more Americans, providing subsidies for health plans to families that lower costs for many households that did not have access to employer-based health insurance or simply couldn't afford the coverage. The law also expanded Medicaid coverage to include all adults with an income below the federal poverty level. It also introduced efforts to promote innovative changes to health care delivery that would generally lower the cost of care and improve the experience and quality of care and population health.

Food and Drug Administration Safety and Innovation Act (FDASIA) (2012)

The Food and Drug Administration Safety and Innovation Act was signed into law in July of 2012. The goal of this legislation was to expand FDA authority and strengthen the agency's ability to safeguard public health. The FDA has oversight over drug approval, medical devices, generic drugs and biosimilars, and related products.

Medicare and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015 (MACRA)

This legislation enacted in April 2015 replaced the former Meaningful Use program for eligible physicians and other improvement programs like the Provider Quality Reporting Systems (PQRS) and the Value-based Modifier Program. The final CMS regulations from this legislation, released in Oct 2016, mandate that Medicare Part B payments will be based on either the merit-based incentive payment system (MIPS) or an advanced payment model (APM). These regulations also replaced the ongoing and contentious sustainable growth rate formula used to manage the Part B provider fee schedule. The program's first reporting year was 2017, with payment adjustments set to occur 2 years later. The stated HHS vision of this legislation and subsequent regulations includes the following tenets:

- Improve beneficiary outcomes and engage patients through patient-centered Advanced Payment Models and MIPS policies.
- Enhance clinician experience through flexible and transparent program design and interaction with easy-to-use program tools
- Increase the availability and adoption of robust advanced APMs
- Promote program understanding and maximize participation through customized communication, education, and outreach—especially meeting the needs of small practices
- Improve data and information sharing to provide accurate, timely, and actionable feedback to clinicians and stakeholder
- Ensure operational excellence in program implementation and development

The official Quality Payment Program officially started on January 1, 2017. Full details about the program can be found on their website [37], including a look-up tool that indicates individual provider or group eligibility by National Provider Identifier or CMS Provider tax id.

The MACRA legislation and related Quality Payment Program focuses on Medicare Part B funding. Still, CMS manages various value-based payment programs [38] designed to reward health care providers and health care systems with incentive payments for the quality of care they provide Medicare beneficiaries and disincentives for poor quality performance.

More Recent Legislation and Regulations

The 21st Century Cures Act (2016) [39] was signed into law on December 13, 2019. This massive legislation had remarkable bipartisan support, with 94 senators and 292 congress people voting in support. The law was designed to promote and fund the acceleration of research into preventing and curing serious illnesses. It aimed to accelerate drug and medical device development and attempted to address the opioid abuse crisis. The law consists of three divisions and various titles. Division A supports medical discovery, development,

and delivery. Division B helps families with mental health issues. Division C aims to increase choice, access, and the quality of health care for all Americans [40].

This law is the first federal legislation to define health care interoperability. The term "interoperability", concerning health information technology, means that the technology:

- Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information without special effort on the part of the user;
- Allows for complete access, exchange, and use of all electronically accessible health information of authorized use under applicable State or Federal law; and
- Does not constitute information blocking, as defined in section 3022(a) of the Public Health Service Act as amended.

In addition, the legislation defines "information blocking" as "a practice that … is likely to interfere with, prevent, or materially discourage access, exchange or use of electronic health information; if that practice *is* known by a developer, exchange, network, or provider as being likely to **interfere with**, prevent, or **materially discourage the access**, exchange, or use of electronic health information."

CMS and ONC officially released the 21st Century Cures Regulations based on the 2016 Statute to the Federal Register on May 1, 2020, after an unofficial release done in March 2020 during the very beginning of the COVID-19 pandemic. The CMS regulations focused on new Conditions for Participation for health systems and health plans, including expanded health insurance plan transparency and exchange requirements. The ONC regulations focused on interoperability and information blocking as defined by statute, outlining those allowable exceptions to information blocking for the three separate categories of "actors"—health care providers, health IT developers, and health information exchange organizations or networks (HIE/HIO).

The ONC Information Blocking regulations were supposed to go into effect in October or 2020. Still, a late-breaking interim final rule delayed the applicability date to April 5, 2021, given the need to address the COVID-19 pandemic.

The regulations outline civil monetary/money penalties up to $1 million *per violation* for health IT developers, networks, and health information exchanges. However, penalties for health care provider "actors" remain undetermined and will be managed through subsequent rulemaking by the HHS Office of Inspector General and CMS.

The ONC regulations specify the requirements for certification of EHR technology for sale in the United States, as this branch of the government manages the certification process. The ONC launched the voluntary Health IT Certification Program in 2010. The requirements for certification are established by standards, implementation specifications, and certification criteria adopted by the Secretary. The Certification Program supports the Promoting Interoperability programs administered by CMS [41].

Electronic information must be shared via health information exchange, patient portal, or APIs for the initial regulatory compliance date as defined by the new United States Core Data Set for Interoperability (USCDI) [42], version 1. This new data set replaces the Core Clinical Data Set part of the previous Meaningful Use program and its subsequent CMS regulatory programs. The USCDI is expected to expand over time in parallel with each organization's definition of the electronic health information (EHI) included in the institution's defined "designated record set". ONC focused the scope of EHI in §171.102 in the final rule to mean electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103. As of this writing, EHI is required to be shared by provider actors in the Fall of 2022, although developer actors do not require EHR certification for this functionality until 2023.

These rules also specify allowable exceptions (Fig. 3.1) to information sharing that would not constitute illegal information blocking and the requirement to respond to requests for information from patients and other entities. The final rule contains eight explicit, allowable exceptions, and the two most important to clinicians are the risk of physical harm to the patient and others and patient privacy. Providers must take these elements into account before sharing information electronically with their patients.

Importantly, these regulations also establish a new standard for FHIR Application Programing Interfaces used in interoperability (see Chap. 14), setting the HL7 FHIR Specification Release 4 as the standard. ONC publishes the Interoperability Standards Advisory (ISA) [44] to track and understand syntactic and semantic standards, although variably adopted, in the health IT space. It is a great resource for informatics students and seasoned implementers alike.

The CMS regulations specify the Conditions of Participation (CoP) for CMS payments and include new requirements regarding event notification of hospital or emergency department admission or discharge. Health systems must make an effort to notify the primary care provider, referring provider, other providers, or the patient's practice based on who the patient identifies as their clinical care team or place of clinical care. There are also much more complex requirements for health plans that participate in CMS payment, including electronic patient access via application pro-

Fig. 3.1 Eight exceptions to the information blocking provisions released by the Office of the National Coordinator for Health Information Technology in response to the 21st Century Cures Act. Image was created by ONC and is available in the public domain [43]

gramming interfaces (APIs) to their explanation of benefits (EOB) and the requirement to publish an easily accessible network provider directory.

TEFCA

ONC Released the first draft of its Trusted Exchange Framework and Common Agreement (TEFCA) in January of 2018 [45]. TEFCA was also a result of the 21st Century Cures Act Legislation. In Section 4003 of the legislation, Congress directed ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally," which may include:

(I) A common method for authenticating trusted health information network participants;
(II) A common set of rules for trusted exchange;
(III) Organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and
(IV) A process for filing and adjudicating noncompliance with the terms of the common agreement.

TEFCA is designed to scale EHI exchange nationwide and help ensure that health information networks, health care providers, health plans, individuals, and other stakeholders have secure access to their EHI when and where it is needed. In April 2019, ONC released Draft 2 of the TEFCA framework. Later that year, they selected The Sequoia Project to be the Recognized Coordinating Entity (RCE), or the governing body of the TEFCA to work with ONC policymakers on final versions of the legally binding "Common Agreement" that would serve as the contract between data exchanging entities and networks and the key supporting documents. This includes the QHIN Technical Framework, which outlines the technical specification requirements for any Qualified Health Information Networks (QHINs) and the Minimum Required Terms and Conditions (MRTCs) that would support the voluntary practices agreed to by any QHIN in the framework. At the time of writing, a draft Common Agreement had been published with an open call for comments. It is expected that ONC will publish final regulations for the Common Agreement in 2022.

Fraud, Stark and Anti-Kickback Laws

The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health and Human Services Office of Inspector General (OIG), and the Centers for Medicare and Medicaid Services (CMS), enforce these laws. Any informaticist must understand these laws, because following them is the right thing to

do and because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your state medical board [46].

Veterans Access, Choice, and Accountability Act of 2014

In 2014, Congress responded to delays in care at the VA by passing legislation that expands access to care at VA facilities as well as non-VA facilities if the VA is unable to provide access within a reasonable timeframe or a Veteran lives more than 40 miles from a VA medical facility. While this does not immediately suggest a change for clinical informatics, it has major implications for how the VA captures and shares information about Veterans who receive care both in and outside the VA [47].

The Veterans Choice Program, modified by Public Law 115-26, enables Veterans to seek increasing amounts of their care in the community. This benefits Veterans by expanding access to care, but it has implications for further fragmenting Veterans' clinical data across VA and non-VA providers. The law has enormous implications for HIE as VA and non-VA providers will need to share data to effectively care for Veteran patients. Health systems also have an incentive to ask about someone's Veteran status and document this in the EHR, as it allows the provider to bill the VA rather than write the visit off as uncompensated care. Implementation has been slow, but the VA is making progress and, as of the writing of this book, is quickly shifting from a major care provider to a major payer for Veterans. This will have significant implications for how we care for Veterans in the US for decades. It may also nudge progress on interoperability and HIE between private providers and the VA.

State Health Care Oversight

Like the federal government, State Governments have an important role to play in the regulatory environment. As is often mentioned, Federal regulations like HIPAA "set the floor but often the state regulations set the ceiling". Patient access rights to medical information and privacy are one key example.

However, the patchwork of often incompatible state regulations, particularly regarding data elements related to adolescent privacy, reproductive health care, substance use disorder treatment, and mental/behavioral health, can prove challenging for any large, multi-state health delivery system or program. Indeed, some federal mandates and regulations, like those regarding unclassified but confidential health information for federal health agencies, and the need for additional data segmentation have made true interoperability even more challenging.

One might suggest that the US unwillingness to support a unique health consumer identifier, combined with a patchwork of competing privacy regulations across states and the federal government, has contributed more to the challenge of national interoperability than the technology itself, vendor IP concerns, or even misaligned provider financial incentives.

Advocacy

Clinical informaticists must be familiar with state and federal regulations to support compliant use of health information technology, but developing greater expertise can also help us advocate for better laws and regulations through active engagement in policymaking. Partnering with Government and Community Relations staff and healthcare advocacy groups, many of us have become familiar with our state and federal government legislative calendars and health policy-related committees that develop the final legislation and related technology and economic impacts. We follow and monitor the submission of new legislation and the release of new regulations. We track media coverage and listen to recordings for various committee meetings, sometimes providing testimony or organizational support. We may participate in the open comments period available to all as part of the Notice of Proposed Rulemaking process. We must always ask if the law or regulation will have the *desired effect* or may result in *unintended consequences* and anticipate the effects on technology, workflows, staffing, and reporting needs.

Once a law is enacted or regulations become final, we must review the details of the regulations, often working with our Legal and Compliance offices to fully understand the requirements and reporting obligations. Then we return to our operational partners, technology partners, and technology vendor organizations to develop implementation plans that comply with these regulations until the cycle starts again. For hospital leaders, perhaps the best example of this annual process is the routine release of interim and final rule covering Medicare payments for Part A and Part B, outlined respectively by the Inpatient Prospective Payment Program and the Physician Fee Schedule regulations.

Summary

Health Care policies and regulations are an ever-evolving field with a myriad of opportunities to learn and participate. Whether in the form of health policy development, research, advocacy, or implementation, an interest in health policy and regulations will keep informaticists busy and engaged forever.

Questions for Discussion

1. Why should clinical informaticists care about federal and state policies that regulate health IT?
2. What can clinical informaticists do to change a law or regulation?
3. Where can concerned clinical informaticists go for support with engaging in the rulemaking process?

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The U.S. Health System

4

Craig D. Norquist

Learning Objectives

This chapter will provide the reader with a basic understanding of the history and current structure of the U.S. Health System. It gives a system-level context for clinical informatics and describes how clinical informatics fits into the complex health care delivery system. After reading this chapter, individuals will be able to:

- Describe components of the health care delivery system
- Summarize the state of health care delivery in the United States
- Explain the role of data in health system planning and policymaking

Practice Domains: Tasks, Knowledge, and Skills

- K020. Primary domains of health, organizational structures, cultures, and processes (e.g., health care delivery, public health, personal health, population health, education of health professional, clinical research)
- K022. Forces shaping health care delivery and consideration regarding health care access
- K023. Health economics and financing
- K052. Care delivery and payment methods

Case Vignette

In March of 2020, early in the phase of what was to become the COVID-19 pandemic, a 36-year-old Caucasian male presents in the emergency department of a hospital in a major metropolitan area complaining of flu-like symptoms. He was visiting family locally but lived in an area experiencing a much worse outbreak of the contagious viral illness. He had been seen at a neighboring but unaffiliated hospital several days earlier with similar symptoms and tested for SARS-CoV-2 but was discharged without receiving his results. Upon arrival, he provides his health insurance registration information to a patient access representative at the triage window as his first step into the new hospital system. As the representative enters his demographics and personal information into their electronic health record (EHR) system, an alert is immediately visible with the results from his SARS-CoV-2 test performed at the neighboring hospital, via the state health information exchange (HIE) through an admission/discharge/transfer (ADT) query. Even though the previous hospital is in a different health network, through their participation in data sharing with the HIE, the systems can share results and visit information even from disparate electronic medical records (EMRs). The positive results for SARS-CoV-2 infection alert the staff to place him into a quarantined area where he is not in contact with other patients and all staff are wearing full personal protective equipment (PPE). Soon a nurse enters the room in full PPE, provides a mask for the patient, introduces herself, asks the patient his name, and logs into the computer. She begins asking the patient to describe the symptoms he has been experiencing. As he talks, she enters the information he shares into his EMR. He describes having a low-grade fever, some difficulty breathing, and a worsening cough. The patient shares that he is visiting from an area experiencing a vast outbreak of COVID, but he could fly out to visit family just before travel bans were instituted. To the best of his knowledge, he has not been around anyone who was sick or was a known positive case. The nurse then takes his temperature by pointing an infrared thermometer at his forehead.

The patient is hooked up to various monitors to track his vital signs while the doctor suits up to perform a complete assessment. The doctor and the entire clinical team were able to access the results from the swab performed at the neighboring hospital even before seeing the patient for the first time and were alerted and able to protect their staff from being exposed to the contagious and potentially deadly virus. After finishing his exam, the doctor documents his new find-

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ings in the EMR and reviews the patient's past medical history, current medications (verified earlier with the patient by the inpatient pharmacist), and checks for any allergies entered earlier by the nurse. Based upon these findings, the doctor locates the appropriate order set for working up his patient and looked through the list of testing options, leaving all of them checked—multiple types of bloodwork, an X-ray of his chest, and a few other tests. He then looks at the treatment options and selects oxygen, IV fluids, and medication for his fever, as at that time, there were no viable medications for treating the viral disease. Other orders are written for the nurses and respiratory therapists to follow in their daily care. He thinks of how good it is that they now have these standardized order sets created to know they are delivering consistent, evidence-based medicine.

In the background, the National Electronic Disease Surveillance System (NEDSS) is activated, and the State Health Department is informed that the patient has a "notifiable" disease per the Centers for Disease Control (CDC) National Notifiable Diseases Surveillance System (NNDSS). Per protocol, the State Health Department then notifies the CDC of this patient through the same electronic tracking system.

Fortunately, the patients' blood tests, chest X-ray, and oxygen levels showed no signs of worsening infection or reason requiring admission to the hospital at this time. The health care team was hesitant about discharging him home where he could potentially spread the virus to others but having him stay in the increasingly crowded hospital was not an option either. They provided detailed instructions for the patient to isolate at home, away from others who were not sick, and to have his contacts all quarantine for 14 days from the time of being exposed to him to minimize the spread of the disease.

As the nurse prepares him to be discharged, she goes over a set of post-discharge instructions with him. Then, she shows him how to set up his patient health portal, get logged in, and goes over how to send secure messages to his caregivers, look at past lab results, radiographs, clinical notes, and other diagnostic tests. He is also set up with a text-based application to track his temperature, heart rate, and pulse oximetry while in isolation to ensure his condition is not worsening. As a part of his follow-up instructions, she reminds him that he is to schedule an appointment with his primary care provider in a clinic in 2 weeks. She shows him a scheduling tool in the portal where he can do this online if he would like, and he will get an email reminder to schedule his appointment if he hasn't done so in a week.

Throughout the patient's stay, charges for all of the testing, supplies, and daily care he received from the hospital were entered into the hospital's billing system through his EMR. At the end of his stay, these charges were submitted electronically to the insurance company on file. The summary data from his hospital stay was copied to the hospital's data warehouse to be utilized for quality review and other internal projects, and it was copied to the state HIE to make it available to physicians at out-of-network hospitals who might treat the patient in the future.

Introduction

The U.S. Health System is composed of a highly complex network of organizations, institutions, and resources focused on monitoring, maintaining, and improving the health of individuals and populations. Health care delivery, public health, clinical research, education and health professionals, and personal health are all health system domains. Health information has a specific and vital role in each of these, including health policies and economics. Understanding the basic structure and function of the health system and the flow of information (data) within and between its various domains is critical to clinical informatics. This chapter will examine the multiple domains of the health system and serve as a foundation to understanding the role of clinical informatics in this intricate and complex system.

Health or Wellness Versus Sick Care

Health is a defining human characteristic and integral to the human experience. As health care providers, we often think of health in the context of organ systems, disease states, and functioning status. Our current system has been developed more to treat illness or disease than to track wellness or healthy conditions. Standard terminology and coding are essential for everyone to understand what each other is doing or what has been done. In this vein, the International Classification of Diseases (ICD), now in its tenth version, from the World Health Organization, provides a standard coding system, as are the Current Procedural Terminology (CPT) codes from the American Medical Association. Both coding systems, along with Diagnosis Related Groupings (DRGs) from the Centers for Medicare and Medicaid, have been used primarily for billing services and can also identify patients to be included or excluded in disease registries.

Delivery of care is complex for reasons that are sometimes out of the purview of the healthcare system and may not have received the attention necessary in the past. Social Determinants of Health (SDOH) are felt to have a more significant role in patient health than the care delivered to them by our system. Poverty, for example, is a social factor commonly associated with health and also related to the physical environment, another determinant of health. People living in poverty are more likely to reside in low-income communities where health care resources are scarce and difficult to access. Regardless of their genetics, poor individuals living in low-

income communities are more likely to experience barriers to accessing healthcare services than their more affluent counterparts. This simple example illustrates the complex nature of human health and those dimensions beyond the bounds of health care delivery. While it is not incumbent on the system to fix these social determinant issues, it is increasingly important for providers to be aware of certain 'insecurities' to provide the best possible care for their patients. For instance, a patient with diabetes and no social determinants of health issues may have access to healthier foods and refrigeration for their medications such as insulin.

In contrast, a patient with food and housing insecurities may not have access to healthy foods or refrigeration for their insulin. This information is crucial to understand a patient may struggle to maintain an adequate level of health or wellness. The information can also enable referral to social services, facilitating support for patients' nutritional, behavioral, and/or housing needs.

Unfortunately, except for some screening exams to detect disease processes early, wellness care has often been treated as or considered an afterthought or left to the patient to manage themselves.

Individual Versus Population Health

Health is measured at individual and population levels. Individuals exist within populations, and their unique characteristics are woven into the fabric of the people. Whereas individuals have a unique set of factors contributing to their health, populations are comprised of groups of individuals, which generally share some defining characteristics, demographic, geographic, or social, and can be categorized or binned in registries. Population health then is a reflection of the health of individuals within a defined group. Healthcare providers are caring for the individual patient in front of them and populations or their census of patients, which often comprise multiple different populations. The diabetic patient is cared for as an individual and is part of the diabetic registry or population and manages care gaps or necessary screenings as determined by best practices of the specific population.

Health information is used to evaluate and monitor trends in individual and population health. Health information generally summarizes as a set of characteristics or outcomes relating to health at the personal level. Health information includes the distribution of characteristics and outcomes within a specific group [1]. There are often pressures to control costs of a population by using lower-cost medications or testing that seem to the provider challenging to maintain when facing the individual patient. However, this should not be the case if the health of the population is aligned with the health of the patient.

Individual health information has been part of health care delivery from its start as a tool for practitioners to document and monitor patient health. Historically, data were entered in record books by hand. Handwritten records evolved into patient charts, which are now health information systems employing sophisticated technologies. Health care providers gather health information to determine patient's health status and inform diagnoses and treatment planning, but individuals are increasingly monitoring their health. New and emerging technologies empower individuals to collect and monitor their health through step or activity tracking, heart rate monitoring, weight or blood pressure tracking, or even glucose levels for diabetic patients. Much of this patient collected data is not collected as part of the patients' medical record, though this is changing rapidly.

Population health information has also been recorded for many years. The earliest population health information includes mortality records and recordings of significant epidemics that occurred throughout history. The 'Bill of Mortality' from 1665 depicted in Fig. 4.1 demonstrates how early data on the cause of death were recorded and reported. The British physician John Snow did the first documented recording of population health data to monitor trends in health and disease to determine the source of causation. Snow, a nineteenth-century anesthesiologist from London, England, is credited with systematically studying a cholera epidemic in his community and identifying polluted drinking water as the source. This study of an epidemic and subsequent intervention, removing the water pump handle to the contaminated drinking water supply, successfully stopped the cholera epidemic [2]. It further led to Snow becoming known as the 'father of epidemiology,' the branch of medicine that deals with the incidence, distribution, and possible control of diseases and other factors relating to health [3].

Florence Nightingale, a nurse in the British military in the 1860s serving in the Crimean War, noticed horrible sanitary conditions and linked that to the unnecessary death of many British soldiers, also decades before the discovery of the germ theory of disease. She used detailed accounts and statistics in a presentation to the Royal Commission on the Health of the Army. Instead of using tables for her data, which was the standard method, she used data visualization in the form of a 'rose diagram' (Fig. 4.2) or modified pie chart to show the staggering differences that sanitation made in the mortality of the injured troops in the hospital at Scutari.

As we explore later, population health data are critical to the public health system. Still, they also play an essential role in modern health care delivery, where individual patient health information is now aggregated within large health care organizations/systems for clinical decision support (see Chap. 7) and quality improvement and between systems through statewide Health Information Exchange (HIE) networks (see Chap. 14). As detailed in the case vignette at the

The Diseases and Casualties this year

Abortive and Stillborn	617	Executed	21	Murthered and Shot	9
Aged	1545	Flox and Small-pox	653	Overlaid and Starved	45
Ague and Feaver	5257	Found dead in streets, fields etc	20	Palsie	30
Apoplexie and Suddenly	116			Plague	68596
Bedrid	10	French Pox	84	Plannet	6
Blasted	5	Frighted	23	Plurisie	15
Bleeding	16	Gout and Sciatica	27	Poysoned	1
Bloudy Flux, Scowring and Flux	185	Grief	46	Quinsie	35
		Griping In The Guts	1288	Rickets	557
Burnt and Scalded	8	Hanged and Made away themselves	7	Rising Of The Lights	397
Calenture	3			Rupture	34
Cancer, Gangrene and Fistula	56	Headmouldshot and Mouldfall en	14	Scurvy	105
				Shingles and Swine Pox	2
Canker and Thnish	111	Jaundices	110	Sores, Ulcers, broken limbs	82
Childbed	625	Imposthume	227	Spleen	14
Chrisomes and Infants	1258	Kild by several accidents	41	Spotted Feaver and Purples	1929
Cold and Cough	68	King's Evil	86	Stopping Of The Stomach	332
Collick and Winde	134	Leprosie	2	Stone and Stangury	98
Consumption and Tissick	4808	Lethargy	14	Surfet	1251
Convulsions and Mother	2036	Livergrowne	29	Teeth and Worms	2614
Distracted	5	Meagrom and Headach	12	Vomiting	51
Dropsie and Timpany	1478	Measles	7	Wenn	1
Drowned	50				
				Total	97306

Fig. 4.1 Bill of Mortality from 1665. The 'Bill of Mortality' from 1665 demonstrates how early data on the cause of death were recorded and reported

beginning of the chapter, sharing such health information on individuals and populations provides new perspectives on health and its determinants. From the early recognition of recent disease outbreaks such as influenza, COVID-19, *Escherichia coli*, or even better-distributing patients after a mass casualty event such as the Boston Marathon bombing of 2013, data shared via HIEs have an essential role in transforming the United States health system.

Complexity

Health and healthcare in the United States are very complex. Healthcare organizations now have robust data and information systems because of multiple health policy reforms over the past two decades (see Chap. 3). Although the United States reports the highest percentage of GDP is spent on health care, its population lags behind other developed countries in life expectancy and other population health measures. Contributing to this is an inefficient and uncoordinated disease-focused health system.

Health information is used to assess individuals and populations within the health system and drive activities within the system. Patient health information has historically been collected and analyzed at the individual level as a part of patient care. Health information is collected and studied at the population level to determine the distribution and patterns of disease and inform health policies. Individual health information is being aggregated into large population health information systems with the capacity to inform health policy and drive health system change.

Where genetics are the foundation of human health, information is the foundation of the health system. The following section reviews the major domains of the current United States health system explores the flows throughout the system.

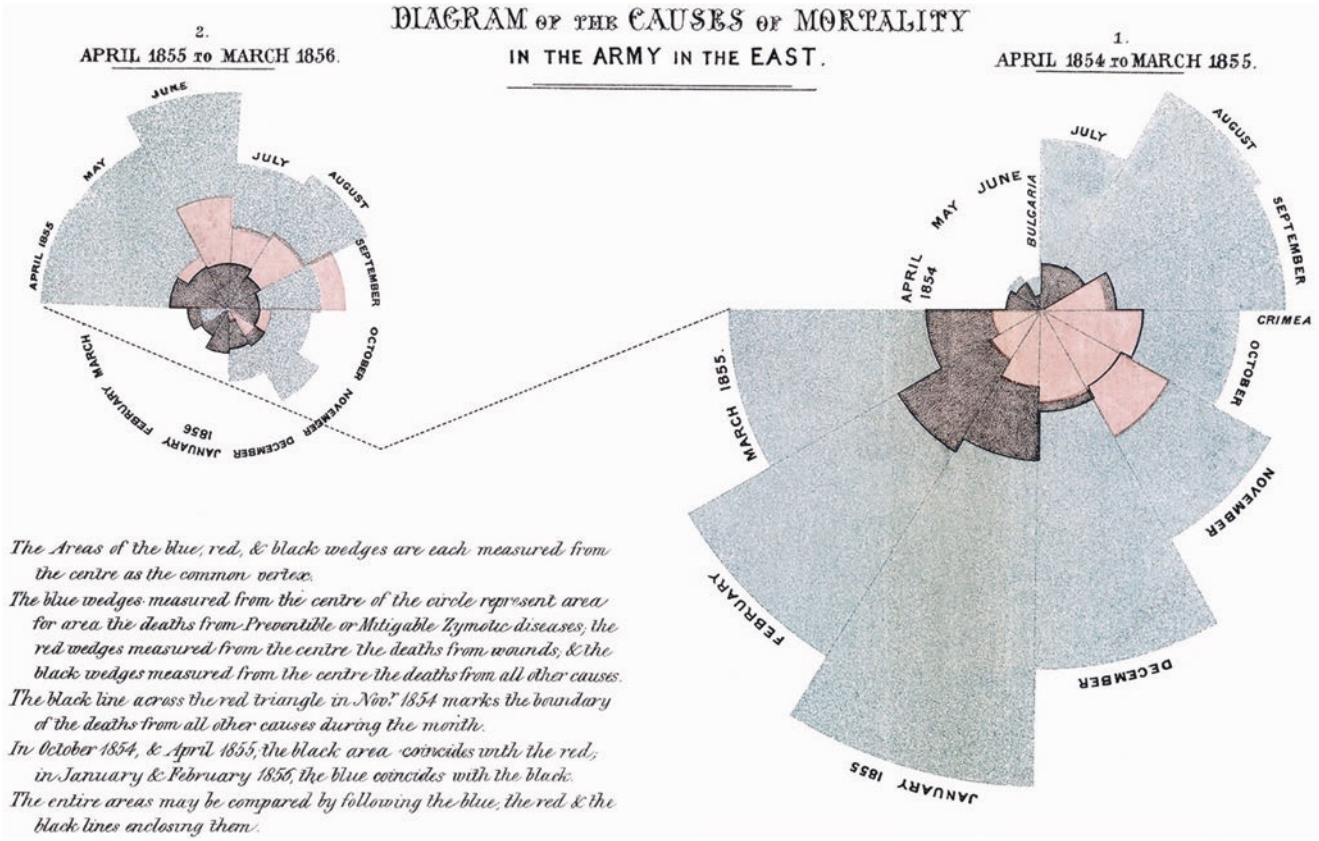

Fig. 4.2 Rose diagram by Florence Nightingale to illustrate the impact of hospital sanitation practices on mortality during the Crimean War

The United States Health System

A **Health System** may be *described as a sum of organizations, institutions, and resources focused on health at a high level*. The health system may be thought of as a network of diverse entities and cutting across multiple sectors. This section presents background information on five domains (health care delivery, public health, clinical research, education of health professionals, and personal health) of the United States health system pertinent to clinical informatics. To appreciate the role and flow of data within and throughout the health system, a basic understanding of this system and its key domains is required. We explore each significant component of the health system in this section.

Health Care Delivery

Health care delivery *generally refers to the resources and processes which enable people to receive health care services* [4]. For many reasons, the United States has the most expensive, highly complex healthcare delivery system in the world. Its complexity may be summarized into four broad components: providers, payers, suppliers, and regulators.

Health Care Delivery: Providers

Providers refer to all organizations, services, and resources (including the workforce) that directly deliver or facilitate healthcare services to patients. At the organizational level, providers include a vast array of organizations and services. Acute care hospitals, primary care physician offices, dental offices, rehabilitation facilities, home health services, telemedicine, and numerous other organizations and services are considered providers within the health care delivery system.

In addition to organizations, the workforce of health professionals that deliver health care services is also a significant component of health care providers. This workforce includes licensed health professionals such as physicians, nurses, dentists, therapists, and many other health professionals. In addition to the professionals traditionally thought of as "health care providers," many other professionals support delivering health care services. In addition, clinical informatics professionals are providers as they play a critical role in the health care delivery process. This is especially true as health care delivery increasingly relies heavily on clinical information technologies in process improvement

and newer delivery processes such as telemedicine or asynchronous visits where prescription refills can be obtained without requiring an in-person visit.

At the intersection of clinical informatics and health care delivery, the healthcare workforce has a significant and vital role in the health care system. While delivering care to patients, the workforce is asked to oversee the collection and recording of patient health information increasingly as discretely filed data elements in addition or in place of the text or prose format most common in charting. Additional information on the education of health professionals is explored later in the chapter.

Health Care Delivery: Payers

Organizations (public and private) that finance health care services, such as government-sponsored health insurance programs (Medicaid and Medicare), as well as commercial insurance carriers, managed care organizations, and self-insured employers, are commonly referred to as **payers**. Although healthcare payers are typically larger organizations or entities, *individuals directly paying for their services are also considered a payer* within the health care delivery system.

Health insurance is the foundation of health care financing in the United States and is also the most common mechanism. Insurance is grounded in two basic principles: Risk Spreading and Cost Sharing. **Risk spreading** is *the process of minimizing the chance of significant losses to the payer*. This is typically accomplished by setting insurance premiums concordant with a patient's risk level, selectively denying coverage based on risk, or increasing the rate of cost-sharing. **Cost-sharing** is *a financial risk-management strategy that requires patients to share in a portion of healthcare costs*. Common cost-sharing mechanisms include premiums, deductibles, copayments, coinsurance, or benefit limits. Due to the high costs, few individuals pay the entire fee of health care services out of pocket. **Cost shifting** is different than cost-sharing in that the providers may need to charge higher costs to those patients who are insured or covered to afford the services rendered to those who are not able to pay or are un- (or under-) insured. This healthcare system is unique to the United States, represents a significant source of inefficiency, and threatens equity within the system. Understanding how this system evolved is essential.

Although health insurance is the primary mechanism for financing health care today, this was not always the case. Health insurance has only been in existence since the mid-twentieth century when major automotive manufacturers began to offer health benefits to employees to offset the cost of health care as an incentive [5]. Employer-based health insurance expanded throughout the latter half of the twentieth century and became a major recruiting incentive for employers. During this same period, incredible advancements in medical science were also being made. Advances led to the development of technologies and treatments for many previously untreatable and/or incurable conditions. These innovations came with a high price tag, but patients were largely unaware of the cost as most services were reimbursed, on their behalf, through their health insurance program. Cost-sharing described earlier was introduced more recently to increase patient awareness regarding the cost of health care.

The advent of health insurance and the availability of new health services increased health care utilization and costs in the United States. As costs and utilization increased, the system evolved to become heavily dependent upon financing through health insurance. It became increasingly difficult for individuals without health insurance to access health services.

Financing health care in the United States largely determines who has access to health care and who does not [6]. **Access** *refers to the ability of an individual to obtain health care services when needed* [4]. Individuals typically must finance health care through one of the following mechanisms to have access to care.

1. They must have health insurance through their employer
2. They must be covered under a government health care program
3. They must be able to afford to buy insurance with their private funds
4. They must be able to pay for services privately [4].

The ability to finance health care services through one of these means does not guarantee access. In addition to the 'ability to pay' for health care, an adequate supply of health care providers (organizations and professionals) is needed to ensure access to health care services. Laws and regulations such as EMTALA (Emergency Medical Treatment And Labor Act of 1986) were instituted to ensure people are treated regardless of their ability to pay when presenting to an emergency department. A seemingly unexpected outcome of such well-intended policies is that emergency departments have become the safety net of care for many uninsured patients who have nowhere else to obtain medical services.

Unfortunately, health care providers are also not evenly distributed across the population. Health care financing has a considerable influence on the supply and distribution of health care services. Health care providers are clustered in metropolitan areas with high population densities in which more significant proportions of the population have health insurance coverage. Rural communities with small populations and low-income urban communities with less robust financing mechanisms are more likely to experience shortages of health care providers and associated health services.

In addition to its influence on the geographic supply and distribution, financing has also had a prominent role in shap-

ing providers in the current health care delivery system. For example, historically, **fee-for-service** (FFS) *payments, or payment of a fee for each specific health care service or visit,* were the primary form of reimbursement to health care providers. FFS payments are issued to providers retrospectively after the service is provided based on ICD and CPT codes with modifiers to account for care complexity and regional allowances. Advanced and specialty health care services, requiring greater expertise and more resources, are reimbursed at a higher FFS rates, while primary health care services focused on disease prevention and health promotion were reimbursed at lower rates. Understandably but unfortunately, the FFS reimbursement system may incentivize health care providers to increase the volume of specialty services.

Health Care Delivery: Suppliers

Healthcare suppliers provide resources to the health care delivery system, such as pharmaceutical companies and medical equipment manufacturers. Additional levels of complexity are added by entities such as pharmacy benefit managers, whose role is to provide the best cost for prescription medications to their customers, who are often benefit managers or insurers themselves and not always the patient. Suppliers are a diverse group ranging from large pharmaceutical firms and durable medical equipment manufacturers to small companies that produce hospital linens and medical uniforms. In addition to organizations that supply medications and materials, organizations that provide services such as biohazardous waste disposal companies, medical laboratory curriers, and health information technology companies are also included in this category. Any industry or organization that provides goods, materials, or services which directly or indirectly support health care delivery is considered a supplier.

Health Care Delivery: Regulators

Because of its substantial impact on human health, health care delivery is the most regulated industry in the world. Regulation occurs at all levels within the health care delivery system. **Regulators'** primary responsibility is to *direct or influence the actions, behaviors, or decisions of the providers, suppliers, and payers of the health system to ensure safety and balance the objectives of enhancing quality, expanding access, and controlling costs* [7]. Currently, most regulation occurs within the various sectors (providers, suppliers, and payers) through governmental and private agencies that develop and oversee guidelines and policies around cost, access, and quality. Table 4.1 summarizes the regulation occurring within each healthcare delivery sector and provides examples of the most prominent regulators within those sectors. It is important to understand that many of these regulators span multiple or all healthcare delivery sectors, although their primary responsibility may reside within one of the three sectors. Although a large number of entities are engaged in regulation, their efforts are not currently coordinated. Unfortunately, many previous efforts to implement health planning at the system level have failed. This lack of coordination sometimes causes seemingly contradictory or difficult-to-understand regulations.

At the system level, **health planning** processes, the *government develops a plan to align and distribute health care resources to achieve desired health outcomes* [4]. Several regulatory initiatives aimed to ensure an equitable supply

Table 4.1 Summary of critical regulators within various sectors of health care delivery

The sector of healthcare delivery	Scope and purpose of regulation	Examples	Role of regulators	Examples of regulators
Provider	Direct delivery or facilitating the delivery of health services and collecting and recording patient health information	• Physician offices • Hospitals • Rehabilitation facilities • Tele-medicine • Health care workforce	Ensure safety, quality, and access to health services.	• HIPAA[a] • Agency for Healthcare Research and Quality (AHRQ) • Joint Commission on Accreditation of Healthcare Organizations (JCAHO) • Det Norske Veritas (DNV)
Payer	Financing health care services	• Medicare • Medicaid • Private insurers • Self-pay	Regulate the cost of healthcare against services provided	• Department of Health and Human Services (HHS) • Centers for Medicare and Medicaid (CMS)
Suppliers	Provide resources to the health care delivery system	• Pharmaceutical companies • Biohazard waste disposal • Health information technology	Ensure quality of health care resources	• Centers for Disease Control and Prevention (CDC) • Federal Drug Administration (FDA) • United States Agency for Toxic Substances and Disease Registry (ATSDR)

[a]Health Insurance Portability and Accountability Act of 1996

and distribution of health care through health planning efforts throughout the United States. In 1974, the federal Health Planning and Resource Development Act was enacted, which provided incentives and penalties to encourage states to adopt certificate-of-need (CON) legislation [8]. A CON is a control exercised by a government planning agency over expanding medical facilities [4]. CON statutes were enacted through the adoption of policies at the state level. These statutes required that health care facilities receive approval for expansion of existing or building new health care facilities. The approval of CONs was primarily based on demonstrated need for additional services or supplies within specific communities. In 1986, the Health Planning and Resource Development Act was repealed as the federal government moved away from health planning.

As a result of the implementation of the Affordable Care Act (ACA), community health needs assessments (CHNA) and implementation strategies are now required of tax-exempt hospitals, much like CONs before 1986. CHNAs help ensure that hospitals and other health care facilities have the necessary information to make informed decisions regarding what services to provide to their respective community. These efforts aim to improve the health of communities by using data to identify areas of need within communities. Once again, clinical informatics practitioners are an essential component of community health needs assessments. Health data at the patient, community, and population levels are the driving forces behind CHNAs, which directly influence supply initiatives within the U.S. Health System.

Regulators are primarily responsible for patient safety and health system quality and efficiency. Unfortunately, health care delivery and its regulation are disorganized and fragmented between and within the various sectors. Figure 4.3 illustrates how the sectors are regulated and work together within the delivery system to finance, supply, and serve consumers' health care needs.

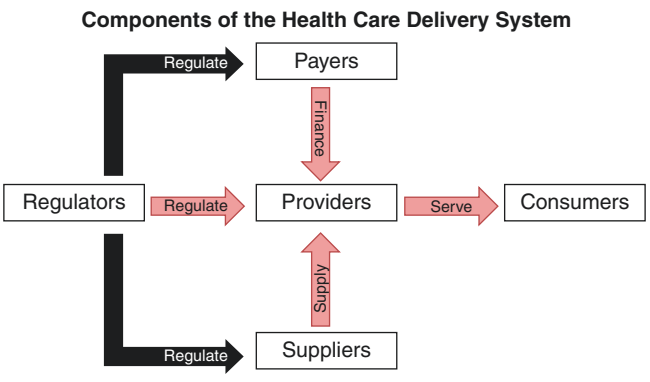

Fig. 4.3 Components of the United States Health Care Delivery System. This figure identifies the relationship between the four major components of the health care delivery system: Payors, Providers, Regulators, and Supplies

Forces Shaping Health Care Delivery

Health professionals recognize the need to improve the health system's quality while increasing access and reducing costs. However, the health system's complexity continues to grow and can be "characterized by more to know, more to do, more to manage, more to watch, and more people involved than ever before" [9]. As a result, population health and health outcomes in the United States have been primarily impacted by poorly organized and uncoordinated health care delivery. In 2001, The Institute of Medicine released a report that stated, "bringing state-of-the-art care to all Americans in every community will require a fundamental, sweeping redesign of the entire health system" [9]. IOM identifies six quality components necessary for improving the health system in the report, summarized in Table 4.2.

For the United States health system to make substantial improvements, the system must be safe, effective, patient-centered, timely, efficient, and equitable. Clinical informatics is essential in demonstrating or measuring these fundamental quality components, which significantly shapes today's healthcare delivery.

A Culture Change

As illustrated throughout this chapter, the Health System comprises several sectors that play a fundamental role in health care delivery and ultimately determine the system's ability to provide affordable, high-quality care to everyone. Therefore, an entire redesign of the health system that aims to improve the six quality component identified by the Institute of Medicine must be supported by a commitment to change from all sectors of the health system: Providers, Payers, Supplies, and Regulators. A shift from a volume-

Table 4.2 Summary of Institute of Medicines (IOM) six aims of quality components

Institute of Medicine: six aims of quality components [9]	
Quality component	Specific aim
Safety	Avoiding injuries to patients from the care that is intended to help them
Effective	Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit
Patient-centered	Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions
Timely	Reducing waits and sometimes harmful delays for both those who receive and those who give care
Efficient	Avoiding waste, including waste of equipment, supplies, ideas, and energy
Equitable	Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

based (FFS) model towards value-based systems using bundled payments or accountable care organizations (ACOs).

The ACA seeks to improve access to high-quality and affordable health care for all Americans. One mechanism in which the ACA seeks to reduce health care costs is through the promotion of provider networks, called Accountable Care Organizations (ACO), that coordinate patient care and effectively deliver care more efficiently. An **ACO** *is a network of doctors and hospitals that share financial and medical responsibility for providing coordinated care to patients to limit unnecessary spending* [10]. For ACOs to effectively deliver health care efficiently and improve health outcomes, ACOs rely on comprehensive patient data. The use of aggregated patient data and connected, interoperable electronic health systems to drive improved quality of care is ideal for ACOs and Patient-Centered Medical Homes utilization. Similar to ACOs, **The Patient-Centered Medical Home** is a care delivery model that provides coordinated health care services through a primary care provider to ensure they have access to health services when and where they need it. Clinical informatics, once again, is a vital component to the development, implementation, and management of systems capable of population health tracking and patient information management. These systems require the use and the continuing refinement of these information management systems grounded in clinical informatics.

The culture of the United States health system has historically been that of diagnosis and treatment of disease. In recent years, the U.S. has recognized the inefficiencies of the system and its impact on population health. The culture within the system is currently moving away from one that is focused on diagnosis and treatment. It now emphasizes the importance of patient-centered and managed care, promoting disease prevention and population health. Figure 4.4 illustrates the change in culture within the health system by demonstrating how health professionals have begun to shift their understanding of a few fundamental healthcare concepts.

Public Health Systems

Public health plays a significant role in health but is generally lesser understood than health care delivery. Whereas the health care delivery system's primary focus is on restoring the health of individual patients, the public health system focuses on ensuring the health of populations. Defined in 1920 as 'the art and science of preventing disease, prolonging life, and promoting health and efficiency through organized effort' [11], public health focuses on prevention and health promotion, and is concerned with the broader social and environmental determinants of health, described earlier in this chapter. In the United States, the public health system is comprised of official government public health agencies, other public-sector agencies (such as schools, Medicaid, and environmental protection agencies), and private-sector organizations whose actions have 'significant consequences for the health of the public' [12]. Many local public health agencies provide direct, primary care services to patients. The public health system also includes federally qualified health centers and other 'safety net' providers. It is important to note that in other countries, public health activities are carried out by a Ministry of Health, which also manages healthcare administration and delivery for the nation.

Population health information is the driver of public health. In a landmark 1988 report, the Institute of Medicine recognized assessment, policy development, and assurance as the three core functions of public health [13]. Monitoring or assessing population health, more commonly referred to as public health surveillance, is one of the primary functions of the public health system, and it is often referred to as the cornerstone of public health practice [14].

John Snow's work documenting Cholera in the mid-nineteenth century, mentioned earlier in this chapter, represents early public health surveillance work where cases were manually identified and recorded. More recently, administrative data and national surveys have been used for public health surveillance. Claims databases contain information on

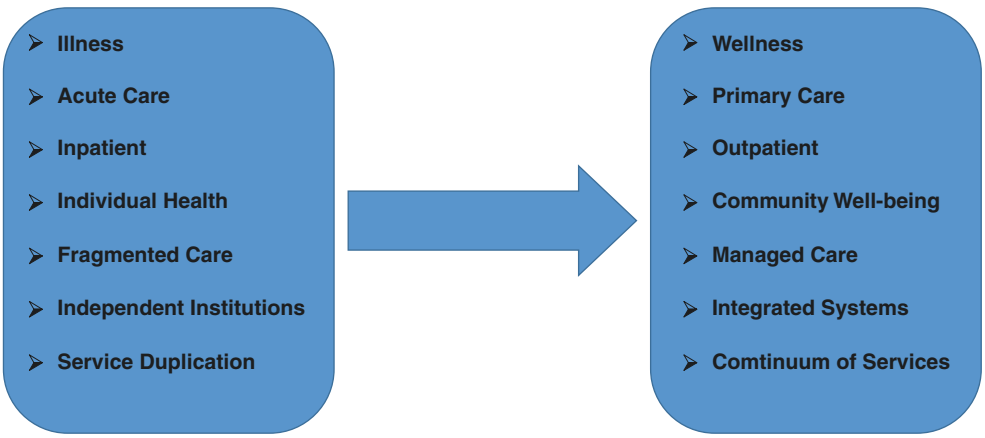

Fig. 4.4 A shift in thinking and culture: moving health care delivery from treating acute conditions to prevention and health promotion. This figure illustrates the change in culture within the health system by demonstrating how health professionals have begun to shift their understanding of a few fundamental healthcare concepts

health care utilization and have been widely used for public health surveillance because they are relatively inexpensive and available in electronic formats [15]. Unfortunately, no one administrative data set includes the entire United States population, making these data sets limited . National surveys, such as the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System (BRFSS), collect information from representative population samples to determine health status and the prevalence of health behaviors and risk factors.

Whereas patient-level information is used to drive clinical decision-making within health care delivery settings, population-level health information is used to guide public health policies that contribute to the environment where health care delivery occurs. However, as data are integrated across the health system, clinical information is becoming increasingly important. It will likely play a significant role in public health decision-making, as described in the vignette. Additional information on public health informatics, including the data and information systems used in public health organizations, can be found in Chap. 25.

Clinical Research

Medical knowledge continues to grow at ever-increasing rates and amounts through both outcomes and clinical research. Clinical research is the health system domain that determines the safety and effectiveness of medications, devices, diagnostic products, and treatment regimens intended for use in individuals and populations. Traditionally research has been conducted using randomized controlled trials (RCTs) or otherwise controlled experiments in which an intervention was compared to "usual care." Evidence that a given intervention is "better" than usual care, or another intervention, should prompt clinical providers to change practice. However, it has been observed that the gap between published research and a change in clinical practice requires, on average, approximately 17 years, and often less than 14% of it becomes standard of care [16]. Additional details on research methods and the development of evidence-based medicine (EBM) guidelines to influence clinical practice can be found in Chap. 5 of this book.

Clinical informatics experts empower clinicians, allied health professionals, and organizations to provide the best possible care to patients by optimizing health information technologies within the current workflows and practices. Clinical organizations provide frontline staff in a health system with access to the latest evidence via clinical libraries or online access to scholarly journals and scientific publications easily searchable. Users can access resources from the U.S. National Library of Medicine (NLM), such as MEDLINE or PubMed, searching for available evidence across a wide range of publications. However, with the doubling of health information now at an astonishing 65 days, it is impossible to keep up with the knowledge, let alone incorporate it into practice. Many EHRs include hyperlinks to relevant evidence when browsing a patient's chart [17]. For example, a primary care physician might desire more information about a medication prescribed by a specialist because they do not typically prescribe it. A link in the EHR would allow the PCP to connect to a website that would describe the medication, its indications, and its side effects. A second method for implementing research-derived evidence is through clinical decision support (CDS). The EHR system prompts the clinician to perform a "best practice" task in a given context with CDS. For example, the PCP might be reminded to order a glycosylated hemoglobin test for a patient with diabetes because the EHR system detected no such test for this person within the past 13 months. Available evidence-based clinical guidelines recommend that people with diabetes have their glycosylated hemoglobin tested once every 12 months. Additional information on research and evidence-based guidelines and their implementation through CDS can be found in Chaps. 5 and 6.

Personal Health

Although public health is primarily concerned with improving and maintaining families, communities, and entire populations, its success is mainly dependent on personal health. As the U.S. healthcare delivery system continues to realize its vision of patient-centered primary care, patient activation has become increasingly important. **Patient activation** *refers to a patient's knowledge, skills, ability, and willingness to manage their health and care* [18]. One important factor influencing a patient's ability to manage their health by working with healthcare providers to personalize care is the patient's ability to collect personal health data and maintain comprehensive personal health records that may be used to inform treatment plans and health strategies. A personal health record (PHR) is an electronic, lifelong resource of health information used by individuals to make decisions related to their health. PHRs contain various personal health information (PHI) and are typically a combination of individual records and data collected from healthcare providers. **Personal health information** or protected health information primarily refers to personal data such as demographic information, medical history, diagnostic results, insurance information, or any other data that is collected by a health care professional to identify an individual and determine what type of care that individual should receive [19]. PHRs and other information systems used directly by patients are described in Chap. 24.

As more people track their health data on their personal devices, they have an ever-increasing desire to combine their personally recorded data such as step counts, weight, vital signs, and perhaps calorie tracking with their medical data from the health system. This has the potential to have a robust and increasingly complete picture of the health of an individual. Still, it also comes with security concerns and the inappropriate access of personal health information (PHI) by organizations or people who do not or should not have access to solicitation of goods or services. Improper release of PHI is penalized significantly by CMS via HIPAA laws, which is covered more in Chap. 3.

The Flow of Data, Information, and Knowledge Within the Health System

Understanding the Flow of Data

In the vignette, there were prominent examples of how the flow of data through the electronic medical record and within the health system was critical to the care and treatment of the patient during the hospital visit. The vignette also revealed how the electronic flow of data could be utilized to maximize multiple aspects of healthcare delivery related to efficiency, quality, and even public health. When the patient's registration information and some critical laboratory results were already on file in the EHR because he had visited another hospital, this saved time for the patient and allowed all of the information from his past visits to be available in his pre-existing EMR, his list of current medications was available, and only needed to confirm and updated by his current caregivers. Even summaries of his records from out-of-network care were available through the state HIE, giving his current care providers a much broader and more accurate past medical history. Order Sets were utilized to promote standardized practices and evidence-based medicine delivery, and archives of his completed hospital stay were stored in a data repository for aggregated patient quality analyses and internal outcomes tracking. Public health needs were addressed through the activation of the NEDSS so that the appropriate agencies could track, assess, and minimize the potential threat to public health posed by introducing the disease into the community. To understand the actual depth of the complexity efficiency and impact of electronic data flow in a fully integrated health system today, see Fig. 4.5, which illustrates the data flow for the patient vignette. While examining the illustration in Fig. 4.5, keep in mind that this complexity is the domain of the clinical informatician as they are

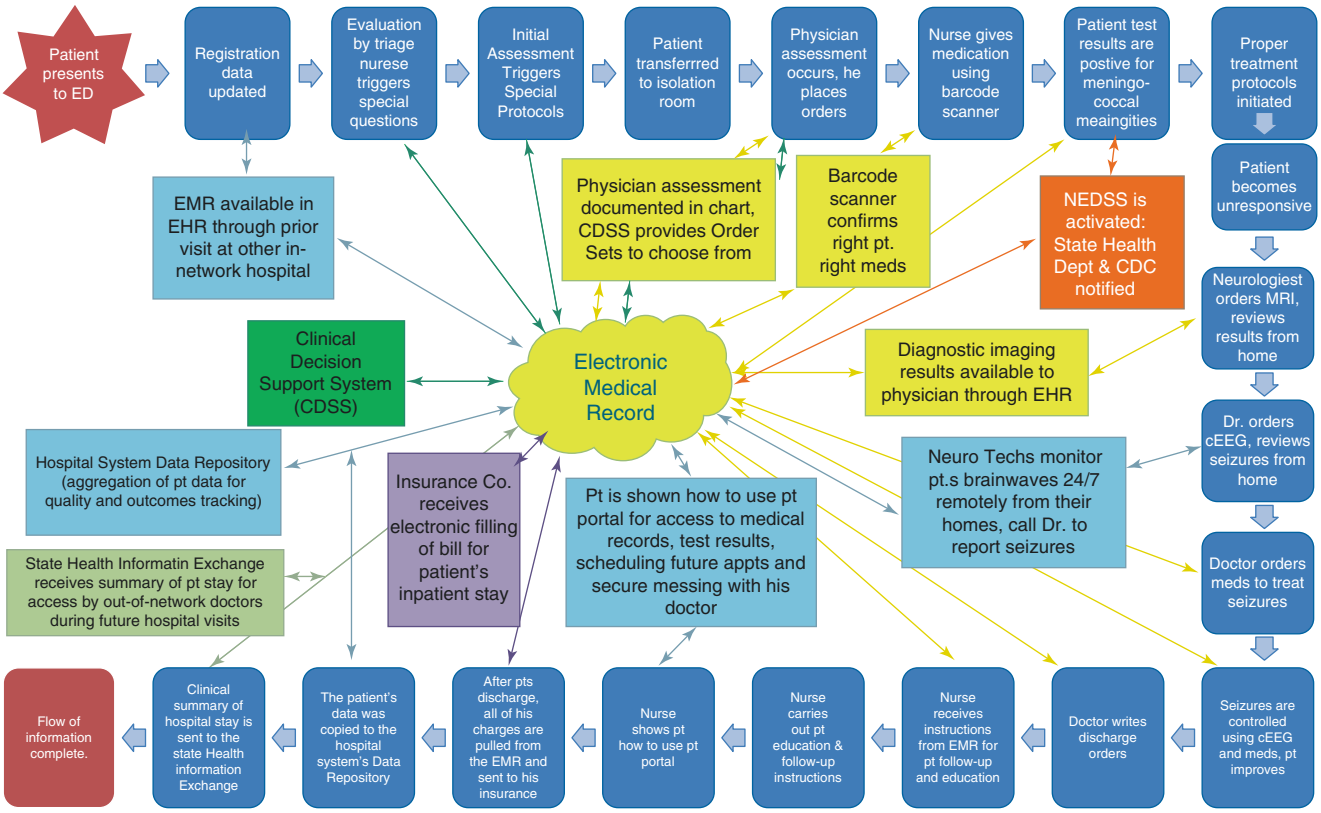

Fig. 4.5 Flow of data and information within the health system. This figure shows the flow of patient data and information within the health system by tracking the data from the beginning of a patient visit. The figure also shows that electronic medical records and clinical informatics are at the center of this complex process

generally tasked with sorting out information flows and implementing systems to improve care using redesigned health care delivery workflows.

Unfortunately, the current health system does not function as efficiently, and is not as connected, as described in the vignette. The vignette provides a vision for how the health system might operate in the future, and it illustrates the critical role that clinical informatics plays in a connected health system where electronic information systems are ubiquitous.

Clinical Informatics: Unifying the Health System

As shown through the previous demonstration of the electronic flow of patient information, the field of clinical informatics is unifying our system of health care. With the patient's electronic medical record at the center:

- Information flows throughout in-network and out-of-network health systems for easier access of patient information to providers, allowing them to deliver better patient care;
- Clinical decision support engines and guidelines-based order sets drive standardized, evidence-based best practices;
- Barcode scanning of everything from medications and patient supplies to paper documents scanned into the EMR reduces medical errors and increases charting and billing accuracy;
- Electronic notifications to state health departments and the CDC inform them of threats to public health;
- Electronic remote viewing and monitoring of patient data by off-site care providers allows more timely and effective care delivery;
- Patient access to their medical records and test results online, with the ability to securely send messages to their care provider, access assigned patient education, schedule upcoming appointments, and pay their bills, gives them much more control and ability to influence their health and healthcare;
- Electronic submission of billing claims to insurance companies improves efficiency and accuracy of claims submissions; and
- Submission of the patient's data to the health system's data repository allows the system to run multiple types of analyses of aggregated patient data to improve the quality, efficiency, and overall outcomes of care for the patients they serve.

The clinical informatics specialist is best positioned to incorporate new technologies or alerts within the existing workflows that improve patient care while respecting the sacred patient-doctor experience and not interfering with it. Efficiencies accomplished through the improved use of technologies need to be recognized by increased time and attention paid to individual patients and less into productivity metrics and increased numbers of patients cared for in the same amount of time. These strategies are often based on the current dissatisfaction or burnout shared by so many providers of care at all levels.

Emerging Trends in Clinical Informatics: An Effort to Improve Quality

In 1999, the Institute of Medicine (IOM) released a document to *Err is Human: Building a Safer Health System*, followed closely by *Crossing the Quality Chasm: A New Health System for the 21st century*. Many have thought these texts to light many of the inconsistencies and seemingly uncoordinated and sometimes unsafe systems to deliver healthcare. They serve as a wake-up call for all in healthcare to work towards a safer, more coordinated, and more efficient healthcare system. This lofty goal is challenging but is now more possible than ever with the guidance of clinical informatics.

Learning Health System and Electronic Health Records

EHRs provide vast amounts of data captured during routine clinical care that allows learning or inference of patterns of evidence. This observation led the Institute of Medicine to propose the notion of a Learning Health System in which health care providers not only provide care using established clinical guidelines based on evidence from clinical research but also by the evidence they infer from their EHR system [20]. Using evidence-based practice, utilization, and outcomes data, a learning health system would shorten the feedback loop and optimize care delivery. Clinical informatics is instrumental for implementing and using health information technologies within their organization and the data and results to optimize care delivery processes.

The vast amounts of patient data available through the use of electronic health records have led to the implementation of artificial or augmented intelligence (AI) via machine learning (ML) or deep learning (DL) with neural networks (NN). These tools enable researchers or informatics professionals to sift through the big data to find diseases or patterns, automate some redundant tasks, or augment the skills or abilities of physicians. An example from these tools would be 'digital twins', which search for patients with nearly identical presentations of diseases or illness. These 'twins' will provide several treatment choices based on previous cases

and outcomes with prognosis, side effects, and the likelihood of improvement based on the treatment provided at the time of prescribing or ordering. Of course, the promise of AI in medicine is still yet to be realized in many aspects. Regulation of artificial intelligence tools is currently a topic that is under discussion. Many provide the output of AI systems in terms of recommendations while allowing providers to choose not to follow to avoid some regulation. Reimbursement for A.I. tools is also yet to be determined. Still, informatics will be at the forefront of the vetting and implementation of A.I. systems in healthcare. An overview of AI, ML, DL, and NN are provided in Chap. 16.

Chapter Summary

As the U.S. Health System aims to improve overall population health by enhancing the effectiveness of and efficiency of the system. Clinical informatics plays an integral role in the path to a coordinated health system that effectively improves health outcomes by delivering high-quality and affordable health care to health care all Americans.

Application Exercise/Questions for Discussion

1. What is the difference between individual and population health?
   (a) Compare and contrast the determinants of each.
   (b) How are they monitored differently?
2. How are insurance costs determined?
3. How will the shifts in health system culture (from treating acute problems to promoting wellness) impact health care delivery?
4. How does clinical informatics support the U.S. health system?
5. How will health reform likely impact the flow of information through the health system?

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Part II

Clinical Decision Making and Care Process Improvement

Evidence-Based Health Care

5

Arlene E. Chung, Christopher S. Evans, P. Jon White, and Edwin Lomotan

Learning Objectives

- List various types of clinical research
- Describe grading criteria and apply them to clinical evidence
- Define characteristics of high-quality clinical guidelines
- Name sources of clinical evidence
- Identify and evaluate evidence to apply appropriately to clinical information systems and tools

Practice Domains: Tasks, Knowledge, and Skills

- Sources of evidence
- Evidence grading
- Clinical guidelines
- Use of evidence to inform practice (K003)

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Case Vignette

As a physician informatician at a large health system, you have been asked to simplify and standardize the diagnostic imaging ordering process in your electronic health record system for clinicians caring for pregnant patients with suspected appendicitis. You hope to implement an electronic clinical decision support (CDS) tool to assist clinicians with determining the most appropriate and evidence-based imaging modality, but also recognize that the CDS tool must be flexible given the different types of imaging modalities available across your system. You assemble a representative team of invested stakeholders and clinical experts from emergency medicine, obstetrics/gynecology, surgery, internal medicine, pediatrics, and radiology. It quickly becomes apparent that significant variation exists with the most commonly used imaging modality in this patient population between abdominal ultrasonography, magnetic resonance imaging (MRI), and, in some cases, computed tomography (CT). Members of the group can each provide the latest published literature that supports different approaches. As the clinical informatician leading this initiative, you are tasked with developing a CDS tool in the EHR for point-of-care ordering of diagnostic imaging based on the available clinical research evidence base, high-quality clinical practice guidelines and on imaging modalities available at each hospital. When developing the CDS tool, identifying appropriate guidelines and evaluating mixed evidence can be complex, and the solutions require weighing the relative benefits and risks.

Introduction

The delivery of quality healthcare is based on the core principles of evidence-based care [1]. Evidence-based care incorporates the latest and strongest research while considering various limitations of study designs. The application of evidence-based clinical informatics and clinical research is essential to the design, development, and

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implementation of informatics systems and tools. Clinical informaticians have a crucial role in incorporating and translating research from clinical informatics and clinical medicine. Thus, it is vital to understand how to search and examine the evidence base for quality and understand its limitations and biases, and how to reconcile evolving and conflicting evidence.

Evidence-Based Health Care

Clinical research and the scientific method continue to be the bedrock of clinical medicine and practice across a wide breadth of topics, such as delineating pathophysiology of conditions to disease transmission to longitudinal outcomes of disease processes and risk. As the evidence base evolves and changes more quickly due to the pace of research and dissemination of results, the way research informs clinical guidelines and day-to-day care decisions have become increasingly complex and more dynamic. In a sense, "evidence-based health care" has come to describe a set of concepts. In this chapter, *evidence-based health care* is defined as applying the best available research results with clinical expertise when making healthcare decisions [1]. The term "evidence" is also fundamental to the ensuing material. Evidence is defined as the results of clinical research that have been selected for the relevance of the motivating question and the rigor of the study methods.

The concept of quality in health care is a fundamental reason for using evidence. Without qualifiers to describe evidence as 'high' or 'low,' quality is a complimentary term that has been used in recent decades to connote a virtuous state of health care structure, processes, and outcomes. The most widely used definition of quality comes from the Institute of Medicine (IOM), which characterizes *quality health care* as safe, timely, effective, efficient, equitable, and patient-centered [2]. Although evidence is most closely associated with effectiveness, it can address any of the characteristics listed.

Types of Research Studies

Clinical research questions can be answered by employing various study designs, each with its advantages and disadvantages [3, 4]. The decision to use one study design over another can be driven by multiple factors, including the desire to assess causality or association, the prevalence of the disease or outcome, time constraints, cost, and existing knowledge based on prior literature and ethical considerations. Clinical research can be delineated in terms of experimental and observational study designs.

Experimental Study Designs

When a study utilizes an experimental design, investigators determine the allocation of an intervention or exposure to individuals or groups of study participants. The most well-known and rigorous experimental study design is a randomized controlled trial (RCT). Individual participants are randomly assigned to one of two or more study arms to receive treatment, intervention, or exposure. In an RCT, a new treatment or intervention is usually compared to a placebo group or a standard of care control group. The process of randomization aims to limit the unequal distribution of baseline characteristics between groups that may confound the observed associations between treatment allocation and study outcomes. Although outside the scope of this textbook, randomization techniques are not limited to a single participant and can include methods such as block randomization or cluster randomization [3]. Furthermore, RCTs can be designed with the intent to measure efficacy (how a treatment works in ideal conditions) or with the intent of measuring effectiveness using a pragmatic study design that attempts to understand how a treatment performs in "real" world settings.

Observational Study Designs

In observational studies, participants are observed throughout the study period for a given outcome, but study investigators do not actively determine the allocation of study treatment or exposure [4, 5]. Observational studies can be prospective, where data is collected over time, or retrospective in the case where study data has already been collected. A *cohort study* follows groups or "cohorts" of patients over time to better understand the incidence of a given outcome or assess associations or risk factors for a study outcome [6]. Notable examples of longitudinal cohort studies include the Framingham Heart Study [7] and the Nurses' Health Study [8]. An important limitation of cohort studies is the time and resources required if a disease or outcome is rare or requires a long time to develop. A *case-control study* assesses the presence of exposure in patients who have a condition (cases) compared to those without the condition (controls) and is well suited for research questions related to rare diseases, but this design is more susceptible to selection bias. For example, consider a study that uses EHR data from the hospital to match cases, such as individuals with diabetes, with controls who represent individuals admitted for other causes. Although the controls do not have diabetes, these individuals may not be representative of healthy individuals living in the community. In a *cross-sectional* study, investigators measure all the study variables at a single point in time, usually among a large population. This study design is typically best suited to assess

the prevalence of a condition and potential associations of covariates with a condition, but it cannot evaluate causal relationships or calculations of incidence [3, 9]. Lastly, *case reports* and *case series* are the initial descriptions of individuals or groups of individuals with a clinical presentation and are often used to prompt more rigorous study designs.

Systematic Reviews and Meta-analysis

A unique but vital form of clinical research is a systematic review and meta-analysis, which involves a meticulous methodology called "research about prior research." Systematic reviews assess a specific clinical question across multiple research studies previously published in the peer-reviewed literature. A well-conducted systematic review includes specific clinical questions with strict inclusion and exclusion criteria, follows a rigorous methodology to search multiple medical literature databases extensively, and determines the quality of studies. The process should be transparent so that other investigators can reproduce the findings. These systematic reviews are incredibly time and resource-intensive, so it is increasingly important not to duplicate systematic reviews when not needed. Therefore, the prospective registration of ongoing systematic reviews through registries such as PROSPERO is strongly advisable [10]. Rigorous systematic reviews should also follow best practices for transparency and reproducibility, such as those outlined in the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement, which was recently updated in March 2021 [11, 12]. The most well-known professional group that conducts systematic reviews is the Cochrane Collaboration [13].

A meta-analysis is a formal quantitative study design used to assess the prior body of research studies to develop conclusions about the evidence base and are often considered to be at the top of the hierarchy of the evidence [14]. A meta-analysis can also provide a pooled estimate across all the studies included in a systematic review.

Other Study Designs

The study designs discussed in this chapter are by no means meant to be an exhaustive list. Still, they include the most commonly referenced designs in the hierarchy of evidence in clinical decision making [4]. Other basic study designs discussed in later chapters that may also inform evidence-based healthcare include qualitative or survey-based studies, human-computer interaction or human factors research methods, as well as prediction models that use statistical methods versus machine learning- or artificial intelligence-based methods.

Grading the Quality of Evidence

Grading the Quality of Evidence and Strength of Recommendation

Medical literature continues to increase with numerous clinical trials and systematic reviews being published daily [15, 16]. Given the sheer volume of research production, a transparent, objective, and reliable methodology for grading the quality of evidence is needed to compare results across multiple studies and inform recommendations for clinical practice. Although many grading schemas have been proposed, the most widely utilized one is from the Grading of Recommendations Assessment and Evaluation (GRADE) working group [17]. In the GRADE approach, a research study is first assessed in terms of quality of evidence into four categories (high, moderate, low, and very low). Subsequently, the strength of recommendation (strong or weak) is determined based on balancing the quality of evidence and the following characteristics: uncertainty about the balance between desirable and undesirable effects, variability in values and preferences, and uncertainty about whether interventions represent a wise use of resources [17].

Clinical Guidelines

Clinical guidelines and closely related terms, including Clinical Practice Guidelines (CPGs) and position statements, have become ubiquitous in healthcare and are generated by more than 350 professional groups spanning thousands of guidelines for various clinical questions [18, 19]. The Institute of Medicine (IOM) defines *clinical practice guidelines* as "statements that include recommendations intended to optimize patient care that is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" [19].

Clinical guidelines can be generated by various stakeholders and professional societies, including independent volunteer panels of national experts such as the United States Preventive Services Task Force (USPSTF) [20], and national professional organizations representing specific conditions such as the American Cancer Society and even within specialties like the Eastern Association for the Surgery of Trauma and the Western Trauma Association which produce clinical guidelines for the care of trauma patients. Although there are ongoing efforts to standardize the processes of guideline development further, variability in the methodologies used in evidence synthesis, composition of the group making the recommendations, what (if any) recommendation is made in the setting of insufficient evidence, frequency and cadence of revisions or updates, and potential conflicts of interest have

led to concerns about the overall trustworthiness of clinical guidelines [18]. The issue of trustworthiness of clinical guidelines is critically important given their role in helping establish the standard of care, as well as downstream implications for reimbursement and determination of coverage by payers. Clinical guidelines are also instrumental in establishing and continually modifying clinical decision support tools (CDS) with the latest evidence base, which is covered in the following chapter. Thus, a foundational understanding of the nuances surrounding the development of clinical practice guidelines is critical for the clinical informaticist.

Quality Measurement

Quality measurement has been increasingly important in the shift to value-based care in the United States. While initially reported electronically through registries, most reporting is now generated via EHRs using digital or electronic clinical quality measures (eCQMs) [21]. eCQMs provide a way to deliver practical, patient-centered, and high-quality care based on evidence-based practice and are utilized by payers for reimbursement incentives. At times, there is some discordance between the latest evidence base and guidelines and what payers will reimburse for performance based on eCQMs. This discordance can confuse both clinicians and patients.

Evidence Sources

Primary Medical Literature

After clinical research has been peer-reviewed, its findings are typically ready for dissemination and sharing with the broader medical and scientific communities. Clinicians have multiple resources to access clinical research and retrieve new literature directly through medical journal print issues or online. However, searching the literature can be cumbersome, so centralized databases of primary medical literature such as PubMed are widely used. PubMed, which includes biomedical literature indexed in MEDLINE, is maintained by the National Library of Medicine [22]. Other commonly searched biomedical literature databases include Scopus and Web of Science.

Summarized Evidence

In addition to clinical practice guidelines and systematic reviews, other forms of evidence include summary reports generated by private institutions or non-profit organizations. The Agency for Healthcare Research and Quality (AHRQ) has established Evidence-Based Practice Centers (EPCs), which develop comprehensive reports on a wide range of medical conditions and treatments. These EPC reports are then used to aid public and private organizations with quality improvement efforts [23]. Additionally, multiple subscription-based services are available to aid clinicians at the point of care with easily accessible search functionalities for clinical questions like Up-To-Date [24]. Up-To-Date uses subject matter experts to review the evidence base and transform the information into summaries that guide clinicians on various topics. While this type of resource often includes pertinent citations to primary medical literature, these typically do not follow the rigorous systematic reviews performed by organizations like the Cochrane Collaboration or EPCs.

Electronic Health Records

Learning Health Systems generate and leverage data and information within health systems from electronic health records (EHR) to inform best practices [25, 26]. These data are a consequence of routine care delivery processes. Secondary use of EHR data is increasingly utilized for both research and to develop real-world evidence through care delivery [27, 28]. There are also efficiencies in using EHR data to create guidelines and to inform care as it reduces the life cycle of data generation to insights without having to conduct a clinical trial that can takes years to produce evidence that is incorporated into routine care [29].

Emerging Trends

The landscape for how the clinical evidence base is developed and disseminated has continually changed over time, but never as rapidly as seen during the COVID-19 pandemic. The COVID-19 pandemic has been an exemplar of the challenges and benefits of a rapid research cycle, publication, and dissemination. With the gap in knowledge related to the novel COVID-19 virus, we have seen numerous electronically available pre-print publications and preliminary results from research during the past year, which exposed several challenges related to the rapid generation and use of evidence [30]. While some of the early research findings have been replicated in further studies, other early results have revealed threats to the validity and safety of translating preliminary research findings into clinical practice with an expedited research dissemination process [15]. The potential risks of the application of evidence generated rapidly, where conclusions may change over time, have to be weighed carefully when there are novel use cases such as with COVID. In these cases where the evidence base may quickly evolve, it is important to systematically monitor the situation and make course corrections when necessary.

As the evidence base evolves, so does the measurement of the quality of care through electronic clinical quality measures or eCQMs [21]. It is more critical than ever to ensure that the weight and strength of evidence inform clinical practice guidelines and informatics solutions, and that clinical informaticians consider the potential limitations or gaps of research studies before applying their findings. Clinical informaticians are uniquely positioned to guide the development, interpretation, and transparency of CDS tools and their content while also ensuring the design and usability of such tools are appropriate for end-users and clinical workflows.

Increasingly researchers and health systems are utilizing artificial intelligence methods to generate new evidence on risk factors and prognosis for various patient sub-populations. For example, machine learning has been utilized to identify clusters of patients with clinical and comorbid patterns associated with an elevated risk of super-utilization in the year following elective surgery [31]. Moving forward, evidence generated by advanced computational methods such as machine learning and artificial intelligence will likely be incorporated into guideline development processes as these methods can be applied to extremely large EHR datasets across multiple institutions. However, current approaches have been shown to have biases that warrant caution [32, 33]. More information on artificial intelligence and analytical approaches like machine learning can be found in Chap. 16.

Summary

More than ever, it is critical to use high-quality evidence to inform health care decisions. Many study designs for research can be selected based on the research questions at hand and the advantages and disadvantages of each method. The findings of research studies can be further graded for quality and rigor and synthesized into systematic reviews and meta-analyses, which can inform clinical practice guidelines and the strength of clinical recommendations. Clinical informaticians should understand that evidence-based health care is essential to delivering high-quality and patient-centered care as well as the creation of learning health systems. Furthermore, evidence-based health care is critical to the design, development, and implementation of technologies and methods utilized in care delivery. As the availability of clinical research data increases and more efficient means to disseminate research findings evolve, so will the need to continually re-evaluate the evidence base that informs widely adopted practices and guidelines. Clinical informaticians must be prepared to adapt and lead efforts within health systems to assess new evidence and redesign processes and systems to apply knowledge to care delivery in order to maximize patient safety and outcomes.

Questions for Discussion

1. Describe the differences between cross-sectional and cohort study design.
2. Define the benefits of randomization in randomized clinical trials.
3. What are the strongest and weakest study designs in the hierarchy of evidence?
4. What is the Cochrane Collaborative? And how is their work used to guide evidence-based practice?
5. What are the methods to grade and assess the quality of evidence reported in clinical research?
6. Describe the Institute of Medicine standards for trustworthiness for the development of clinical practice guidelines.
7. How can learning health systems leverage EHR data to generate evidence compared to traditional clinical studies?

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Clinical Decision-Making

6

Stephen M. Downs

Learning Objectives

- Describe the basic concepts and main schools of probability.
- Use Bayes Theorem to update probabilities in the face of new evidence.
- Recognize potential biases and heuristics in probability estimation and decision making.
- Construct and analyze decision trees.
- Apply axioms of expected utility theory to quantify preferences in decision models.
- Assess trade-offs of cost and clinical outcomes using cost-effectiveness analysis.
- Identify advanced decision-modeling techniques used in CDSS.
- Explain the relationship between decision science and clinical informatics.
- Understand real-world contexts for clinical decision analysis and CDSS.

Practice Domains: Tasks, Knowledge, and Skills

The following core competencies are covered in this chapter:

- K026. Decision science (e.g. Bayes theorem, decision analysis, probability theory, utility and preference assessment, test characteristics, clinical decision support, shared decision making)

Case Vignette

You are working in the fast track (low acuity) of an urban primary care clinic. The next patient to be seen is a 34-year-old woman with a chief complaint of a sore throat. Before you enter the room, what is the probability that she has strep throat (streptococcal pharyngitis)? What questions and physical examination findings will you rely on to help narrow down the differential diagnosis? Are there any decision support tools that you could use to help you make the correct diagnosis?

Introduction

Decision-making under conditions of uncertainty is challenging. There may be many courses of action to follow, and the outcomes of those actions are not known with confidence. Although one action can lead to the most desirable result, there is a chance that it may go awry. Perhaps a safer, more middle-of-the-road approach would be better.

Consider the classic case of the patient with abdominal pain and one episode of vomiting. Her belly is moderately tender without significant rebound. Could she have appendicitis?

This is the nature of making decisions under uncertainty. Any time there are limited resources, different potential courses of action, uncertainty about what will follow the chosen action, and preferences over the potential outcomes, the benefits of formal decision-making techniques come into play.

Cognitive Aspects of Decision-Making

As a decision-making machine, the human brain is prone to errors. As recently as 1944, humans were thought of as rational agents whose thoughtful actions could explain the behavior of, for example, economic systems [1]. Decision modeling was considered descriptive of human behavior. However, by the 1960s, a growing body of psychological research showed that human decision-making could (and often did) deviate from the idealized model [2, 3]. Decision analysis moved a

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presumed description of decision-making to a normative prescription for how decisions should be made [4].

Probability: The Heart of Rational Decision Making

Probability estimation is a well-understood metric for representing uncertainty. But even this has been a relatively new notion in human history [5]. What is a probability? A **probability** is a number between zero and one representing the likelihood (or our belief) that something will happen or that a proposition is true. What is the probability a roll of two dice will come up with "snake eyes" (two ones)? What is the probability an infant with fever will have a urinary tract infection? What is the probability the president of the United States will walk into your office on his hands?

A probability of zero means *absolute* certainty that an event will not happen. A probability of one means *absolute* certainty that it will. All other probabilities are gradations in between. In mathematical terms, p(A) represents the probability of A. Probabilities have certain behaviors described as axioms. An **axiom** is a statement accepted as true for the purposes of developing and proving a theorem [6]. In addition to zero and one representing certainty, the axioms include that the probability of A *and* B is equal to the probability of A times the probability of B:

$$p(\text{A and B}) = p(\text{A}) \times p(\text{B}),$$

A and B are assumed to be *independent*, a notion discussed in the section under Bayes' rule. This notion is intuitive with respect to dice. If the probability of rolling a one on a single roll of one die is 1/6, then the probability of getting one's on both of two dice is 1/6 × 1/6 = 1/36.

Finally, the probability of A or B is the probability of A plus the probability of B:

$$p(\text{A or B}) = p(\text{A}) + p(\text{B}),$$

If A and B are mutually *exclusive*, meaning they can't occur at the same time. So, the probability of getting either a one or a two on the roll of a single die is the sum of the probabilities of getting each, 1/6 + 1/6 = 1/3.

There are several schools of **probability theory**. The three most common are classical, frequentist, and subjective [7].

Classical Probability Theory

The classical school refers to the early concepts of probability. These applied to games of chance and are fairly easily understood. For example, when flipping a coin, we easily understand that the probability of getting heads is 50%. If I roll a die, I interpret the chance of getting a six as one in six. A card chosen randomly from a deck of 52 cards has a one in 52 probability of being the ace of spades.

The reader would have come up with the same probabilities, or at least understand them as reasonable. But how? Few people have flipped a coin hundreds of times, carefully tracking the percentage of times the result was heads. And among those who have, a vanishingly small minority will have gotten exactly 50% heads. Yet, we understand the "true" probability of heads to be 50%. This is the classical interpretation of probability, which can be derived from understanding the underlying mechanisms. We know that the result of a coin flip can only be heads or tails (ignoring the extremely rare case where a coin may land balanced on its edge).

Moreover, we have no reason to believe that either outcome, heads or tails, is more likely than the other. Therefore, we divide our total belief in the result (100%) evenly between the two outcomes in the so-called "sample space." Heads get 50%, and tails get 50%. Likewise, if we believe a die, when rolled, is equally likely to land on any of its six sides, the probability of it landing on any given side is 1/6.

Thus, calculation of a classical probability requires no empirical data, as it is mostly analytical. Unlike frequentist probabilities (see below), it does not require infinite sets. **Classical probabilities** are objective (as we have seen) as long as there is consensus about the underlying mechanisms. However, they require knowledge of elementary events and are strongly model-bound.

Frequentist Probability Theory

Another school of probability, widely used in scientific disciplines, is the frequentist interpretation. The concept here is that the probability of a specific outcome of an experiment can be estimated by repeating the experiment N (a large number) times. The ratio of the number of times a specific outcome occurs (n) to the number of experiments performed (n/N) is an *estimate* of the probability of that outcome [8]. This conceptualization assumes the existence of some underlying "true" probability of the outcome. It posits that this true probability could be determined if we could conduct an infinite number of experiments. Since this is impossible, **frequentist probabilities** are estimates. This is why we are fond of notions like 95% confidence intervals and p-values to tell us how far we might be from the true value. Frequentist probability theory also gives rise to the "law of large numbers," the principle that the larger the number of trials, the more precise the probability estimation.

A frequentist probability requires historical data. It is empirical and cannot be derived from first principles. The frequentist school presumes a stable world because the underlying "true" probability is assumed not to change. It requires exact replication of the experiment and cannot be

applied to a unique event. Therefore, estimating the probability of success for the first manned trip to mars could not be done in a strictly frequentist way. The experiment cannot be repeated multiple times. Frequentist probabilities are never exact because infinite replication is not possible.

Subjectivist Probability Theory

The third school of probability is the subjectivist school. Subjectivist probabilities require neither data nor formal analysis, but the subjective probability school subsumes the other schools philosophically. Subjective probabilities are the most commonly estimated and used by far and are critical to the decision modeler. To illustrate a subjective probability, answer the following question: What is the probability that you will find the word "computer" on page 100 of this book. Don't look; just write down your probability, a single number. How did you choose your probability? You might have thought about the number of pages you have read so far in this book and the number of times you read the word "computer." That would be a frequentist approach. Or you might have thought I was going to "game" the system by making sure the word "computer" appears on page 100 (classical). Or you might have considered that this is a book about informatics, so most pages will mention a computer—something between classical and frequentist. **Subjective probabilities** are best thought of as a measure of belief. They may differ from person to person, but they can be applied to all conceivable uncertainties. They deny the possibility of objective probabilities. Instead, they simply represent what is going on "between your ears," a measure of your belief that the word "computer" is on page 100 [7].

Now, look at page 100. Did you find the word "computer?" So if your subjective probability was 10%, were you wrong? If it was 90%, were you wrong? No, because you were only expressing your degree of belief that "computer" was on page 100. The only way you could conceivably have been "wrong" would be if you had said the probability was zero or 100%. Now that you've looked at page 100, of course, your subjective probability has changed.

I emphasize subjective probabilities because they are the most commonly used and because their necessity is inescapable in clinical practice and formal decision modeling. Consider the physician who sees a patient with a sore throat. According to the Centor criteria [9, 10], the probability this patient has streptococcal pharyngitis can be estimated by adding points for the patient's age, signs and symptoms as follows:

- History of fever
- Tonsillar exudates
- Tender anterior cervical adenopathy
- Absence of cough
- Age <15 add 1 point
- Age >44 subtract 1 point

The probability of strep is estimated based on the score. A score of –1, 0, or 1 implies the probability of strep is <10%. If the score is 2 points, the probability of strep infection is 15%; if 3, 32%. If the score is 4 or 5, the probability is 56%. This is a purely frequentist probability estimation because it is based on the number of times strep was found in the throats of a sample of patients with different combinations of these findings. But if we learn that two other household members have had positive strep throat cultures or observe that the patient has a scarlatiniform rash—findings not included in the Centor criteria—we would certainly adjust our estimate upwards because our *belief* that the patient has strep would be increased. Now the probability is subjective. No patients or circumstances are identical to those in a randomized controlled trial or a formal observational study. So subjective adjustment of probabilities is the norm.

Subjective probability is equally indispensable in formal modeling simply because all probabilities must be represented in a formal model. There are rarely clinical studies that provide a robust and appropriate measurement of all needed probabilities.

Biases in Estimating Probability

Despite the necessity for subjective probability estimates, a large body of literature shows that humans are naturally prone to errors or biases in their probability estimates. Fortunately, there are techniques for improving one's skills at probability estimation.

The human mind uses various "tricks" to estimate probabilities. Kahneman and Tversky described the best known of these tricks in their seminal work [2, 3]. To illustrate, consider this well-known example:

Linda is 31 years old, single, outspoken, and very bright. She majored in philosophy. As a student, she was deeply concerned with discrimination and social justice issues and participated in antinuclear demonstrations. Please check off the most likely alternative:

❑ Linda is a bank teller.
❑ Linda is a bank teller and is active in the feminist movement.

In their study, Kahneman and Tversky found that 10% of respondents chose the first alternative and 90% chose the second, even though quick reflection will reveal that the population of bank tellers active in the feminist movement is a strict subset of all bank tellers. Therefore, Linda is at least as likely a bank teller as she is a bank teller and active in the feminist movement.

This cognitive error is known as the representativeness heuristic. A **heuristic** is a mental shortcut to solving a

problem, producing an approximate solution. The **representativeness heuristic** involves gauging the probability of an event based on how representative it seems to be of a class. In this case, a woman who was deeply concerned with issues of discrimination and social justice and participated in anti-nuclear demonstrations sounds like someone who would be active in the feminist movement. This representativeness apparently made 90% of respondents overlook the logic of the problem.

Similar problems occur with what Kahneman and Tversky call the **availability heuristic**. Like the representativeness heuristic, availability refers to estimating the likelihood of an event based on how easily it comes to mind. Although this works much of the time, it can lead one astray. For example, most people believe breast cancer is the number one killer of women because of this condition's massive press. While over ten times more women die each year from cardiovascular disease than breast cancer [11].

One variant of the availability heuristic is the **vividness effect**. This bias occurs because we tend to rate the probability of something based on how vividly it is described or, sometimes, how emotionally evocative it is. When this chapter was first written, according to surveys, Americans were nearly as worried about Ebola as they were about catching the flu. At that time, exactly one person in the US had died from Ebola—ever. *Every year*, between 3000 and 49,000 people die of influenza in the US alone. In most years, this is higher than the number who have *ever* died of Ebola *anywhere*. But we heard so much more about Ebola, sometimes in excruciating detail. It makes getting Ebola seem more real and, therefore, more likely.

Combining Probabilities: Bayes Theorem

Estimating probabilities is one thing, but the more common challenge in medical reasoning (and any other reasoning for that matter) is how to update probabilities given new evidence. Although we do it all the time (a patient suspected of having an infection has an elevated white blood count or a pedestrian judges the traffic volume before endeavoring to cross the street), we often do it badly. Test yourself.

Table 6.1 Classic 2-by-2 contingency table

		Truth (disease)		
		Positive	Negative	
Test	Positive	9	999	1008
	Negative	1	8991	8992
		10	9990	

The average patient has a one in one thousand chance of having a disease. A test for that disease has 90% sensitivity and 90% specificity (pretty good!). The test is positive. Now, what is the chance the patient has the disease? Write down your guess. In a test of Harvard medical students, most guessed it was in the neighborhood of 90% [12]. The probability is slightly less than 1%. The math required to avoid this potentially catastrophic miscalculation is surprisingly straightforward.

Let's begin with the classic 2-by-2 contingency table (Table 6.1).

The table depicts 10,000 hypothetical patients. In the columns, we see that one in one thousand, ten patients have the disease (truth), and 9990 do not. If the test is positive in 90% of those with the disease (the definition of sensitivity), then 9 of the ten patients with the disease will have a positive test result. Among the 9990 without disease, 90%, or 8991, will have a negative test (the definition of specificity). So now, if we look across the rows, we see that of all 1008 patients with a positive test, nine or about 0.9% have the disease. The rest are *false positives*. Of the 8992 patients who have a negative test, only one *false-negative* will have the disease.

Using a 2-by-2 table to make these calculations is a bit cumbersome. However, the calculations can be made in a closed-form equation. We use the term *prevalence* to refer to the probability of disease before the test is performed (also called the *prior probability*) and the term *positive predictive value* or *PPV* (also called *posterior probability*) to refer to the probability of disease after a positive test is observed. Note the *negative predictive value* or *NPV* is the *posterior probability of no disease* after observing a negative test. We can calculate the *PPV* as follows:

$$PPV = \frac{Prevalence \times Sensitivity}{Prevalence \times Sensitivity + \left(1 - Prevalence\right) \times \left(1 - Specificity\right)} \tag{6.1}$$

A more general form of this equation, using terminology introduced earlier in the chapter, is:

$$p\left(D|T\right) = \frac{p\left(D\right) \times p\left(T|D\right)}{p\left(D\right) \times p\left(T|D\right) + p\left(\neg D\right) \times p\left(T|\neg D\right)} \tag{6.2}$$

where $p(D)$ is the prior probability of disease, $p(T|D)$ is the probability of a positive test given disease (the *sensitivity*), $p(\neg D)$ is the probability of not having the disease (1-*prevalence*), and $p(T|\neg D)$ is the probability of a positive test given not disease (1-*specificity*).This is Bayes' formula,

attributed posthumously to Reverend Bayes in 1763 [12]. A more compact version of Bayes' formula can be derived by dividing formula (6.1) above by the equivalent formula for calculating the *negative predictive value* as follows:

$$\frac{PPV}{1-NPPV}=\frac{\left[\dfrac{Prevalence\times Sensitivity}{Prevalence\times Sensitivity+\left(1-Prevalence\right)\times\left(1-Specificity\right)}\right]}{\left[\dfrac{\left(1-Prevalence\right)\times\left(1-Specificity\right)}{Prevalence\times Sensitivity+\left(1-Prevalence\right)\times\left(1-Specificity\right)}\right]} \tag{6.3}$$

Formula (6.3) reduces to

$$\frac{PPV}{1-NPPV}=\frac{Prevalence}{1-Prevalence}\times\frac{Sensitivity}{1-Specificity}$$

The term $\frac{Prevalence}{1-Prevalence}$ is referred to as the *odds* of disease; it is the probability divided by one minus the probability. The term $\frac{Sensitivity}{1-Specificity}$ is known as the *positive likelihood ratio (LR⁺)*. The term $\frac{PPV}{1-NPPV}$ is the *posterior odds* of disease ($odds_{post}$). Thus, Bayes' formula can be expressed as

$$Odds_{post}=Odds_{prior}\times LR^{+}$$

The *posterior odds* following a negative test are calculated in the same way, using the *negative likelihood ratio (LR⁻)*, which is given by $\frac{1-Sensitivity}{Specificity}$.

This is known as the *odds ratio* form of Bayes' formula [13]. It can become relatively easy to use this formula to estimate posterior probabilities in one's head with practice. Let's revisit our earlier example of a patient with a one in one thousand chance of disease and a positive test with 90% *sensitivity* and 90% *specificity*. The *prior probability* of disease is one in a thousand, so the *odds* of disease is (1/1000)/(1 – 1/1000), which is very close to 1/1000. (For very low probabilities, the odds are approximately equal to the probability.) The *positive likelihood ratio* is the *sensitivity* divided by one minus *specificity* or .9/.1=9. The *posterior odds* are nine times 1/1000 or 9 in 1000. The *posterior probability* is the *odds/(1+odds)* or 0.009/(1+0.009), which is very close to 0.009, or 0.9%, as we saw with the 2-by-2 table above.

Table 6.2 Sample collection of likelihood ratios (LR) for a hypothetical decision support system. Each LR describes the relationship between evidence (symptoms, findings, test results) and a given diagnosis (see text)

Evidence	LR^{+}	LR^{-}
Symptom A	2.3	0.8
Exam Finding B	3.0	0.2
Test Result C	4.1	0.85
Test Result D	3.1	0.1

Bayes' formula's odds ratio invites an attractive algorithm for computing updated probabilities as new evidence is acquired. Because we can treat the posterior odds of disease following one test as the prior odds of disease for a subsequent test, we can string together likelihood ratios to calculate the posterior odds after an arbitrary number of bits of evidence have been evaluated. What's required is a *prior probability* of disease and a catalog of positive and negative *likelihood ratios* for the evidence to be considered (Table 6.2)

A diagnostic program could evaluate the likelihood of a diagnosis with a prevalence of 2% in a patient who has

$$Odds_{prior} := Prevalence/(1\text{-}Prevalence) = 0.02/0.98 = 0.0204$$

$$Odds_{post} := Odds_{prior}\times LR^{+}_{A}\times LR^{+}_{B}\times LR^{-}_{C} = 0.0204\times 2.3\times 3.0\times 0.85 = 0.12$$

symptom A, exam finding B, and negative test C, but for whom the results of test D are unknown as follows:

$$\text{PPV} := \text{Odds}_{\text{post}}/(1 + \text{Odds}_{\text{post}}) = 0.11, \text{ or } 11\%$$

With a sufficient knowledge base of LRs, such a diagnostic program could process an arbitrary number of findings, returning an updated probability each time. However, there is one critically important caveat. The relationship of each finding to the hypothesized diagnosis must be *conditionally independent* of the other findings. In other words, the probability of exam finding B, given the diagnosis, must not depend on the presence or absence of symptom A. This assumption is rarely precisely true. However, it is often close enough that the algorithm works. This approach has been successfully employed in several decision support systems [14–16].

So far, we have only considered Bayes' formula for the binary case in which two hypotheses are being considered, i.e., that the patient has the disease or the patient does not have the disease. The formula is much more general and can consider an arbitrary number of mutually exclusive and exhaustive hypotheses. The posterior probability of a given hypothesis, H_1, is given by the formula

$$p(H_1|E) = \frac{p(H_1) \times p(E|H_1)}{\sum_{i=1}^{N} p(H_i) \times p(E|H_i)}$$

The posterior probabilities for the other hypotheses H_2 through H_N are calculated in the same fashion. Although this formulation is not as compact as the odds ratio form, complex diagnostic problems can be addressed with an adequate knowledge base of conditional probabilities. Likelihood ratios can also be expanded to multiple levels of a test result (interval likelihood ratios) to account, for example, for how a 3+ leukocyte esterase test result increases the probability of urinary tract infection more than a 1+ result [17].

Decision Science

Decision analysis (DA) is a method for choosing a course of action under conditions of uncertainty. For the purposes of DA, a decision can be thought of as having three components

1. Two or more alternative courses of action,
2. Uncertainty about the outcomes of those courses of action, and
3. Preferences for the different outcomes that are possible.

A decision also involves an irreversible commitment of resources (no "do-overs").

DA provides a formalism for representing each of these components.

1. Courses of action (and their potential consequences) are represented in a decision model, often a decision tree as discussed below.
2. Uncertainty is represented with probabilities and Bayes' theorem, as we have discussed in the previous section.
3. Preferences are represented with utilities, a numeric quantification of an individual's relative preferences for different outcomes. These are discussed in the next section.

Decision Trees

A **decision tree** is a branching diagram representing courses of action that can be taken and the events that may happen as a result. Consider the following example. A 12-year-old patient presents to an emergency room with a mild fever and abdominal pain. She has vomited once. Based on a detailed history and physical examination, you have decided that there is a 30% chance she has appendicitis. You have decided on two possible courses of action. You can take her directly to surgery and remove her appendix. This surgery comes with a small risk of surgical death, about 1 in 10,000. Alternatively, you can observe her in an observation unit overnight. Let's make some simplifying assumptions. First, assume that if she *doesn't* have appendicitis, she has a self-limited viral infection, and if you observe her overnight, she will recover and go home.

On the other hand, if she *has* appendicitis and you choose to observe, there is a 35% chance that her appendix will rupture. In that case, she will require surgery, and the risk of surgical death is ten times higher. If her appendix does not rupture, she will still need surgery (because she has appendicitis), but the risk of death will not be higher.

Figure 6.1 shows a decision tree representing this situation. The tree consists of a series of nodes with branches coming out of them. It is read from left to right. There are three types of nodes; the square node on the left is a *decision node*. The branches coming from a decision node represent the choices under the decision maker's control, in this case, taking the patient to surgery or observing overnight. Each of these branches leads to a round *chance node*. Each branch coming from a chance node represents something that might or might not happen but over which the decision-maker has no direct control. The branches are associated with probabilities. In the case of the "Surgery" node, the chance of "Surgical Death" is 0.0001 (one in ten thousand). The chance of "Survive Surgery" is 0.9999. In statistical vernacular, chance nodes represent random variables, with the branches representing possible values in the outcome space. As such, the branches must be mutually exclusive and exhaustive, meaning the probabilities of the branches emanating from a given chance node must sum to 1.0.

The third type of node is a *terminal* or *value* node, shown along the right side of Fig. 6.1. These nodes hold numeric

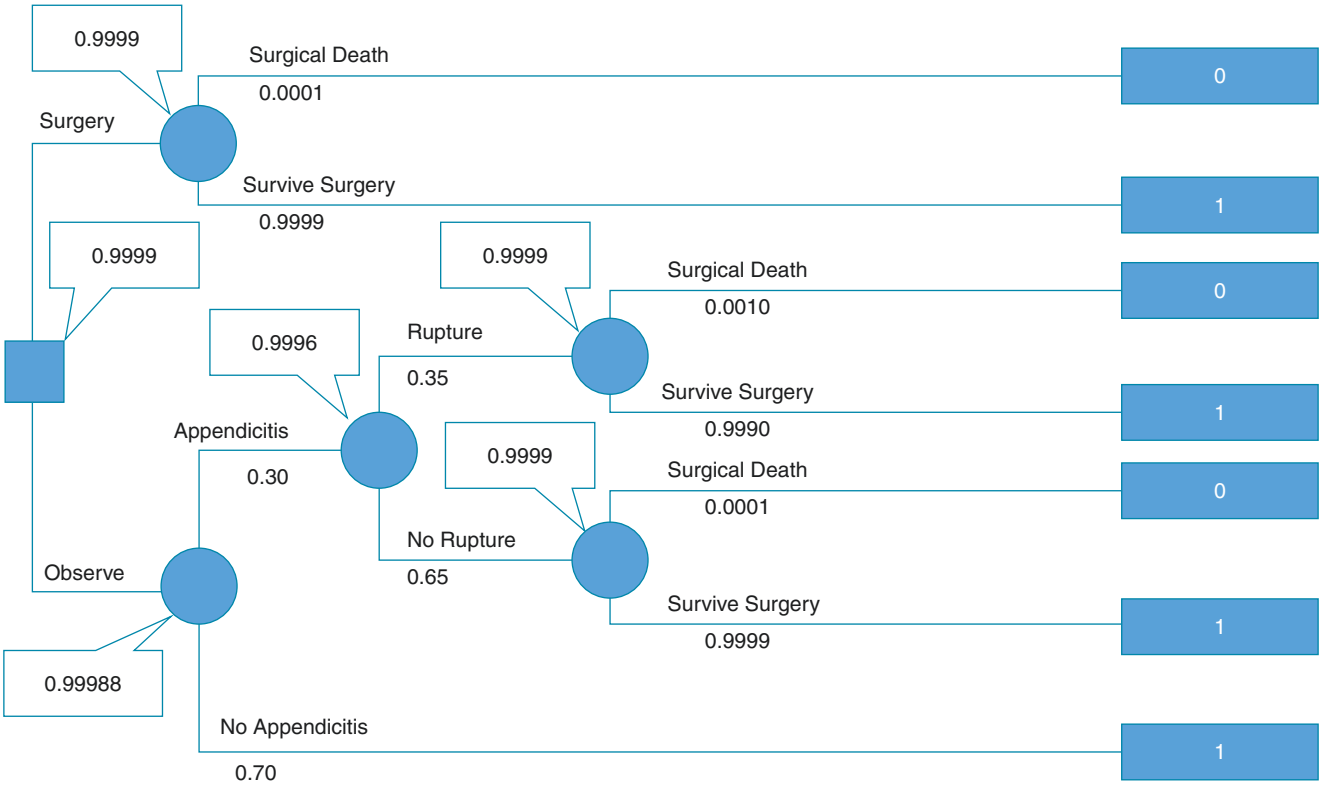

Fig. 6.1 The appendicitis decision tree. As described in the text, this decision tree illustrates the three main types of nodes in a decision tree: square decision nodes, round chance nodes, and terminal nodes at the end of each path

representations of the decision-maker's values on the outcomes at the end of the decision tree. This numeric representation is called a utility. For the moment, we will use the world's simplest utility measure, 1 for surviving and 0 for dying. The theoretical basis for assigning more precise values to outcomes is discussed in the section "Expected Utility Theory" below.

Following the tree from left to right, if the decision-maker decides on the surgery option, we have said there is a 9999 in 10,000 chance the patient will survive. If observation is chosen, there is a 30% chance the patient will have appendicitis. In that case, there is a 35% chance the appendix will rupture. If the appendix ruptures, there is a one in 1000 (0.001) chance of surgical death and a 999 in 1000 chance of surviving an appendectomy. If the appendix does not rupture, the chance of surgical death from an appendectomy is still 0.0001. Finally, if the patient does not have appendicitis, her symptoms resolve, and she goes home.

The decision tree is analyzed moving from right to left, using a recursive algorithm. If a node is a utility node, its value is its utility. If it is a chance node, its value is the expected value of its branches, that is, the sum across its branches of the product of the value of the branch times the probability of the branch. If the node is a decision node, its value becomes the value of whichever of its branches has the highest value—the decision that should be taken.

The values of the nodes in Fig. 6.1 are shown as bubbles pointing to the nodes. The expected value (EV) of the *Surgery* node is the value of dying times the probability of dying plus the value of surviving times the probability of surviving, $(1 \times 0.9999) + (0 \times 0.0001) = 0.9999$. The value of the *Rupture* node is $(1 \times 0.9990) + (0 \times 0.0010) = 0.9990$. The value of the *Appendicitis* node is $(0.35 \times 0.9990) + (0.65 \times 0.9999) = 0.9996$. Finally, the value of the *Observe* node is $(0.30 \times 0.9996) + (0.70 \times 1) = 0.99988$. Because the EV of *Observe* is lower than EV of *Surgery*, surgery is the preferred option.

The thoughtful reader will have some objections to this simple analysis. First, the difference in the EVs of the surgery and observation options seems trivially small, only two in 100,000. This decision seems like a "close call" that may change with minor changes in our estimates of probabilities and utilities. This is a legitimate complaint that we will address in the section "Sensitivity Analysis" below. A second concern might be that our utilities, 1 for survival and 0 for death, maybe overly simplistic. Surely, a patient would rather be observed overnight and go home than have a ruptured appendix and undergo emergent appendectomy and treatment for peritonitis. A more nuanced approach to quantifying preference is discussed in the section "Expected Utility Theory."

A third point might be that we have missed an alternative. Instead of choosing surgery or observation, perhaps we can perform a test that will help us decide. The option of using a diagnostic test is easily modeled with a third branch from the decision node, as shown in Fig. 6.2. We have modeled a test with 70% sensitivity and 80%

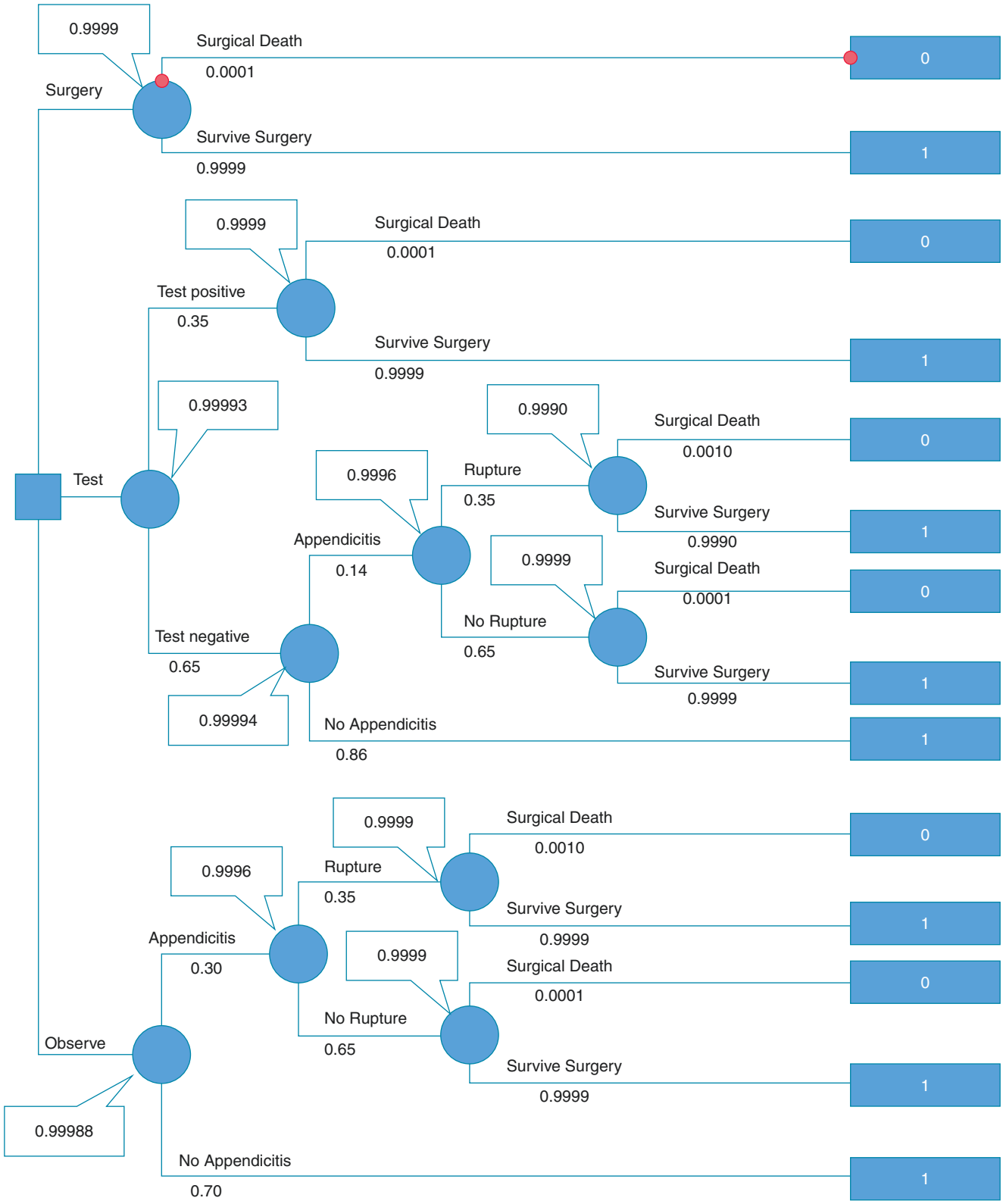

Fig. 6.2 The appendicitis decision tree with a "test" node. As described in the text, this version of the appendicitis decision tree includes the option of obtaining a test to decide how to treat the patient

specificity. Between the *Surgery* and *Observation* nodes, we have inserted a *Test* node. Under the assumption that we would take the patient to surgery if the test is positive and observe the patient if negative, the *Test Positive* branch has the same structure as the *Surgery* branch. The *Test Negative* branch has the same structure as the *Observe* branch, assuming that we will respond to a positive or negative test, respectively.

However, note that the probability of appendicitis given a negative test is now 14% instead of 30%. This 14% is calculated using Bayes' theorem, the probability of disease given a negative test or one minus the negative predictive value (see above). The probability of a positive test is given by $p(T^+|D) \times p(D) + p(T^+|\neg D) \times p(\neg D)$, the denominator of Bayes' theorem (Eq. 6.2 above).

We calculate the expected utility of the *Test* node in exactly the same way we did for the other two branches, getting a value of 0.99993, slightly higher than the EV of surgery. So the test option is the best. The difference in expected value between the best option without the test (surgery at 0.99990) and the expected value of testing (0.99993) is known as the *expected value of information* from the test.

But now let us consider another scenario, another patient with abdominal pain, but with higher fever, vomiting, and pain that is more typical for appendicitis, with migration to McBurney's point. Your subjective judgment is that the patient has a 50% chance of having appendicitis. When we evaluate the tree, the results are those in Fig. 6.3. Some find it surprising that the EV of testing has fallen below the EV of surgery. In other words, it is worse to obtain more information with the test than to just take the patient to the operating room. The test offers no *value of information* in this scenario.

To understand why this is so, consider the six probabilities that have changed, circled in Fig. 6.3. The probability of a positive test has gone up to 45%, and the probability of a negative test has gone down to 55%. More importantly, the probability of appendicitis given a negative test (the false-negative rate) has increased to 27%. In other words, if the test is negative (and we choose to observe), there is still a 27% chance the patient has appendicitis. Which decision is best depends on the prior probability of appendicitis.

Sensitivity Analysis

The exercise of varying a parameter in a decision model (like the prior probability of appendicitis) to see how it effects the decision is known as **sensitivity analysis**. Figure 6.4 shows a one-way sensitivity analysis of the probability of appendicitis. The x-axis shows the probability of appendicitis varied from 0 to 100%. The y-axis shows the expected value. Each line on the graph represents one of the three strategies—surgery, test, observe.

When the probability of appendicitis is low, *Observe* has the highest EV. As the probability of appendicitis goes up, the EV of *Observe* drops rapidly while the EV of S*urgery* stays the same (because the risks of surgery are the same regardless of the probability of appendicitis). The EV of *Test* drops more slowly as the probability of appendicitis rises. We see that at low probabilities, *Observe* is best. At high probabilities, *Surgery* is best. Only in the middle area does *Test* have the highest EV. The points where the lines cross are known as thresholds, and they represent points where the best decision changes. Figure 6.4 has dotted lines projecting the thresholds onto a "threshold bar" at the bottom [18]. This bar represents a decision rule suggesting which option is best given the estimated risk of appendicitis.

Expected Utility Theory

One objection to our appendicitis decision tree is the way the outcomes are valued. All outcomes resulting in survival were counted as 1, and those resulting in death were counted as 0. However, spending a night in observation with no surgery, is certainly better than surviving after having a ruptured appendix, requiring emergency surgery and resulting in peritonitis-although both result in survival. A more nuanced measure of preference is needed. That measure is known as a utility, and we describe the theory behind it here.

To develop the theory, let's consider a decision with a more quantifiable outcome, money. Imagine that you have the opportunity to play a game. In the game, a coin will be flipped. If the coin comes up heads, you will win $20. If it comes up tails, you win nothing. You have to pay to play this game. So there is a choice: pay to play or keep your money. Stop now and ask yourself what's the most you would pay to play this game. To help make this decision, you might calculate the EV of the game and compare it to the cost of playing. Assuming a "fair" coin, the EV of the game is 50% times $20 plus 50% times $0, or $10. If you are happy with this result, you should be willing to pay anything up to $10 to play the game because the EV of the game worth the same as $10 in your pocket. However, many years of experience (and research) have shown that the vast majority of people are unwilling to pay anything close to $10 for this game. How about you? This unwillingness to pay an amount for a gamble equal to the EV of the gamble has been termed risk aversion.

So perhaps the whole EV idea doesn't work. Nicolas Bernoulli came up with an even more dramatic example[19]. Imagine a game in which we will flip a coin. If it lands on heads, you win two dollars. If it lands on tails, the game

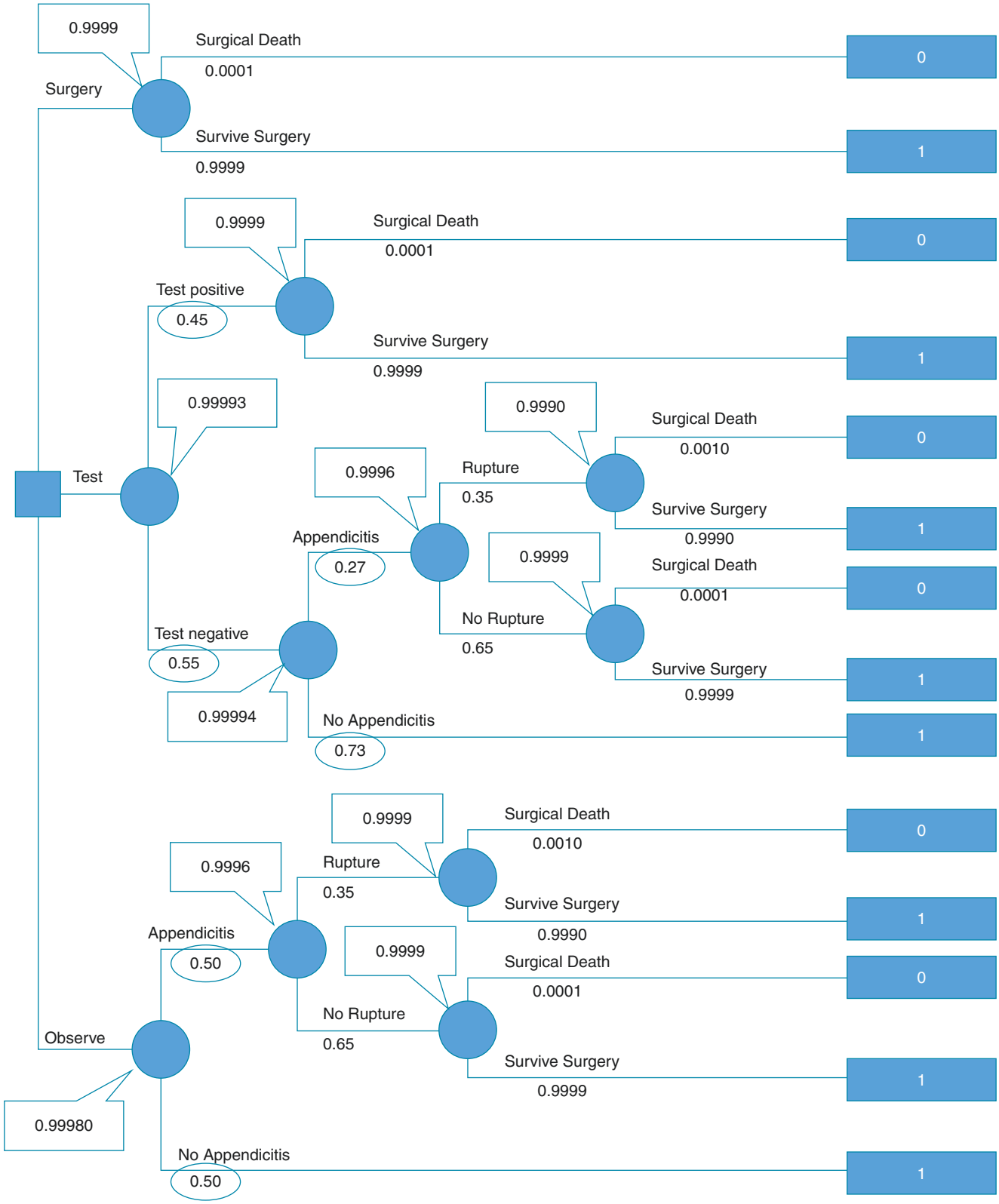

Fig. 6.3 The appendicitis decision tree with the prior probability of appendicitis increased to 50%, illustrating that which option is best changes as the parameters in the decision model change. The circled probabilities are those that change as the prior probability of appendicitis is increased

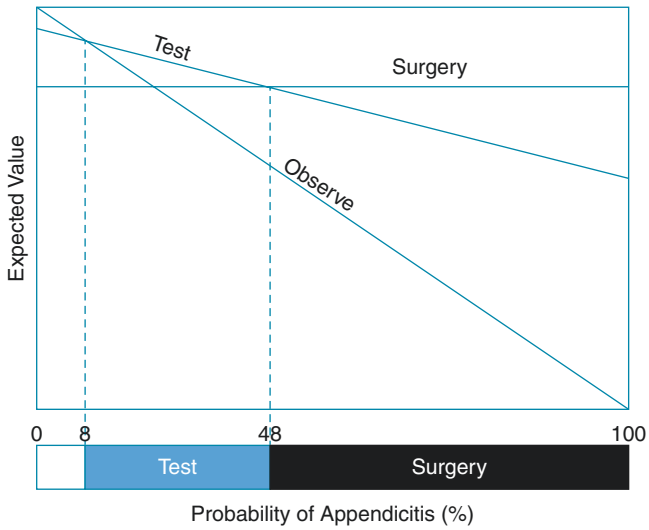

Fig. 6.4 One way sensitivity analysis of the prior probability of appendicitis. The x-axis shows the probability of appendicitis. The y-axis shows the expected value of each decision option as the probability increases. Points where the lines cross are known as thresholds

ends. Otherwise, we flip again. If you get a second heads, you win $4; a third, $8; a fourth, $16; and so forth, doubling each time you get heads but ending as soon as you get tails. How much would you pay to play that game? Most people would pay a few dollars at most, but the EV of this game is infinite because the infinite series, $\lim_{n\to\infty}\Sigma\left(\frac{1}{2^n}\right)\times 2^n$, is unbounded.

Nicolas Bernoulli appears to have contradicted EV as a basis for decision-making. However, his cousin, Daniel Bernoulli, proposed a solution, suggesting that the marginal benefit of each unit of money gained decreases as the person receiving it gains more and more. To paraphrase Bernoulli, a dollar surely means more to a pauper than to a rich man.

This idea implies that we need a new metric, a function on dollars that behaves the way we want it to behave—that is, its expected value is a basis for making a decision. Such a function is known as a **utility**. **Expected utility theory** was first formalized by von Neumann (a mathematician) and Morgenstern (an economist) in 1944 [1]. Starting with a set of axioms or postulates, they developed a formal proof that the expected value of their utility function should be the basis of rational choice. Raiffa and Howard have developed more intuitive versions of this proof [20]. What follows is adapted from Howard's axioms of expected utility theory.

The axioms of expected utility theory, as framed by Howard, are (1) orderability, (2) transitivity, (3) monotonicity, (4) decomposability, (5) continuity, and substitutability [21]. To illustrate how they lead to utility theory, imagine you have a condition called the *clinical epidemioma (CE)*. Left untreated, a CE is uniformly and rapidly fatal. Of course, CE is not a real disease; I have invented it for this illustration. There are three treatments available: (1) Tumorex, which results in a 10-year survival in the 50% of patients whose bodies absorb it; (2) GastroSorb, which is absorbed by all patients but is effective in 50% of tumors, resulting in 10-year survival; and (3) Mediocrin, a generic that results in 4-year survival for all patients who take it. In one arm of a randomized controlled trial, the combination of Tumorex and GastoSorb was tried. The combination was fatal in 20% of patients because of an enzyme in 40% of patients that renders GastroSorb toxic in the presence of Tumorex.

Figure 6.5 illustrates the choice of treatments in the CE in a decision tree.

At first glance, the combination seems like the obvious winner because it offers the highest life expectancy (5.5 years), but let's review the axioms of expected utility and see how they apply.

1. **Orderability** simply means that we are willing to order the outcomes in our decision problem according to preference. Two outcomes may be deemed equally desirable. In the CE example, we probably would prefer 10 years to 4 years to 0 years.
2. **Transitivity** says that if we like A better than B and B better than C, then we must like A better than C. A violation of this axiom can turn you into a "money pump" because, if it is not true, I can get you to pay me a small amount to take B in exchange for C, then a bit more to take A in exchange for B. But then I can get a bit more to take C in exchange for A and continue like this indefinitely.
3. **Monotonicity** means that, given two gambles with prizes A and B, if I like A better than B, I will prefer the gamble that gives me the higher probability of A–I want the gamble with the higher probability of the thing I like better.
4. **Decomposability** is also known as the "no fun in gambling" axiom. It states that all we care about is the probabilities of the outcomes, not how the sequence of events leads to them. For example, Tomorex is 50% absorbed but 100% effective, and GastroSorb is 100% absorbed but 50% effective. These are equivalent because both represent a 50% chance at the outcome, 10 years.
5. **Continuity and substitutability** states that for any three outcomes (for example, 0, 4, and 10 years), there exists some probability, p, at which the decision-maker is indifferent between a lottery with probability p of the best outcome and 1-p of the worst outcome and taking the intermediate outcome with certainty. In the case of the CE, given a choice between 4 years for sure and a gamble with a probability, p, of living 10 years and a probability, 1-p, of dying, there is some probability, p, at which the certainty and the lottery would have equal preference.

Let's consider just the Combination branch to show how these can be applied to the CE tree in Fig. 6.5. The

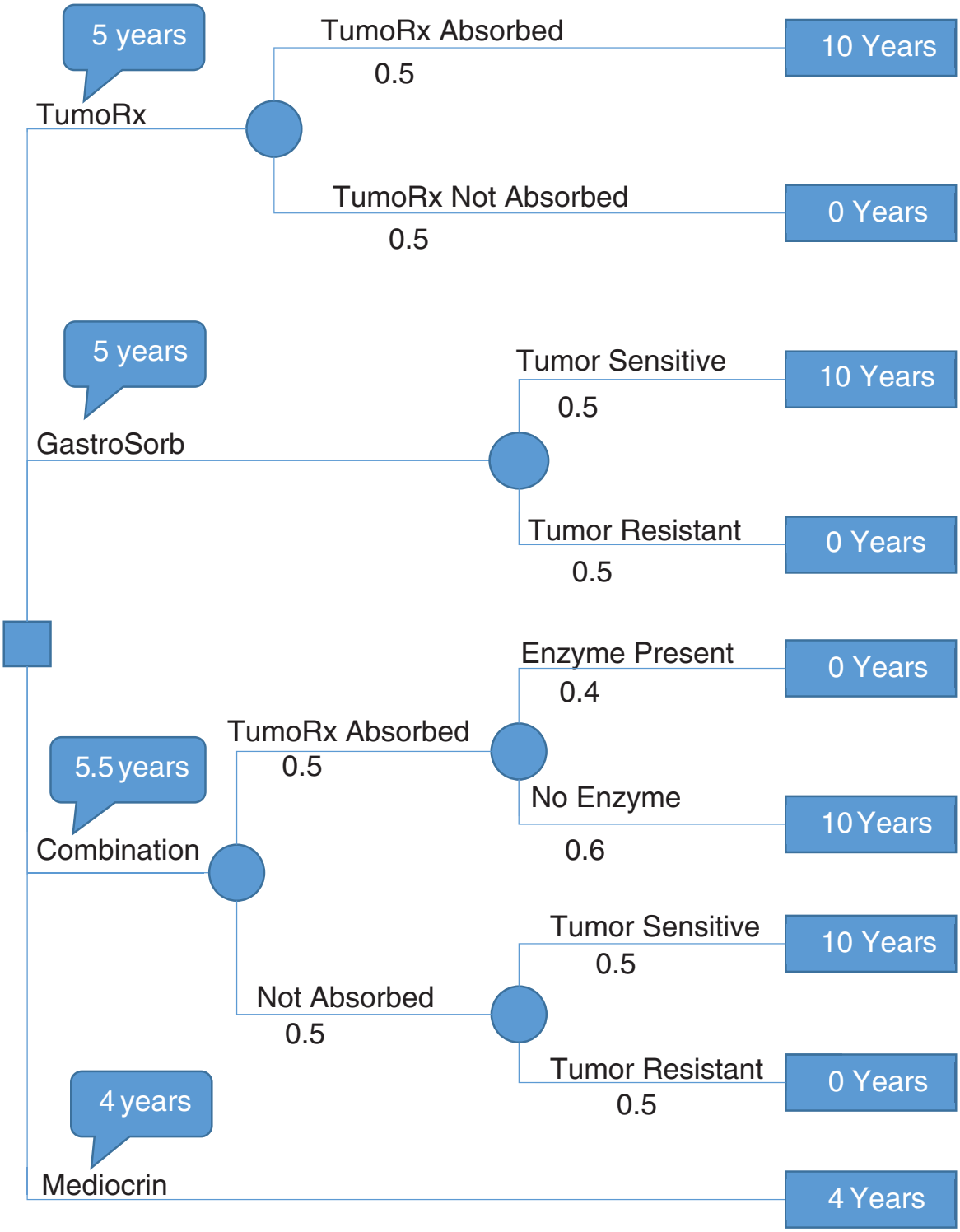

Fig. 6.5 Decision tree illustrating the choice of treatments for the *clinical epidemioma*. The combination treatment appears to offer the highest expected survival. However, application of the axioms of expected utility theory shows that this may not be the best choice (see text)

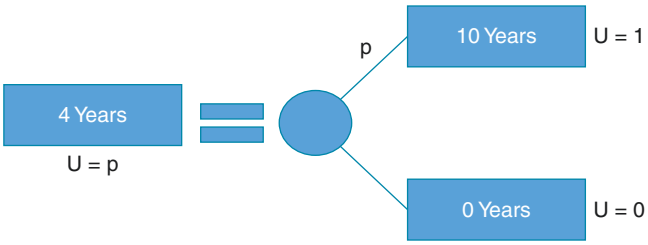

Fig. 6.6 The standard gamble. The relative utility values for outcomes in a decision analysis are calculated in threes. A forced choice is set up between a gamble, consisting of a probability, p, of the most preferred outcome and probability, 1-p, of the least preferred outcome, or a certainty of the intermediate outcome. The probabilities are adjusted until the decision maker is indifferent between the gamble and the certainty. At this point, the utility of the certainty is equal to the expected utility of the gamble. If the utility of the most preferred outcome is set to 1, and the utility of the least preferred set to 0, the utility of the certainty is equal to p

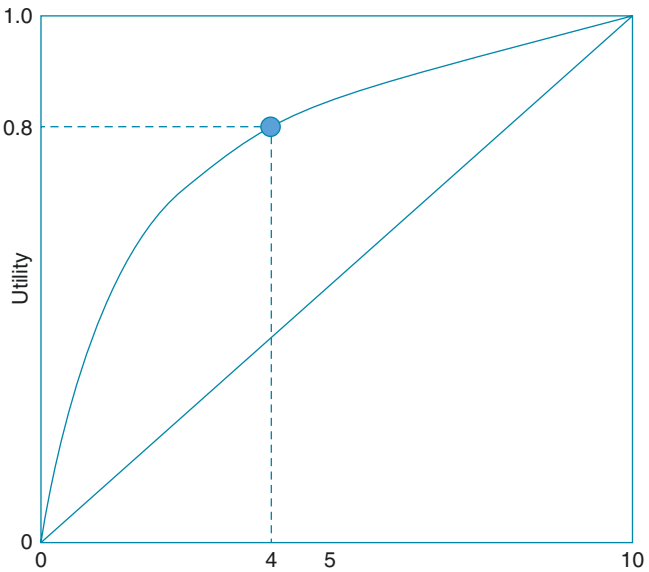

Fig. 6.7 Utility curve on years of life. The curve shows one decision maker's utilities on remaining years of life as a function of years of life. The figure highlights the that the utility of 4 years of life, U(4 years) is 0.8 on a scale where U(0 years) = 0 and U(10 years) = 1. The curve is bowed up and to the left (concave up), indicating the decision maker is risk averse

decomposability axiom says that multiplying and adding can change that branch to a single gamble with a 55% chance of 10 years and a 45% chance of 0 years without changing our preference for that option. The continuity and substitutability axiom says that, in the *Mediocrin* branch, we can replace the 4 years for sure with a gamble between 10 years at probability, p (where p is the indifference probability), and 0 years with probability 1-p without changing our preferences.

Comparing the *Combination* and *Mediocrin* branches, we compare two gambles with the outcomes 10 and 0 years. One offers 10 years with a probability of 55% and the other a probability p. So the preferred option depends on the indifference point, p. This is assessed using the standard gamble (or standard reference gamble described below).

The Standard Gamble

Von Neumann-Morgenstern (vNM) utilities are assessed with the **standard gamble**. This is simply a process for finding the indifference point. This is done by setting up a trade-off between a gamble with the best and worst outcomes and an intermediate outcome for certain, as illustrated below (Fig. 6.6). A series of forced-choice questions are asked as follows. A value between 0 and 1 is assigned to p (e.g., 50%), and the respondent (decision maker) is asked whether she would prefer a gamble with a 50% chance of 10 years (the best outcome) and a 50% chance of 0 years (the worst outcome), or if she would rather have 4 years for sure, referred to as the certain equivalent. If she says she would prefer 4 years for sure, p is adjusted upward, perhaps to 75%. Then the respondent is asked whether she would prefer a gamble with a 75% chance of 10 years and a 25% chance of 0 year, or if she would rather have 4 years for sure.

The probability, p, is adjusted in this way until p has a value at which the respondent cannot choose between the alternatives. For the standard gamble in Fig. 6.6, a common indifference point is at about p = 80%. For convenience, we arbitrarily set the utility of the best outcome in a decision to 1 and the utility of the worst outcome to 0. Thus, at the indifference point, the value of the intermediate outcome is the expected utility of the gamble or p. If the respondent were indifferent at an 80% probability of 10 years (and a 20% risk of death), the utility of 4 years (the certain equivalent) would be 0.8.

This process can be repeated for all of the outcomes in a decision tree with preference weightings between the best and the worst. And the proof put forth by von Neumann and Morgenstern means that the expected utility is an appropriate basis for choosing alternatives. If these utility values are plotted as a function of the outcomes, the result is typically a curve, as shown in Fig. 6.7. This curve, said to be concave up, is typical of risk aversion. It is consistent with Daniel Bernoulli's proposal that the marginal gain of each unit of outcome goes down as the total number of units goes up.

Most individuals will be risk-averse under most circumstances, but there are risk-seeking individuals and situations in which individuals will exhibit both risk-seeking and risk-averse preferences [2, 3].

Time Trade-Off

By virtue of arising from vNM expected utility theory, the standard gamble is generally considered the gold standard for utility assessment. However, because it can pose a

cognitive burden, other methods have been developed. The most important of these is the **time trade-off** (TTO) [22]. The TTO is most suitable for assessing utilities for time spent in a chronic health state. In the TTO, the respondent (decision maker) is presented with his remaining life in a chronic, less than ideal health state. For example, living with total blindness for 20 years (followed by death). He is then asked how many of those 20 years he would give up to have his vision back. This can, and often is, posed as a series of forced-choice responses. For example, would you give up 10 of those years to have your vision back? This would be repeated, adjusting the number of years in good health until an indifference point is reached, much as is done with the standard gamble.

So if the respondent is indifferent between living 20 years with blindness and living only 15 years with vision, his utility for blindness is calculated as the number of years with vision divided by the number of years with blindness, 15/20 = 0.75. Utilities derived from the TTO can be shown to be consistent with those derived by standard gamble under the assumption that the respondent is risk-neutral, something that we've said is rarely true [23]. Additionally, the TTO assumes a constant proportional tradeoff, meaning that if the trade-off were based on 10 years in a health state or 30 years in a health state, the response would yield the same ratio of ¾ described above.

Quality Adjusted Life Years

Over the last two decades, quality-adjusted life years (QALY) has become the most widely accepted utility model in medicine [24]. QALY is a multi-attribute utility model, meaning that it takes separate measures of health outcomes and combines them to form one utility measure [25]. One dimension of the QALY is the length of life measured in years. The second dimension is the quality of life during those years. Typically, but not always, the quality term is a utility, often assessed with the TTO method. Other utilities for quality adjustment can come from standardized utility indices such as the Health Utilities Index (HUI) or the EQ-5D, EuroQual [26, 27]. Utilities used to adjust QALYs must be anchored at zero for death and 1.0 for perfect health. The basic formula for a QALY is the length of life multiplied by one or more quality adjustments.

Because QALYs are normalized to 1 QALY for a year in perfect health and zero QALYs for death, QALYs for time spent in different health states can be added together to total the QALYs over changing health states even for an entire lifetime. This is especially useful for Markov models and simulations, as described below.

Cost-Effectiveness and Cost-Utility Analysis

The concept of **cost-effectiveness analysis** arises because it can be helpful to consider costs and health outcomes of a decision problem separately. As we have seen, it is possible to measure utilities for monetary outcomes and clinical outcomes. Moreover, vNM utilities can be assessed over global outcomes that include both health and monetary components. However, when different parties (e.g., government or insurance companies) are paying for health outcomes experienced by others, it can be helpful to consider cost and health outcomes separately.

This is done easily enough by assigning both a health outcome and a monetary outcome to each terminal node of a decision tree and solving the tree twice, once for each of the outcomes. The general term for this is a cost-effectiveness analysis (CEA). When the health outcome is a utility, we use the more specific term, cost-utility analysis. To illustrate, below (Fig. 6.8) is a tree for evaluating a hypothetical vaccine. The tree shows two options: provide the vaccine or don't. The tree models a probability of infection, p(inf), for the *No Vaccine* branch. The probability of infection for the *Vaccine* branch is reduced by multiplying p(inf) times one minus the vaccine's effectiveness. The terminal nodes show two values separated by a "/". The first is the cost accumulated along the path leading to the node, e.g., the cost of the vaccine + infection + hospitalization. The second is the utility, in QALYs, for that outcome. (The probabilities are not shown.)

The average or expected cost and QALYs for each alternative are shown in the corresponding bubble. The vaccine strategy costs more ($28 vs. $16) but results in a greater number of QALYs (29.98 vs. 29.97). These differences are typically examined using a marginal or incremental cost-effectiveness table, as shown in Table 6.3.

To construct Table 6.3, the strategies are listed in the first column in increasing order of cost. The average (expected) cost of each strategy is entered in the second column. The third column is the incremental cost, the difference between the cost of each strategy and the next cheapest strategy (the one above it). The average effect is entered next, followed by the incremental effect, the difference in effect between each strategy and the strategy above it. An average cost-effectiveness ratio, the ratio of the average cost to the average effect, is next. It is important to know that this number has very little meaning in isolation. *CEA must always be done in comparison between two or more competing strategies*. The last column is the incremental cost-effectiveness ratio (ICER). This is the ratio of the incremental cost divided by the incremental effect.

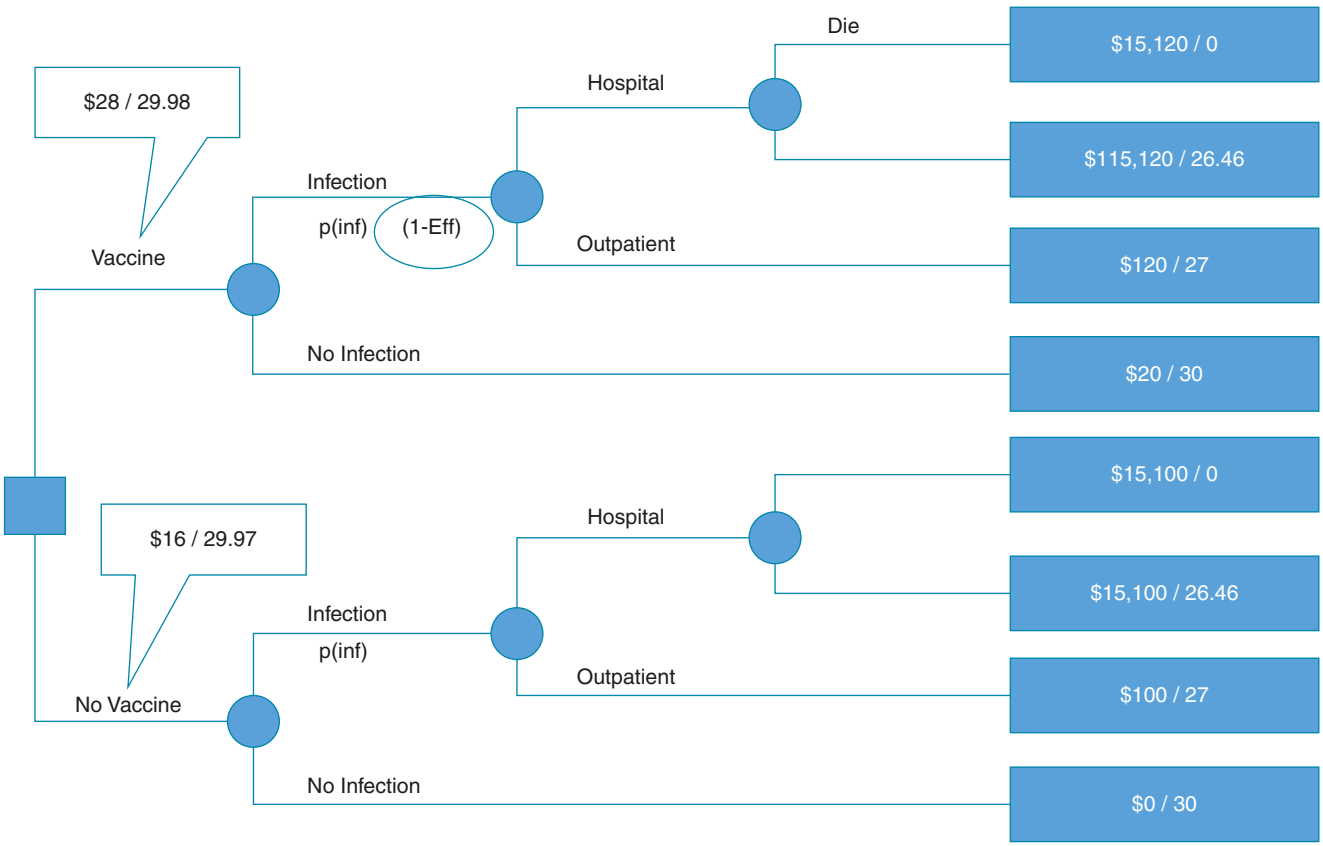

Fig. 6.8 A decision tree for conducting a cost-effectiveness analysis. The terminal nodes show a value and a cost term. The tree is solved once, calculating the expected value of each option, and a second time, calculating the expected cost of each option. The difference in cost between two options divided by the difference in value is the incremental cost-effectiveness (see Table 6.3)

Table 6.3 Table showing the calculation of incremental cost-effectiveness. The options are listed in ascending order of cost. The difference in cost and the difference in effect between the sequential options is entered. The incremental cost-effectiveness ratio is the ratio between the difference in cost and the difference in effect

Strategy	Average cost	Incremental cost	Average effect (QALY)	Incremental effect (QALY)	Cost/ effect	Incremental cost effectiveness ratio (ICER)
No vaccine	$16		29.9668		$1	
Vaccine	$28	$12	29.9834	0.0166	$1	$723

In this case, the ICER is $723. That is, the *Vaccine* strategy will cost $723 for each QALY saved. This is a very favorable ratio. Interventions with an ICER of $50,000–$100,000 per QALY are often considered cost-effective. ICERs are especially useful for comparing alternative health interventions to achieve the most efficient use of healthcare dollars [28].

Calculating Costs

We've discussed the assessment or calculation of utilities. There are some caveats to calculating costs. The first is to understand that healthcare charges rarely reflect costs. Charges are driven more by market forces than actual costs to the system. To make matters worse, healthcare systems may shift costs from one segment of care to another. Payments by government or private insurers may be closer to costs but are largely driven by negotiations between payers and providers. Payments may be appropriate measures of cost if the analysis is being done from the payer's perspective.

But perspective is all-important. Different costs and outcomes are important to payers, providers, and patients. It has been recommended that cost-utility analysis be done from a "societal perspective," accounting for all costs and health

outcomes. Still, it must be acknowledged that no one has a societal perspective [24].

It may be that the best way to calculate costs is with a cost accounting approach, which considers each of the resources that goes into delivering care as well as other costs (e.g., travel or lost work) that may be induced by an intervention or disease process.

Advanced Decision Modeling

Up to this point, we have only considered decision trees to model decision problems. However, two additional modeling approaches deserve attention, especially because modern computer technology makes them useful for computer-based decision support systems. These techniques are Markov models and influence diagrams.

Markov Models

In DA, Markov models are often used to model health states that change over time. Consider, for example, a decision regarding the choice of therapies for cancer. Following the therapy, 90% of patients enter remission and may follow any of a wide number of pathways subsequently. Each year, the patient may remain in remission or may experience a recurrence. If there is no recurrence in the first year, there may be one in the second or the third year, etc. If a recurrence does occur, it may lead to death in the first year, or the patient may spend two or more years in a chronic recurrent cancer state. To try to model all of these possible outcomes in a decision tree would be untenable.

Markov models provide a more compact method for evaluating such models. Figure 6.9 shows a simple Markov model representing this situation. Each node in the model (Well, Cancer, Dead) represents a health state. The arrows show transitions that can happen with each Markov cycle. Each transition is associated with a probability that the transition will happen in a given cycle. Each health state has an associate utility, representing the quality adjustment for the time spent in that health state.

In most computer models of Markov chains like this, it is possible to represent transition probabilities with formulas or lookup tables to make the models more dynamic.

To analyze a Markov model, we simply distribute a hypothetical cohort of patients into each of the health states and begin to simulate what happens. Table 6.4 shows how utilities, in the form of QALYs, accumulate with the first two cycles of the model.

At the initiation of the cycle, we determined that 90% of patients were in remission (the well state), and 10% had resid-

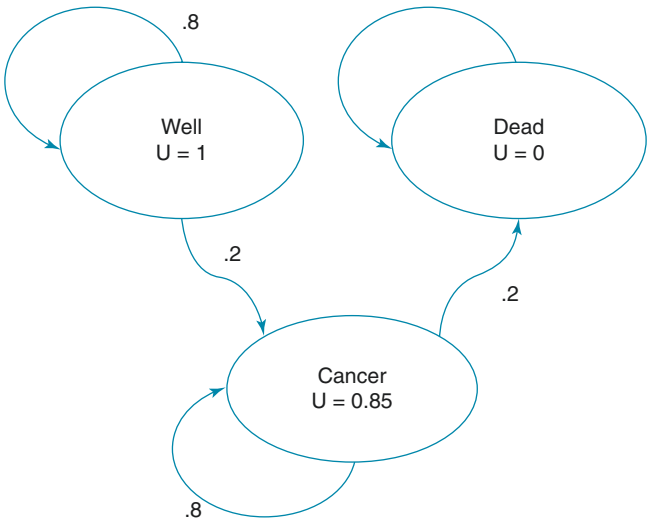

Fig. 6.9 A simple Markov model. The Markov model shows three health states, *well, cancer,* and *dead*. Arcs (arrows) between the health states represent the probability of transitioning from one health state to the next during a *Markov cycle* (for example, a year). Utility is accumulated for each cycle (see Table 6.4)

ual cancer. So in cycle 1, patients in the *Well* state each got a utility of 1. So they accrued 0.9 QALY. The 10% in the *Cancer* state had a utility of 0.85, accruing 0.085 QALY. So at the end of cycle 1, the model accumulated a total of 0.99 QALY.

In cycle 2, 80% of the patients in the *Well* state during cycle 1 remain there in cycle 2, meaning 72% are in the *Well* state for cycle 2. They have a quality adjustment of 1, so they accrue 0.72 QALY. The *Cancer* state acquired 20% of those in the *Well* state in cycle 1 and retained 80% of those in the *Cancer* state in cycle 1 for a total of 0.26 of the cohort. Their quality adjustment is 0.85 so they accrue $0.26 \times 0.85 = 0.22$ QALY. The *Dead* state acquired 20% of those in the *Cancer* state in cycle 1, but since the quality adjustment is 0, they accumulate no QALYs.

So during cycle 2, the health states accumulate a total of $0.72 + 0.22 = 0.94$ QALY. This is added to the 0.99 QALY accrued in cycle 1 to make 1.9 QALYs accumulated by the whole cohort at the end of the second cycle. This process is repeated for as many cycles as we want to model the process or until the entire cohort is in the *Dead* state and can no longer accumulate QALYs.

Influence Diagrams

An influence diagram alternative to a decision tree emphasizes the probabilistic relationships among variables [29, 30]. An influence diagram is an acyclic directed graph with three types of nodes (much like trees): decision nodes, chance nodes, and one value node. Figure 6.10 illustrates a rather generic

Table 6.4 Showing the accumulation of expected utilities (as quality adjusted life years) during two cycles of a Markov model. During each cycle, the probability of being in a state is multiplied by the utility of a cycle in that state. These are summed across states to calculate the expected utility for the cycle. This is repeated for subsequent cycles, accumulating the total expected utility for the whole simulation

Cycle	State	Probability	Expected utility	Cumulative utility
1	Well	.9	.9 × 1 = .9	
	Cancer	.1	.1 × .85 = .085	
	Dead	0	0	.99
2	Well	.9 × .8 = .72	.72 × 1 = .72	
	Cancer	(.9 × .2) + (.1 × .8) = .26	.26 × .85 = .22	
	Dead	.1 × .2 = .02	.02 × 0 = 0	.94 + .99 – 1.9

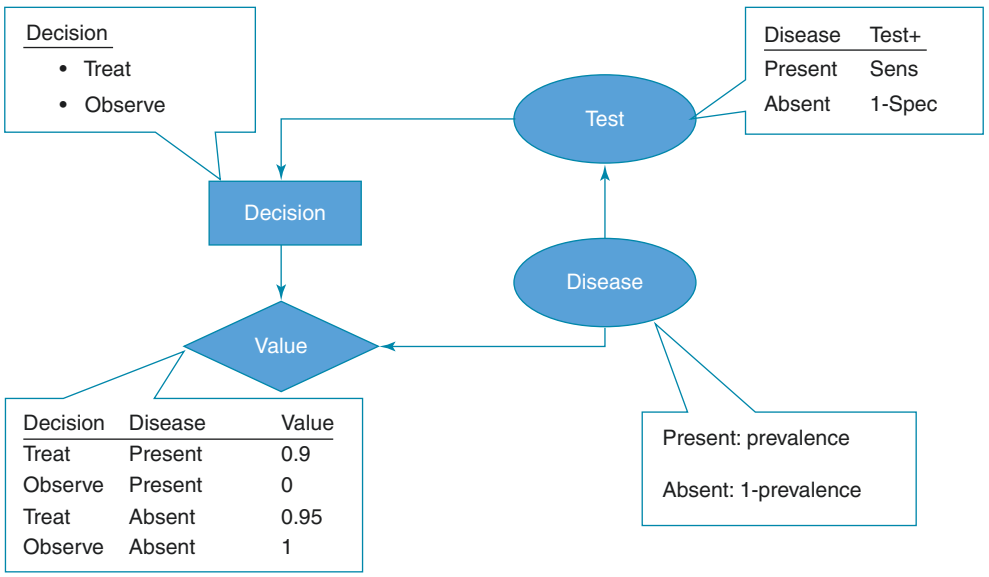

Fig. 6.10 A simple influence diagram. The diagram shows the three types of nodes found in an influence diagram: round *chance nodes*, a square *decision node*, and a diamond *value node*. The contents of each node are shown. An influence diagram with only chance nodes is known as a Bayesian belief network (or belief net)

influence diagram. It represents the decision to treat or observe given a test result and a prior probability of disease.

The round chance nodes represent random variables and store the probability distributions. The decision nodes store potential actions. The value node stores utilities for different possible states of the diagram. Arrows (also called arcs or edges) entering a decision node represent information available when the decision is made. In this case, the test result will be known before a treatment decision is made. Arcs going into a chance node represent variables on which the probabilities will be conditioned. The probability of a positive test result depends on whether the disease is present or not. Arcs going into the value node represent the variables that will affect the value of the diagram. In this model, the combination of the decision to treat or observe combined with the presence or absence of disease determines the value. The bubbles in Fig. 6.10 show the contents of each of the nodes.

Influence diagrams are useful for modeling complex relationships among random variables, often without decision or value nodes. An influence diagram composed of only chance nodes is also referred to as a Bayesian belief network (Bayes net or belief network). They are often used to make inferences on complex data, sometimes with hundreds of nodes. Inference engines that use Bayesian belief networks have been used to detect credit card fraud to complex diagnostic decision support [31, 32]. Bayesian networks in which the directed arcs have a strictly causal meaning are used in causal statistical analyses [33, 34].

One of the most recent applications of influence diagrams has been as a data structure for mobilizing computable biomedical knowledge to share decision support between sites in an executable format [35]. In this context, a decision model can represent a rule that determines what action to take under what circumstances. However, when the "rule" is represented as a full decision model, the various

parameters—probabilities and utilities—used to create the rule can be adjusted to local circumstances. So the "rule" can be tailored to the individual location.

Shared Decision Making

DA in the clinical setting was classically applied to a physician and patient facing a clinical decision where the outcomes are uncertain and high stakes [36]. However, it is rarely practical to complete a formal DA in the context of clinical care. It simply takes too much time and too many resources. For this reason, DA and CEA are generally used to guide practice in general or establish policy.

However, there is a clear need to address the components of a decision analysis at the bedside. This need has led to the emergence of **shared decision-making** (SDM) strategies [37]. SDM has become increasingly important as more clinical interventions emerge that are preference-sensitive [38]. The US Preventive Services Task Force has devoted a category of recommendation ("C recommendations") entirely for "selectively offering or providing this service to individual patients based on professional judgment and patient preferences" [39].

Most clinicians are familiar with shared decision-making in an informal sense, discussing the medical decision with a patient, providing an opportunity for the patient to ask questions and contribute to the decision. However, formal SDM is a more precise and nuanced process. SDM, sometimes called informed medical decision making, should meet three key requirements:

1. The patient is made aware of his or her options
2. The patient understands the likelihood of the important outcomes resulting from each option
3. The patient undergoes "values clarification," some exercise in which s/he expresses preferences over the outcomes

As a check, formal SDM may include a step in which the patient's final decision is evaluated as consistent or inconsistent with his or her expressed values. The elements of shared decision-making clearly correspond to the elements of DA, but the assessments and analyses are less quantitative.

SDM lends itself well to automation. There are large repositories of automated SDM tools, for example, at the Ottawa Hospital Research Institute [40], to which patients can be directed when they face one of these preference-sensitive decisions. Furthermore, there is a growing body of evidence that decision aids that automate SDM improve the quality of medical decision-making [41, 42]. Given the clear value-added from SDM, one might expect it to be incorporated broadly in EHRs [43]. However, to date, this has rarely been done [44].

Decision Support Prioritization

A more novel application of DA techniques to medical informatics and decision support is the prioritization of care recommendations for individual patients. This has been especially fruitful in the prioritization of preventive services. It was long ago well established that the number of preventive services recommended by authoritative bodies exceeds what can be done in a typical visit [45, 46]. Moreover, physicians are likely to spend precious clinical time on services with less value [47].

One strategy proposed to address this problem is to use decision-analytic algorithms to determine which preventive services offer the greatest expected value for the patient and prioritize decision support based on that calculation. Such a calculation would consider the likelihood the patient needs the relevant issue (prior probability), the seriousness of the issue (disutility), and the effectiveness of providing decision support to address it [48]. This approach has been demonstrated in both pediatric and adult settings [49–51]. By prioritizing decision support based on expected value, this approach can reduce alert fatigue while providing the most important decision support.

The Role of Decision Sciences in Clinical Informatics

Medicine is an information-intensive business rife with uncertainty, and humans are flawed data processors and decision-makers vulnerable to bias. Because computers can flawlessly and tirelessly process vast amounts of data, they have the potential, if used correctly, to compensate for these human frailties. But computers are only as correct as their programming. So a strong theoretical grounding for decision-making and decision support is indispensable.

Well-designed and well-executed decision models can form the basis of strong guidelines that you will want to be encoded in your systems. Models of complex Bayesian inference can help guide computer-based clinical decision support or represent decision rules in a format that can be readily adapted to new settings. DA approaches can also prioritize which decision support is provided, avoiding alert fatigue. Even day-to-day decision-making about IT purchases, investments, and distributions can be informed by more careful analysis of decisions made under uncertainty.

Future Directions

The relationship between decision analysis, guideline development, decision support, and quality measurement is growing continuously closer. There is a growing emphasis on

using EHRs and decision support to improve guideline adherence and measure the quality of care through quality indicators. Formal decision sciences techniques can improve every step in these processes.

Chapter Summary

In the clinical setting, you will often face difficult challenges that do not present clear, singular solutions. Maybe the 34-year-old woman has strep throat, or maybe she has seasonal allergies, or something much less common. Knowing the probability of each of these options is vital to effective treatment. Decision trees, expected utility theory, and other DA tools will help guide your decision-making process when deciding on the best course of action for each of your patients. More and more, these theories and models are adopted by technology to create computerized clinical decision support systems. Because a computer can process much more information at a much faster speed than one physician, CDSS can be invaluable in providing an efficient and effective medical practice.

Questions for Discussion

1. A healthy 56-year-old patient presents with influenza-like illness (ILI). How could you apply Bayes Theorem to update the probability of the patient having COVID-19 versus another ILI as you gather evidence?
2. Under what circumstances could a computer make a reliable diagnosis by applying Bayesian algorithms? Would a system be acceptable to patients? Physicians? Payors?
3. Think about a time in the past when your own potential biases or heuristics in probability estimation influenced your decision-making. Did they help you make a correct diagnosis or prevent you from making the right diagnosis?
4. A new CMO at the medical center suggested that primary care clinicians should begin applying formal decision analysis when treating patients to enhance shared decision-making (SDM). As the CMIO, would you support this recommendation? Why or why not?
5. A hospital board member pulls you to the side after your presentation on a new CDS system that uses Markov chains. He says that he believes Markov chains are based on utilitarianism, which he views as un-American. He also expresses concerns about potential Russian influence on the hospital's information system. How might you politely set him straight about the use of Markov models in the CDS system to support rationale decision-making by clinicians?

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Clinical Decision Support: It's More than Just Alerts

7

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Learning Objectives
At the end of the chapter, the reader should be able to:

- Define Clinical Decision Support (CDS) and Clinical Decision Support System (CDSS)
- Compare and contrast the different types of decision support
  - Alerts
  - Reminders
  - Corollary Orders
  - Guidelines
  - CPR
- Identify the components of a CDSS
- Explain the challenges of implementing effective CDS and barriers to effective CDS

Practice Domains: Tasks, Knowledge and Skills
Domain 2: Improving care delivery and outcomes

Tasks

- 2.01. Develop, implement, evaluate, monitor, and maintain clinical decision support (CDS), in alignment with the Five Rights of CDS (information, person, intervention formats, channel, and point/time in workflow).

Knowledge and skills

- K027. Clinical decision support standards and processes for development, implementation, evaluation, and maintenance
- K028. Five Rights of clinical decision support (i.e., information, person, intervention formats, channel, and point/time in workflow)
- K029. Legal, regulatory, and ethical issues regarding clinical decision support

Case Vignette
You are the Ambulatory Associate CMIO of a large academic hospital. You are tasked with creating a structure and system to understand the current state of clinical decision support in your hospital, identifying pain points and creating a road map for future clinical decision support governance, optimization and maintenance. How would you begin? What are the key aspects of decision support you'll need to focus on? How do you anticipate creating a structure for your healthcare system in managing CDS?

Introduction

Despite a robust history of using clinical decision support (CDS) since the 1970s, the effectiveness of CDS remains in question. Changes in clinician behavior are demonstrated in some but not all CDS studies. Demonstration of change in clinical outcomes is lacking due the number of patients needed to generate enough power to show statistical difference and challenges in designing and conducting such studies in operational settings. The design, workflow integration, and usability of clinical information systems are all factors in creating effective CDS.

In this chapter, we will review the definitions of Clinical Decision Support and Clinical Decision Support System, the different types of active CDS, (e.g., alerts, reminders, corollary orders), briefly review the impact of care settings and vendor on CDS design, methods of implementation for success, and future challenges and opportunities.

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Fundamentals:

- Defining and delineating Clinical Decision Support (CDS) and Clinical Decision Support Systems (CDSS)
- Types of CDS
- Governance
- Factors for effective and successful implementation of CDS.

Defining Clinical Decision Support and Clinical Decision Support Systems

Clinical decision support (CDS) can be defined as anything that offers patient specific information in a timely fashion, in alignment with workflows, to aid and improve patient care. CDS is cited as improving clinician's performance but also processes within healthcare [1]. CDS encompasses a gamut of aides from colleagues to electronic alerts. Clinical decision support systems (CDSS) are computerized systems designed to impact clinical decision making about individual patients. For purposes of this chapter, we are only referencing electronic or computerized forms of CDS for use in patient care. Since so much of the CDS referenced and studied today is clearly CDSS, the distinction between CDSS and CDS may be lost. Therefore, we use the terms interchangeably.

In this chapter, we address the history and architecture of clinician facing CDS and prior classification schemes for CDS tools. As health information technology (IT) evolves, delivery methods as well as classification schemes for CDS no longer fit neatly within prior frameworks. Finally, we describe the implementation and maintenance of CDS with newer frameworks in mind.

Architecture of CDS Systems

As Associate CMIO, you're being tasked initially with learning about the architecture of CDS within your system broadly. Can you identify your Clinical Decision Support System's Rules Engine, Knowledge Base and Clinical Repository?

History of CDS

The earliest CDS evolved in the 1970s. The *Leeds abdominal pain system*, developed in 1970, sought to identify causes of abdominal pain. Timely and accurate diagnosis is essential as pain can be managed either medically or surgically. This branch point is critical. The tool used Bayesian probability to identify the level of certainty for each diagnosis.

Internist-I broadened this scope of diagnostic decision support tools and attempted to provide diagnostic support across 500 disease states; this tool was also able to interact with the clinician to provide follow up questions thereby narrowing a diagnosis. However, its limitations included an inability to take anatomical or temporal information into account. Internist-I was also unable to provide the user an explanation or reasoning behind its recommendation.

Dxplain intended to build upon Internist-1 by offering explanations for its diagnostic reasoning, a feature that was not built into Internist-I. MYCIN and HELP were two forms of therapeutic decision support; rather than offering diagnostics, they aimed to help clinicians derive appropriate next therapeutic steps. The HELP system employed CDS that analyzed events directly from the electronic health record (EHR) and presented them to clinicians. HELP was initially used in cardiac catheterization labs and later aided in reducing medical errors, as well as antibiotic prescribing features [2].

CDS Evolution

CDS tools have evolved since the 1970s. There have been four major phases of CDS evolution since the 1970s.

1. Stand-alone CDS systems which are generally limited to one area of medicine (Internist I, Dxplain, MYCIN) as described in the history section
2. Integrated systems which draw data from the CPOE or EHR (HELP)
3. Standards for CDS rules development (ARDEN SYNTAX)
4. Service models which separate the clinical information system and the CDSS and subsequently integrate using an application programming interface (API) (Sage and SEBASTIAN) [3]

Many early CDS tools employed decision tees and Bayesian probabilities. However, evolution of the clinical information systems that CDS often reside in and the capabilities of computer systems and standards that support CDS tools has forced changes in how we design and construct these tools. Integrated rule based and standards-based alerts offer clarity, precision and less ambiguity with respect to why an alert fired. Finally, service models (external CDS tools that function through an API and transmit data to a commercial EHR) offer modularity and performance benefits as advances in computer technology grow; although there are vendors who offer such services, this is currently not a consistently adopted practice. We will now focus on rule based CDS as well as CDS standard for Rules and Knowledge Representation.

CDS Components

CDS design employs three major components that, in aggregate, form a CDS System:

1. The **clinical event monitor** detects new information as it comes into the system [4, 5].
2. The **rules engine** tells the clinical event monitor that there is, or is not, a rule that pertains to the clinical data entering the system.
3. The **knowledge base** is a database of rules.

This modular design allows one to change the rules without having to redevelop the entire CDS tool.

CDS Standards for Rules and Knowledge Representation

Arden Syntax is a widely recognized standard initially created in 1989. Rules within the Arden Syntax model are called Medical Logic Models [6]. Each rule is comprised of three sections called the "maintenance", "library" and "knowledge" sections. The maintenance section contains meta-data about the rule including who owns it, when it was created and when it was last reviewed. The library section contains meta-data describing the purpose of the rule, as well as a citation to the guideline or data supporting the rule. Finally, the knowledge section contains multiple subsections which encode computable parts of the rule; this includes a subsection of logic, and actions as well as urgency.

Arden syntax is patient specific and event driven; therefore, it cannot be used for population-based decision support nor can it be used as a point of care reference. Arden syntax however can be used for drug-drug interactions and critical lab alerts. Secondarily, the vocabulary within Arden syntax is not defined; institutions define the manner in which labs and procedures are coded, perhaps creating challenges with interoperability across institutions. However, Arden Syntax was designed to be shared.

Notably, Arden syntax has been revised since its inception in 1989 and the most recent version is an ANSI and HL7 standard. In fact, some vendors support CDS based on the Arden Syntax model and non-EHR vendors sell CDS tools which follow the Arden syntax. Specifically, the Medical Logic Modules are sold and have the capacity to interface with EHRs.

GLIF (guideline interchange format) was first introduced in 1998 and was developed to support guideline modeling as a flowchart or on complex decision-making steps. To the best of our knowledge, this has not been implemented or integrated within any commercial EHR to date.

With the advent of the HITECH Act in 2009 which lead to the creation of the Meaningful Use program, EHRs were required to demonstrate creation and use of increasing number of CDS alerts. Several measures or criteria in the Meaningful Use program suggested the creation of CDS alerts. Stage 1 of Meaningful Use simply required demonstrating use of one CDS tool (e.g., alert). Stage 2 required multiple CDS alerts. Stage 3 specified that CDS alerts must be tied to quality measures or, in other words, demonstrably changed behavior. The emphasis on outcomes seemed to encourage the development of complex CDS tools.

Types of Clinical Decision Support

As Ambulatory Associate CMIO you want to better understand the use of CDS in ambulatory care and decide to begin by focusing on improving the rate of screening mammograms. Medical group leadership recommended an alert for all outpatient visits, not those with a history and physical. The doctors within the group have resisted, insisting that they always ordered a mammogram if it was due.

How would you identify the best way to deliver the CDS for all visit types?

Active (Push) Versus Passive (Pull) CDS

CDS can be delivered either passively or actively. **Passive decision support** is CDS in which the user actively seeks information via a 'pull' format. The tool requires first, the user to provide an action and seek out the information voluntarily. Passive CDS is considered non-interruptive in that it does not disrupt workflow as it is requested by the user during their desired workflow. It may be available for use within the EHR or outside the EHR (e.g., a website).

Examples of passive decision support are when a clinician happens to be charting in the EHR and realizes they would like additional information to help with diagnosis. A button then redirects the clinician to UptoDate or DynaMed. This information is not patient specific.

Alternatively, InfoButtons within the EHR can also aid in passive decision support. These can be patient or disease specific [7, 8]. An example of a "pull" type decision support is when a clinician is presented with a patient with low calcium. As the clinician, you'd like to correct for low albumin; there is an integration in the EHR with a medical calculator however the clinician has to insert the calcium as well as the albumin data into the calculator.

"Push" clinical decision support, which can also be called **active decision support**, is wherein the receives information and guidance that they neither expecting nor requesting. For

example, the clinician while writing a note the clinician receives an alert telling them that the patient's potassium is low and directing them to supplement it has low potassium. This alert occurs while the clinician is writing their note or reviewing the problem list. This is equivalent to notifications on a smartphone wherein the user is presented data without seeking it out [9].

Active Decision Support: Actionable Versus Non-actionable

Active decision support can be divided into two categories, actionable and non-actionable. **Actionable** is best defined as CDS wherein information and options are presented that can be acted upon. Ideally all of the information required to act upon the information is provided within the decision support. **Non-actionable** is simply information being presented to the clinician, but this may not be patient or disease specific and require interpretation by the user. For example, the clinician is notified that a patient's potassium level is high however there is no text, orders, or options guiding the clinician on steps to remedy the elevated potassium value.

For the purposes of this chapter, we will focus on only active and actionable decision support. This includes alerts, reminders, corollary orders, and guidelines.

Alerts are anything that requires the user to act without delay. An example of an alert is notification of a critical potassium result on a patient who is admitted; an alert appears to show the clinician this value. Reminders are used to inform the user of something that needs to be acted upon, although not necessarily emergently. Examples of reminders are to prompt the clinician to schedule a screening colonoscopy, act upon an elevated hemoglobin A1c value or cholesterol value. When an initial order is placed, corollary orders are provided as additional suggestions; for example, the user places a warfarin order and subsequently a corollary order for a daily INR is suggested by the CDS tool.

Guidelines "are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [10]. Guidelines can be challenging to computerize as often; they consist of multiple pieces of discrete information and pathways [use citations within Kannry Framework paper]. An example is whom should be screened for lung cancer, or when and how should patients be vaccinated for rabies. Guideline interpretation may require large amounts of data, complex decision trees and multistep data input and output tools. GLIF is a format that is built specifically for computerization of guidelines; however, most commercial EHRs are unable to effectively integrate it.

Hybrid Decision Support

Hybrid decision support has characteristics of two or more forms of classic decision support, and is usually an artifact of commercial EHR design. Examples of hybrid support are health maintenance, order sets and panels, as well as soft hard stops in commercial EHRs. Inline alerts, too, are a type of hybrid decision support tool.

Pop-up alerts fit the classic model of alerts being brought to the clinicians' attention. These qualify as active and actionable model as stated above. Inline alerts, though they meet the hybrid criteria, are passive as they require the user to look for the alert and active in that the user was expecting or requesting the information.

Order sets are also a form of hybrid CDS as they allow clinicians to view and act upon additional orders for a specific diagnosis. Order sets can also have embedded decision support such that specific diagnoses or clinical conditions prompt orders to appear; an example would be a generic order set for a urinary tract infection in a male versus female prompts differing duration of antibiotics. On the one hand, this resembles corollary orders in that additional suggested orders are presented.

There is really no analogous form of classic CDS for the guided documentation that vendor systems provide. Through the use of smart forms and templates, users are directed to generate documentation by choosing from suggested lists

Health maintenance and headers are vendor specific functionality and do not necessarily fit neatly into a classic CDS structure. They are hybrid forms of CDS with characteristics of multiple classical forms. Health maintenance topics as we define them are screenings and immunizations that are performed and tracked. Health maintenance is passive in that the clinician must look for it in an inline menu. It is active in that actions can be taken; recommendations are patient specific and orders can be easily written. Headers in the classic model did not provide decision support; however, they can be specific to a care setting and triggered by specific conditions almost like an alert or reminder. Headers are present within the EHR's user interface, don't necessarily require input from the end user to seek out the CDS via a pull phenomenon, nor are they necessarily presented to the end user via a "push" phenomenon. Headers are present within the screen and provide decision support via a hybrid format. Similarly, Health Maintenance tools offer decision support for routine screening tools. These forms of CDS are present in the chat, visible for the clinician to see; however, they are not presented in a pull or push format. This underscores the importance of both vendor specific functionality and user interface and screen design.

These hybrid decision support tools do not directly push information to the clinician, nor do they require the clinician to seek out decision support. These tools have a mix of both modes of CDS delivery (active and passive), as well as a mix of various types of decision support (reminders and alerts).

Care setting specific CDS tools also emerge as vendors recognize the variation in workflows between ambulatory, inpatient, and emergency care settings and vendors provide comprehensive solutions that span multiple care settings. For example, health maintenance and screenings are only available in ambulatory settings. There is a chronic (ambulatory) problem list, and hospital problem list (acute care), and emergency department impressions. A pop-up or interruptive alert for colonoscopy screening for is extremely helpful in ambulatory setting, but it is likely a hindrance to inpatient or intensive care-unit clinicians. In light of this, restrictions surrounding where and when the CDS Tool appears within the user interface is important.

Hard stops are another type of hybrid decision support. These classically mean the clinician cannot take any action in the EHR until they perform the necessary action that the alert or reminder recommends. An example is a hard stop for venous thromboembolism assessment orders in an inpatient admission order set; there are times wherein chemical venous thromboembolism prophylaxis is inappropriate or not appropriate to order at that time. Forcing the clinician to decide at the time of placing the admission order set may not be appropriate.

An inline "soft-hard stop" is one that prompts the user to perform an action; however, the user can easily navigate around the decision support on the screen. Unless the clinician chooses to click on the alert, they are able to perform alternate aspects of workflow with the inline hard stop being present on the screen. This functions as a passive tool as the user could choose to enter into the hard stop by clicking on the inline alert, but is also an active tool as if selected, the user has to address the soft hard stop.

These Hybrid tools are increasingly common, prompting the question as to whether our prior classification schemes are applicable with the advent of commercial systems and which lessons learned apply. Perhaps further study is needed of these new forms of CDS.

CDS Delivery Mechanism: Internal Versus External

Ultimately your institution considered an interruptive (pop-up) alert in ambulatory practices to ensure an increase in appropriate mammography orders. Clinicians were inordinately unsatisfied stating these alerts disrupted workflows. A non-interruptive alert was settled on. A yellow box appeared in a section titled alerts when a patient was due for the mammogram. One click ordered the mammogram, associated the order with the diagnosis of routine screening, and provided the patient with instructions and a map to the imaging center.

What mode of CDS delivery is this? Are there ways to leverage externally delivered CDS for this case?

Traditionally Delivered CDS

Traditionally delivered clinical decision support is provided to the clinician through the EHR. Alerts, reminders, corollary orders may be delivered through multiple mechanisms including the computer screen, texting, or paging. However, the processing of rules and logic occurs solely within the EHR.

Externally Delivered CDS

In externally delivered decision support clinical data leaves the EHR and is processed external to the EHR in a separate CDSS (Clinical Decision Support System), then ideally returns to the EHR with specific recommendations as well as actions (e.g., orders) for the EHR end user to perform. Alternatively, content is provided external to the EHR, delivered to the EHR, and subsequently processing is completed within the EHR. A critical characteristic of external CDS is both its modular capacity and ability to standardize CDS across enterprises and users.

Delivering External CDS

The vision amongst clinicians as well as the AMIA Board of Directors in their roadmap for national action on clinical decision support cites the need for a "robust infrastructure for developing and delivering CDS interventions" that are not necessarily vendor specific, but interoperable in nature [11]. Clinicians also expressed interest in making CDS available through a "public knowledge repository" as shown in a survey and interview-based study by Kawamoto et al. [12]. In alignment with these goals, there are multiple consortiums that aim to develop Clinical Decision Support tools and systems that are shareable and standards-based on a national platform including CDS initiatives through the Agency for Healthcare Research and Quality (AHRQ), Open CDS, CDS Hooks, and Protecting Access to Medicare Act (PAMA)

AHRQ

In 2016, the AHRQ launched a series of grants which aimed to advance CDS by supporting clinicians and informaticists in developing CDS tools [13]. The AHRQ goal was to create freely available, interoperable tools which aim to promote collaborative models of CDS. The CDS Connect Project (Fig. 7.1) allows clinicians and provider organizations, health IT vendors as well as federal health research organizations to collaborate. This approach was successful in piloting several external CDSS, including one that increased the adoption of preventative service guidelines for patients with chronic conditions in Indianapolis and Boston [14].

Open CDS

Open CDS is another multi-institutional and collaborative efforts to develop standards based CDS tools licensed under the Apache 2 license. This project was initially envisioned by Dr. Kensaku Kawamoto in 2010 with the major goals of :

1. Transforming proprietary sources of data from the EHR
2. Evaluate data using a set of rules based on the latest medical knowledge
3. Return appropriate treatment suggestions (OpenCDS.org)

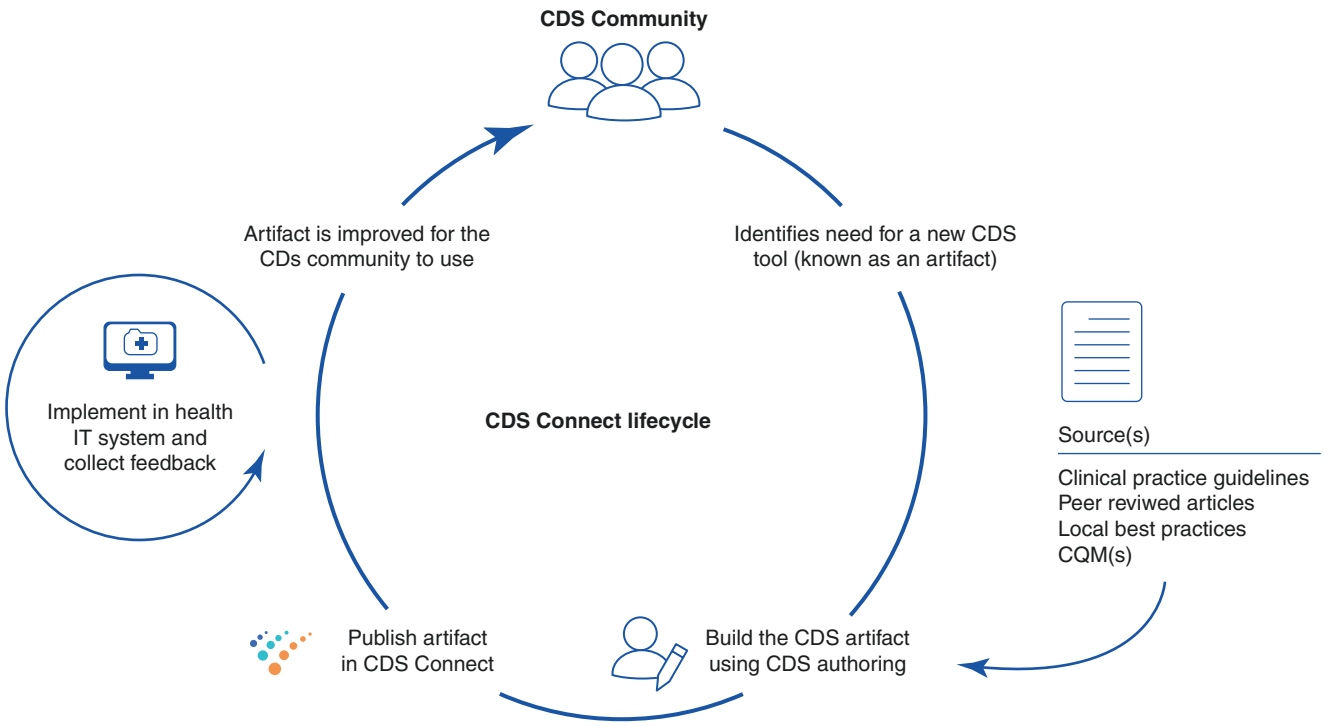
OpenCDS clients can use CDS Hooks and HL7 FHIR (Fast Healthcare Interoperability Resources) as a data model for input and output connecting to their EHR. Rules within OpenCDS can be written using Java, Drools (a business rules management system), HL7 CQL and any other custom rules language. The OpenCDS community is open and freely available for all to join encouraging active engagement.

CDS Hooks

CDS Hooks (Fig. 7.2) is an open-source system that builds a CDS service; it divides its built into a CDS client (EHR, CPOE or clinical workflow system) and a CDS Service (any external service that responds to the CDS client request through cards) or a SMART app (an application which utilized SMART a reusable medical programming technology as described below) [15]. CDS Hooks creates a simplified process by which an EHR triggers a "CDS HOOK" thereby invoking a remote CDS service that is external to the EHR/CPOE. The CDS service processes its own logic and rules and obtains data through a FHIR API (see Chap. 13). The CDS Hooks service then returns "CDS Cards" which are displayed by the EHR. Figure 7.2 is an example of CDS Hooks.

SMART on FHIR

SMART (Substitutable Medical Applications, Reusable Technologies) began at Boston Children's Hospitals and Harvard Medical School's department of Biomedical Informatics through a grant from the ONC (Office of the National Coordinator for Health Information Technology)



Source: https://cds. ahrq.gov/cdsconnect/about.

Fig. 7.1 CDS connect life cycle. Source: https://cds.ahrq.gov/cdsconnect/about

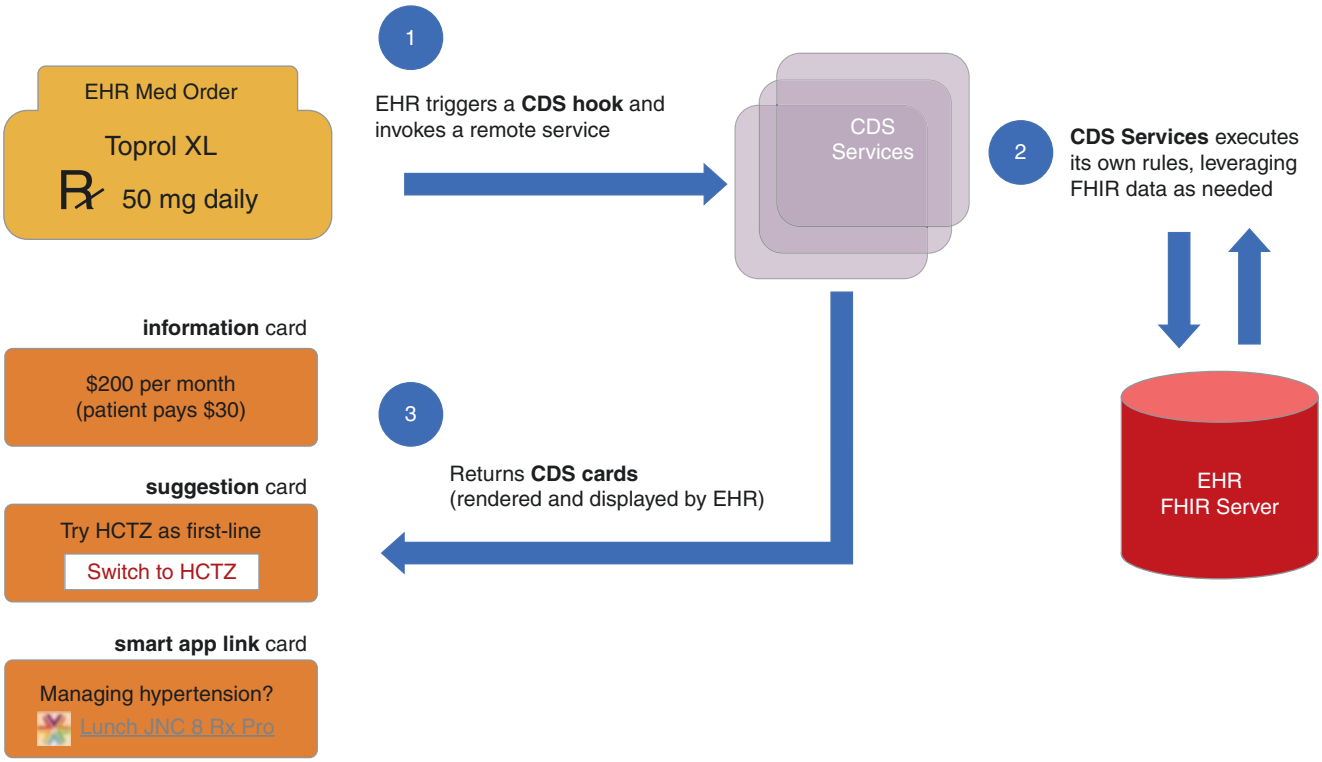


Fig. 7.2 An example of CDS Hooks. Source: https://cds-hooks.org/#how-it-works

[16]. The purpose was to build standard frameworks that allow interchangeable healthcare applications. SMART on FHIR allows for applications to easily and interchangeably develop, install, and update clinical decision support modules, taking advantage of the FHIR standard. Notably, SMART on FHIR standards can be used for non-CDS tools as well.

Protecting Access to Medicare Act and Imaging (PAMA)

Protecting Access to Medicare Act is an initiative through Medicare and Medicaid services that helps clinicians consult use criteria for every Medicare Part D advanced imaging order. PAMA uses pre-existing guidelines to curate content, and subsequently present the knowledge to the clinician [17]. This CDSS uses clinical guidelines to ensure the most appropriate image is ordered, as well as ensures that optimal quality of care and lower imaging costs are pursued (Fig. 7.3).

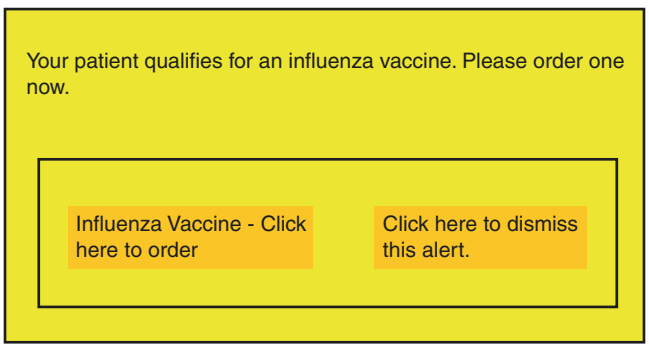


Fig. 7.3 Alert for Influence Vaccine administration

The Reality

Despite access to these CDS tools, getting consensus on the content as well as the process and technical details for implementation remains difficult [18]. Implementing these technologies remains difficult and there remain questions surrounding the practical implementation of these tools.

Knowledge Maintenance

You were informed the guidelines for mammograms have changed. You recollect that previously an alert was implemented for ambulatory clinicians. You struggle to tell your CMIO what version of guidelines you used for the alert, when it was last updated and how you plan to keep track of this information.

What Is Knowledge Maintenance?

Knowledge Maintenance is defined as how an organization "develops, disseminates, maintains, and evaluates its clinical knowledge content" [19]. This is an ongoing task and requires a considerable number of resources as well as tools. Its importance to CDS cannot be estimated, as it this knowledge which supplies the content for CDS.

Knowledge generation and knowledge acquisition occurs prior to knowledge maintenance. First, there must be agreement on the clinical knowledge content by clinical experts using tools to support this practice—this is knowledge generation and acquisition. The knowledge must be consistently represented and stored. Second, there must be consensus on tracking and maintaining both the knowledge within the decision support but also the initial need and vision behind the decision support tool or system as well as the granular changes made within the decision support tool.

Despite varied EHRs, a survey of multiple, geographically varied practice centers (academic and community), found all considered advanced knowledge management systems critical to maintaining CDS [20]. However, in vendor specific EHR systems, knowledge maintenance is a task delegated to each institution or health system. However, this lack of consistent knowledge maintenance complicates CDS design.

There are numerous models suggested in the informatics literature, including creating multidisciplinary teams to maintain the content within your organization, purchasing knowledge from third party vendors, and using online collaborative tools across organizations, to review, aggregate, and maintain the knowledge [19, 21, 22]. Notably, practice patterns vary from academic institutions to community and this distinction surrounding workflows, governance and support is essential in designing a knowledge maintenance infrastructure that is sustainable [22]. Secondarily, although many EHRs have clinical knowledge editors for users to create CDS, few have inbuilt knowledge and content management [23]. Third, although many EHR vendors do offer the capacity to build within their own infrastructure, there remains limited capacity to share and maintain knowledge in a collaborative fashion. Fourth, storing the knowledge in a structured, shareable, and sustainable fashion is critical. Current vendor EHR systems generally do not support this functionality.

What Evidence Is the 'Right' Evidence?

Regardless of having a structured knowledge maintenance methodology and infrastructure, there must be organizational consensus surrounding which evidence to use within the CDS tool. This requires consensus amongst key stakeholders, risk and safety, as well as operational leadership. Second, optimizing and aligning knowledge with changing evidence as new knowledge arises is critical; this underscores the importance of representing the knowledge using standards such as Arden Syntax, Health Quality measure format (HQMF) or Cassandra Query Language (CQL). Standards allow for organization of clinical content and evidence. Standards facilitate a clear way to locate, organize and subsequently find the data.

Efficiency and Usability

Your non interruptive alert has been in place for 6 months. You would like to analyze some metrics surrounding its use. How do you plan to analyze the efficiency of your alert? What will you measure? Second, you hope to understand if the user finds the CDS intervention useful and usable. For example, does the user understand the purpose of the CDS intervention? How do you plan to research and provide this information to leadership?

Efficiency and usability are principles applicable to more than CDS. However, CDS specifically has measurement and assessment challenges that are unique. Both efficiency and usability are critical to effective implementation and subsequent analysis of CDS tools.

What Is Efficiency?

Efficiency can be defined as the percentage of time a CDS intervention results in the user taking the desired action. However often times measuring this efficiency is difficult due to the limitations of EHR vendor's reporting systems.

When one thinks about CDS, the most common tool that comes to mind is an alert. When an alert fires, the user can either accept, adopt ignore, the alert. Acceptance is acknowledging the alert and pursuing the recommended action. Adoption means the user interact with the alert by acknowledging the alert or canceling the alert or unchecking the recommended action [9]. Theoretically this methodology of analyzing acceptance and adoption of the CDS tool can be used for all types of CDS including but not limited to banners, flags, as well as order sets and panels if EHR functionality and reporting supports it.

Assessing the number of firings, or the number of times the CDS tool appeared to the end user is a starting point for assessing efficiency. High rates of alert firing per user or per patient suggest alert being ignored. When assessing CDS acceptance and adoption for high firing alerts, CDS acceptance rates (i.e., following the recommended action) are remarkably low ranging and ignore rates are quite high; in fact, medication alerts have been shown to have ignore rates

as high as 96% [9, 24]. In fact, alerts shown in excess can cause a distraction and result in providers missing other critical information and the same finding has been found in medication alerts [25, 26].

Efficiency is impacted by whether or not CDS appeared in the appropriate context, for the appropriate user and at the appropriate time in the workflow One could perform analysis of whether an alert is effective by doing usability testing, structured interviews with users, as well as surveys. Given these variables, an objective number of firings may not fully capture the picture of whether a CDS tool is firing effectively.

Second, while it is comparatively easier to assess user interaction with the CDS intervention, it is much harder to assess the relationship between CDS and clinical care outcomes. This can aid in determining whether the alert truly is changing clinician behavior—one goal of any and all CDS. Traditional clinical measures such as number needed to treat are difficult to obtain. For example, how many times did the mammogram alert fire before one mammogram order was placed? Did the total number of mammogram orders go up and how many were a direct result of the alert? These queries are actually difficult to do with current EHR vendor functionality. Finally, the ultimate comparison of alert firings and improved detection of breast cancer due to screening is even harder to do.

Studies have attempted to measure the efficiency of clinical decision support systems. Many of the studies are on medication alerts given that acceptance or adoption of the alert and subsequently following recommendations the CDS provides is more easily measurable [27]. A few studies have attempted to quantify changes in scheduling and follow up patterns as well as clinical outcomes such as screenings and lab metrics [28]. Other studies have attempted to use QI methodology to analyze interruptive alert burden and found that a systematic methodology allows for a targeted way to reduce alert burden [29].

In addition, studies have attempted to solicit end user feedback on both the efficiency and usability of an alert [30]. The study identified alerts that required override comments and analyzed the content of each comment in context of where the alert fired and the ultimate actions taken; they found that alert override comments provide a wealth of data surrounding alerts that are broken and/or malfunctioning, therefore can be improved. Some of these studies have also begun to look at whether alerts are broken [30].

Usability

Of course, ultimately the goal is to create an EHR that is easy to use and a joy to use [31]. Usability entails three key principles:

1. Usefulness—meaning the tool is something that is desired and provides utility
2. It's 'usable'—meaning the user can navigate the tool easily and effectively
3. Does the tool fit into a workflow, or a pattern of use

Some also include safety (i.e., is it safe to use) within usability frameworks.

Usability engineering is critical, especially in CDS given high interaction with the tool and an expected interaction and subsequent action to the tool. Focus groups have been tested and clinicians as well as end users have previously been involved in studying the CDS tool as well as performing usability testing [32, 33] In addition, usability engineering techniques such as usability testing can be used. The user is systematically walked through a series of steps and their responses are analyzed.

Governance

Finally, in order to effectively support measuring both usability as well as efficiency, an institution must create and implement an effective governance structure. Governance includes an institutional structure and framework to monitor and regulate new CDS implementation, maintain the CDS that currently exists in the system, and finally ensure that malfunctioning CDS or CDS that is simply ineffective is essential. However, too rigid of a governance structure, can slow and limit agility and capacity to make changes quickly. A balance between flexibility and rigidity is essential.

Wright et al. conducted site visits at five organizations and reviewed best practices from these institutions which were: creating committees that included CDS related staff, creating and sustaining a process for knowledge management as well as customization and finally creating a process for review and monitoring [34]. A second study by Kawamoto et al provides a "pragmatic guide" to establishing CDS governance; again, site visits were conducted and each organizations' respective resources allocated to CDS, committees / working groups as well as an individual alert and efficiency as well as metrics were reviewed in the paper [35]. Ultimately however there are few systematic reviews or large-scale studies on best practices for CDS governance models given variation in resources, budgeting and organizational structure. There are however major themes that emerge from the studies that do exist—notably (1) development of a CDS committee or working group, (2) engagement of critical stakeholders, (3) A structured intake, maintenance, and expiration process, and finally (4) systematic maintenance of knowledge and data within the CDS.

Successful Implementation of CDS

You met with your boss, the CMIO, and overall, the implementation of the interruptive alert was deemed a moderate success. The data you presented demonstrated that the alert has a 10% acceptance rate in the ambulatory practice (meaning only 1 out of 10 users pursued the recommended action presented and ordered a mammogram).

What factors do you feel could be improved for better utilization? How would you systematically review usage and look to the future to improve upon the low acceptance rate?

Beyond the Five Rights

The implementation of a CDS tool must be well thought out and planned both from an efficiency standpoint and a usability standpoint. The "Five Rights" of CDS offers a framework for factors to consider in a successful implementation [36]. The five factors to consider are:

1. Getting the right information
2. To the right person
3. In the right format
4. Through the right channel
5. At the right time

This framework in short states that the decision support tool should present the appropriate, evidence based, patient specific information to the appropriate clinician, at the right time. For example, a patient who is a high falls risks enters the emergency department. The patient is registered and a pop up appears indicating he is high falls risk however does not include a risk score or any information on prior falls not does it include a way to place an order or alert other staff of this risk. This underscores the importance of the first of the Five Rights; it is critical that the data is appropriate. Second, it is critical that the data is provided to the appropriate user in the right format; the registration staff can ensure the patient's status is known to other hospital staff as well and throughout their ED stay but cannot order and ensure the patient has a wheelchair and is safe. A more appropriate way to communicate the information would be to send the alert to the nurse or physician at the time of admission to ensure they could place an order for this along with a physical therapy referral if need be. The channel of delivery here is likely appropriate in that the alert is delivered through the EHR; however alternate options include secure delivery through email which is not urgent enough, nor is it within the clinician's workflow. Finally, the alert must be delivered at the appropriate time; delivering this alert during admission is appropriate however delivery at discharge would have far less utility.

Although the Five Rights model is effective at analyzing an individual CDS tool such as one alert, the five rights model does not address the larger role of governance and maintenance. Furthermore, it does not explicitly address the critical role that workflow analysis plays in determining for whom, what format, and what channel through which to display a CDS tool. It also does not address the role that usability plays in assessing effectiveness of an alert.

Factors for successful implementation.

While the above Five Rights framework allows for a broad framework to assess CDS, successful implementation heavily depends upon IT infrastructure, governance and organizational culture. Major factors apart from content and usability are analysis of alert fatigue and metrics post implementation, workflow integration as well as role-based distribution of alerts to ensure targeted decision support.

In addition to the Five Rights framework, there are additional and complementary frameworks that consider active and actionable alerts, training as well as resources, workflow context, and usability [9].

Legal, Regulatory and Ethics

Members of your CDS governance committee are concerned that the non-interruptive alert aren't prompting them enough to order screening mammograms. They are concerned about liability surrounding the alert if they choose not to follow the recommendations provided. Alternatively, what if the CDS misses a patient who should, in fact, be screened and they later develop breast cancer?

Providers wonder if the vendor will be sued. Some members seem to feel the FDA is regulating the electronic health record and CDS. They are concerned and would like to ensure compliance with government regulations as well as delivering superior patient care.

The Role of the FDA in Regulatory Oversight of CDS

As software continues to become integrated with EHRs and the app economy grows, the term Software as a Medical Device (SaMD) has emerged. This is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device (Software as a medical device). This definition created by the International Medical Device Regulators, a consortium of medical device regulators from around the world, aims to classify the impact of these software applications as well as their risk posed to clinical practice, quality management and clinical evaluation (Software as a medical device).

Notably, however a large distinction is that the FDA has no formal role in evaluating CDS that is internal to the EHR. With external devices sending information to EHRs through an increased availability of APIs, a critical piece that is missing is how the FDA "intends to distinguish machine learning software that can explain its recommendations to a physician from software that cannot" [37]. These challenges will continue to rise as technology evolves.

Legal Model for CDS

The legal model upon which lawsuits are generated in relation to CDS is one of negligence; meaning the clinician pursues a plan of care that is contrary or opposed to that of common practice [38].Therefore, unless gross negligence is proven, the CDS tool or vendor is usually not implicated in patient outcome.

Vendors and CDS Content

Despite this, vendors are hesitant to provide the content within the CDS tool—although some vendors provide a starter pack of CDS content [19].This leaves a gap in the market for CDS content providers. Commercial products have emerged that both provide evidence-based guidance and clinical content, but also maintain, update and monitor the use of these tools.

Impact of the 21st Century Cures Act

The 21st Century Cures Act impacts CDS through the information blocking section of the regulation. This releases all appropriate data to patients through electronic means. The information to be shared electronically includes notes as well as lab results, imaging results, and routine screening information. Given this, the implication is that data will be available and freely shared from disparate clinical sources. The information available to guide and recommend CDS will be far more robust. This prompts questions surrounding first how to obtain the data, whether the data will be shareable and transferrable.

Ethical Challenges of Adaptive CDS

Adaptive CDS is defined as CDS that can "learn and change performance over time, incorporating new clinical evidence" new data and new methods for interpreting data [39]. There are not only legal challenges with AI and Machine learning based CDS but also ethical challenges. As access to data and information grows, adaptive CDS, or CDS that can "learn and change performance over time" is increasingly incorporated into clinical practice [39]. An AMIA position paper discusses specific recommendations surrounding transparency metrics, communication standards, ongoing maintenance and in situ evaluations and testing. Concerns surrounding hidden biases due to poorly defined training sets, as well as AI generated bias to increase health disparities. Notably there remain concerns surrounding racial, ethnic and gender disparities inherent in AI models [40].

Emerging Trends

CDS has developed significantly since the time of being a component of internally developed clinical information systems. However most current CDS still employs the same architecture of a rules engine and knowledge base. Complex multistep algorithms are still challenging to implement despite existing standards such as GLIF that can handle these complex decision support trees.

Three themes that are evolving in CDS are: (1) Commercial solutions for knowledge maintenance, (2) Adaptive CDS and (3) workflow integration for new types of devices that deliver CDS to the user CDS.

EHRs are not equipped with easy to use and robust content management functionality nor do they have good management tools for CDS tracking. For example, there is no easy way to monitor who build a CDS tool, why it was built and the intent behind the tool. Increasingly there are commercial solutions to manage CDS assets, assess efficiency and determine outcomes. These commercial solutions come at a cost and are packaged and not yet well-integrated with EHR vendors.

Adaptive CDS in which artificial intelligence and machine learning grow and change recommendations based on their new data sets is another area of growth. The biggest challenge will be determining appropriate training sets, whether training sets are representative of a population, and ensuring bias is addressed.

Finally, a critical piece of CDS is its placement within individual workflows. Increasingly there is technology that goes beyond delivering alerts solely within an EHR. CDS can be delivered through mobile applications, and wearable devices as well.

Patient centered CDS, or CDS delivered directly to the patient, is in its early phases. As we develop CDS tools, we expect this area of CDS to grow.

Summary

Clinical decision support (CDS) is any tool that aids in clinical decision making about individual patients. Clinical decision support systems (CDSS) however are computer systems that perform this function. CDS evolved in the 1970s and has developed significantly since this time. Standards such as Arden Syntax were developed to ensure standard programming logic and knowledge representation in the development of CDS tools. CDS can be presented to the end user either in an active—or push—methods of delivery versus passive; this can further be developed into actionable versus non actionable CDS which guides the user to perform a subsequent action. Increasingly commercial EHRs pursue hybrid tools which do not fit neatly under either classification. CDS can also be delivered internal to the EHR versus externally; there are many initiatives that aim to integrate external modules with the EHR to bolster commercial CDS. Despite the availability of these tools, the implementation of CDS ultimately depends on much more than the tool itself; frameworks for implementation such as the Five Rights model discuss the "who, what, when, where and how" of CDS. Other frameworks emphasize the importance of workflows, governance and documentation [9]. In addition, the efficiency of the CDS tool depends heavily on factors discussed in the prior frameworks as well as usability, an area that is under study in CDS and workflow context. Increasingly however newer technologies such as machine learning and artificial intelligence are being used to generate CDS; with this comes questions surrounding regulatory affairs as well as ethics of tools that recommend and guide clinicians to pursue specific practices in the healthcare space. As these technologies grow and develop at a rapid pace, CDS will be an area of intense focus

Questions for Discussion

1. How has clinical decision support evolved since its inception in the 1970s?
2. What are the different modes and methods of CDS delivery? Can you describe scenarios wherein the manner in which CDS was delivered was inappropriate?
3. What frameworks can be used to improve implementation of CDS?
4. Describe ways in which knowledge management systems impact implementation and management of CDS
5. Brainstorm ways in which CDS can be optimized. How would you measure changes?

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Clinical Workflow Analysis, Process Redesign, and Quality Improvement

8

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Learning Objectives

By the end of this chapter, the reader should be able to:

- Identify and select appropriate tools and techniques for analyzing workflow in a health setting;
- Appraise the value of process re-engineering and its application to improve health care processes;
- Describe quality improvement tools available for use in clinical settings;
- Discuss the role of workflow in clinical decision making, design, and implementations of health IT and organizational design.

Practice Domains: Tasks, Knowledge, and Skills

The focus of the core competencies [1] in this chapter are:

Domain 2: Improving Care Delivery and Outcomes
- **K030**. Methods of workflow analysis
- **K031**. Principles of workflow re-engineering
- **K032**. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)

Domain 4: Data Governance and Data Analytics
- **K093**. Data associated with workflow processes and clinical context

Case Vignette

During the coronavirus pandemic, the primary care clinics of Huge Hospital (HH) quickly transitioned outpatient visits from primarily face-to-face to predominantly telehealth visits to promote physical distancing. Each clinic was able to manage its transition to virtual care. The move to telehealth represented changes in workflows as clinical and administrative staff and patients adjusted to the new normal. While there were some challenges, after several weeks, the clinic staff and patients seemed to adjust to virtual care.

As the coronavirus pandemic continued, patients who had delayed care eventually found they needed to be seen by their provider. Providers who had initially moved to telehealth visits thinking they were temporary found that the swift move was not sustainable. In some clinics, providers became frustrated by inefficient workflows, such as double documentation and not having a medical assistant or a scribe to assist in administrative tasks. Patients became frustrated at the lack of technical support. Thus, HH moved back to in-person care, and telehealth volumes plummeted. In other clinics, there was a return to in-person care, but telehealth services remained.

HH wanted to learn more about why some clinics maintained telehealth services while others did not. Hospital administration suspected that differences in patient demographics were a reason for differential telehealth uptake. HH partnered with a local university and asked a clinical informatics fellow to investigate. The fellow found that each clinic's patient and provider demographics were similar, so that did not explain the difference. Upon further investigation, the fellow found that each clinic managed its transition differently. The clinics that were the first to move to virtual care were not necessarily those

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who stayed with it. Some moved to encounters with a scribe or medical assistant in the virtual room to assist with the documentation. Others had the providers primarily responsible for their documentation. In addition, the clinics varied in using support staff to obtain specific initial information from the patient and, because of the virtual visit, for technical troubleshooting. The fellow found that clinics that took the time to identify everyday clinical encounters and develop workflows to address them for virtual care managed the transition better than those who were quicker to adopt but did not pay as much attention to sustainable workflow changes.

Introduction

Workflow is a set of tasks and the associated resources needed to complete those tasks to accomplish a given goal [2]. Workflows involve chronologically grouped functions that people complete using resources such as technology, physical space, and equipment. Many people do not think about workflows, yet the consequences can be dire when they do not go as planned. Workflows may be updated in response to a change, as in the case vignette at the beginning of the chapter, or improve patient outcomes and organizational efficiency.

At the beginning of the chapter, the case vignette outlines the importance of paying attention to workflow and processes in a typical clinical setting. When the pandemic first started, HH moved to telehealth rapidly, believing it was a temporary solution. Clinical and administrative staff quickly adjusted to working from home. They canceled all patients who did not need to be seen immediately and moved those requiring attention to telehealth. The idea was that they would see patients in person when the pandemic was over. However, as the pandemic continued and days turned into weeks, then months, the temporary solution was not viable. Providers and patients were not prepared for the long-term implementation and use of telehealth. Thus, workflows needed to be revisited to support sustainable telehealth implementation. Items to consider when updating workflows include identifying places where workflows conflict, updating roles and responsibilities and addressing intersections between workflows.

While the vignette is about telehealth, the lessons apply across all types of changes. Workflows and associated systems must be considered with any change. Also, sometimes inefficient workflows must change to improve patient outcomes and organizational performance.

Workflow and processes are also related to the design and implementation of health information technologies, communication, interruptions, hand-offs, and care coordination.

Process redesign and quality improvement efforts aim to make care delivery more effective and efficient by changing care delivery. Similarly, workflows must be considered when implementing health information technology (IT). This chapter begins with a workflow definition and description of related frameworks. Then we describe tools and techniques to capture, visualize and analyze workflow in health care settings, either to improve the workflows themselves or as part of a health IT implementation. We conclude by discussing several quality improvement approaches to impact the quality of care.

What Is Workflow?

Workflow can be defined as the flow of work through space and time [3]. Workflow as a concept refers to the procedural aspect of a working system [4, 5] and focuses on temporal properties (e.g., unfolding work activities over time). Temporal properties are important because they allow users to employ tools and information at critical moments of activities or enable the user to overview the work process. Other than temporal properties, activities, actors [6], information [6], and additional resources (e.g., technology, materials) [7, 8] are essential building blocks of workflow. Moreover, organizational infrastructure such as rules, policies [9], and the external environment [8] are crucial factors that affect workflow.

One of the intermediate aims of clinical workflow studies is to model "true work" in health settings. Models are a simplified version of a complex system. Health care is "hypercomplex" when compared to other domains [10, 11]. Modeling is an appropriate strategy to make complex systems more comprehendible because of the explanatory power of models [12]. Workflow models should accurately show the essential components and functions of the work that are under investigation.

Multilevel perspectives are needed in the understanding workflow because of the comprehensive scope and complexity of workflow [5, 13, 14]. One possible multilevel workflow approach is describing the scope from lower to higher levels. For example, the cognitive, individual, organizational, and inter-organizational workflow can define the scope of work. *Cognitive* workflow collects cerebral activities such as sensation, perception, decision-making, and response execution [15]. *Individual* workflow refers to collecting physical and mental activities by a single person (e.g., physician, nurse, respiratory therapist). *Organizational* workflow can be defined as a structured and measured set of activities designed to produce a specified output for a particular customer or market [8, 16]. *Inter-organizational* workflow occurs when activities producing a specific output take place in multiple institutions. For example, if a patient diagnosed with asthma is seen in an emergency department (ED) from one facility for a breathing problem, a summary of the visit should be communicated to the patient's primary care office (in another facility). This is essential to the flow of communication and patient management when modifying therapy from one set of providers to another. In health care delivery settings, the output (or outcome) goal is better health status

for patients, lower costs, improved efficiency of care delivery, and patient satisfaction.

Workflow studies should identify the workflow boundaries to ensure a comprehensive yet focused perspective on workflow. Workflow boundaries are essential in designing informatics interventions for geographically dispersed users [17] and patients who need health-related activities outside formal clinical settings [18–20].

Workflow studies are more likely to be reliable and valid when applicable theories, models, and frameworks from disciplines such as health informatics, human factors engineering, cognitive science, organizational behavior are utilized. Theories, models, and frameworks provide validated pathways to link observed phenomena with foundational knowledge, enhancing efficiency and generalizability [21]. We will provide a summary of four approaches to the workflow that were developed within the informatics community.

Pervasive and Specific Levels of Workflow

Unertl et al. [9] proposed that a model has two levels of workflow, *pervasive* and *specific*. The *pervasive* level includes three components that apply to the workflow: context, temporal factors, and aggregate (actors and actions) factors. The *specific* level is composed of: the people performing the actions (actors); the physical and virtual tools the actors are using (artifacts); details of the actions being performed (actions); description of the actions (characteristics) and the end products of the actions (outcomes) (Fig. 8.1). The Workflow Elements Model can be used to describe intended workflow (e.g., how a manager expects a process to occur), perceived workflow (e.g., how a manager or a staff member thinks a process is happening from their perspective), and actual workflow (e.g., an understanding of workflow developed based on data about how the process works). Models using this framework can adjust the actual work performed, align with process expectations more closely, or adjust expectations to reflect reality more closely. A revised model can then be used in designing and implementing health information technology that addresses all elements of processes and incorporates an understanding of how process changes, driven by technology, will impact other individuals and groups.

Workflow as the Collection of Individuals' Routines

Malhotra et al. [6] suggested developing a workflow in care delivery settings by combining the routines of individuals (e.g., nurses, residents, and attendings). They also discussed the requirement of "a framework to relate and identify activities" for representing workflow temporally. For that purpose, they set up conceptual zones (i.e., activity groups) to show the temporal relationship of the activities with each other. This model delineated the workflow into different activities during the day shift and then clustered them based on the critical nature of temporal relevance into seven critical zones (CZ) (Fig. 8.2). This model reflects cognitive, individual, and organizational workflows together.

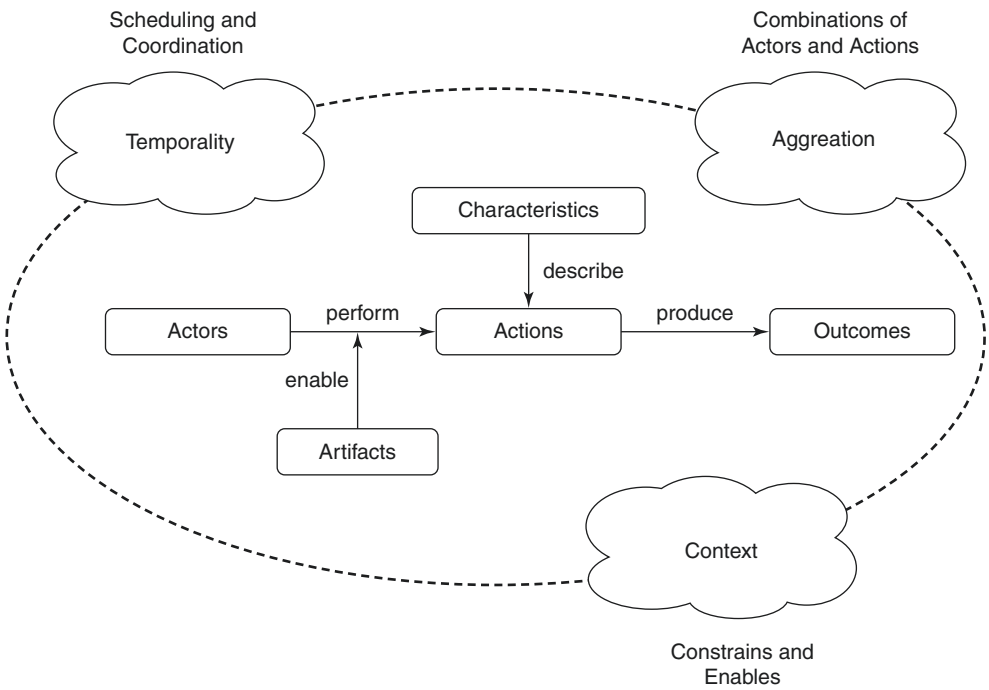

Fig. 8.1 Workflow elements model

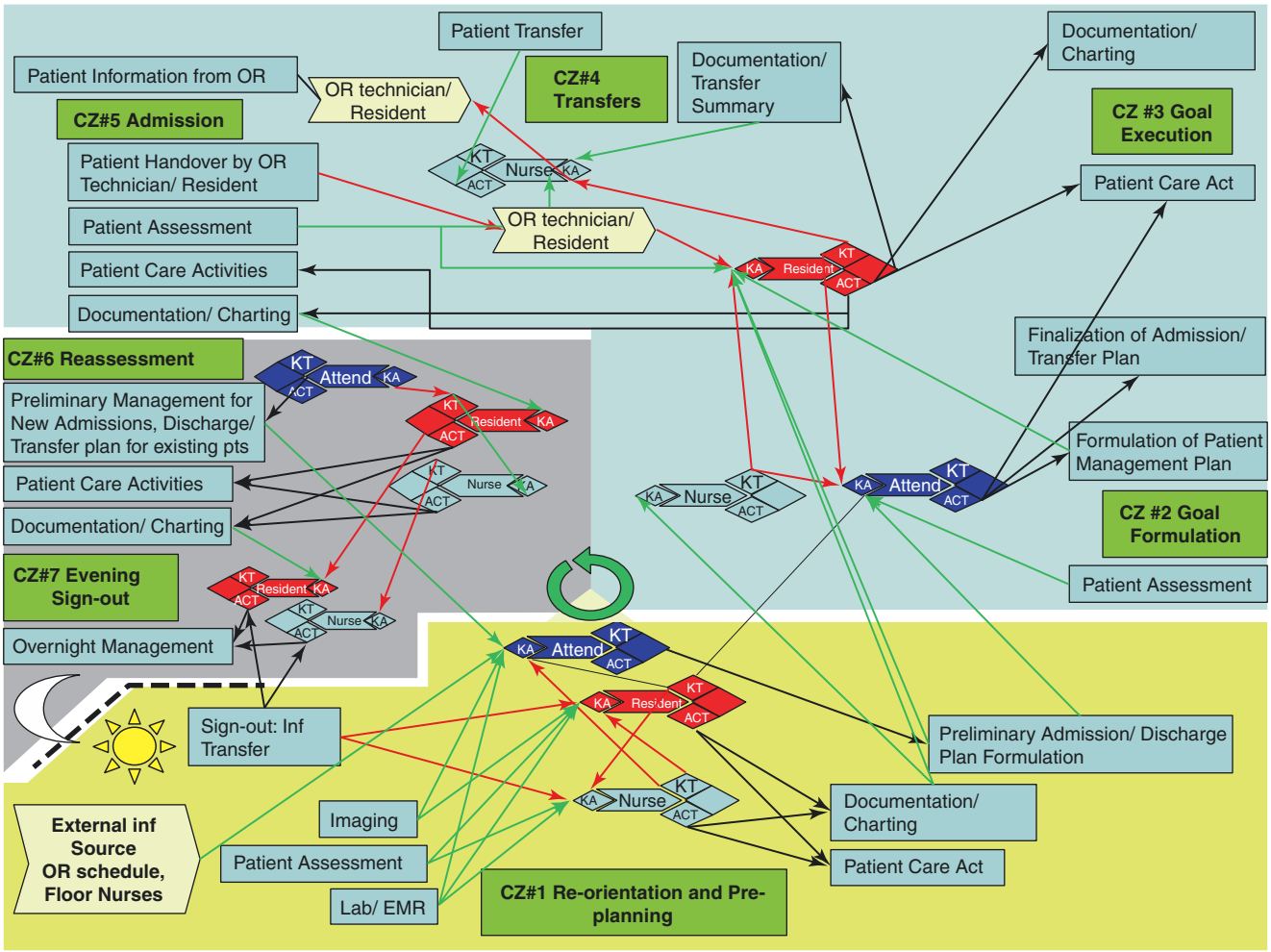

Fig. 8.2 Workflow in an intensive care unit

Patient-Oriented Workflow

Ozkaynak et al. suggested a patient-oriented workflow approach. In a patient-oriented workflow, the patient is the nucleus of the care episode; the gravitational pull of the patient attracts, binds, and choreographs the essential elements of workflow [22, 23]. Patient-oriented workflow models provide the "true flow of the work" [24] by including activities performed by multiple individuals and capturing the cooperative nature of health-related work in patient care. This means decoupling workflow from a single individual who works in formal settings and coupling it, instead, to the patient, who is at the center of all work and spans all settings (both formal and informal). The patient-oriented workflow approach allows us to redefine the boundaries of the system. For example, extending patient-oriented workflow to the study of health-related activities in the home and community environment can capture the patient's work, informal caregivers, and "care partners" [25]. Moreover, patient-oriented workflow focuses on actual episodes or instances rather than "typical" cases. By examining many individual episodes, patterns and variations can be analyzed [26].

Organizational Routines

One way of looking at workflows is through the concept of routines, which are not necessarily codified through policies and procedures but are "repetitive, recognizable patterns of interdependent actions, carried out by multiple actors" [27]. Routines are often implicit and understood by those who are part of them to manage the expectations of others. Workflows generally have two aspects: ostensive and performative [28]. The ostensive element of the routine is the norm, as it occurs in theory or as it should be done. The performative aspect of routines is how routines arise in practice. Ostensive and performative elements of routines vary for several reasons. Reasons for variation include a mismatch between routines

and technology, inefficient routines, emergencies or other factors outside of the routine, or inconsistent understandings of the routine by the people involved. For example, participants in the routine may conceptualize it differently, and thus their actions differ. That could be because of inconsistent understanding of roles or responsibilities or inability to describe activities within the routine [29].

Unpacking and uncovering routines is an essential piece in understanding workflows [30]. Routines can be studied as a whole or in parts and at a single point or longitudinally. Studying routines, components, and relationships between components can be helpful in understanding workflows [31]. The differences between the ostensive and performative aspects can be used to identify areas of improvement to inform workflow redesign and organizational change.

These four workflow approaches (explained above) can guide studies. However, each process has a different focus and purpose. "The pervasive and specific levels of workflow" approach provides a holistic approach that includes various building blocks of workflow. "Workflow as a collection of individual routines" approach shows how different clinicians' routines intersect with each other. Patient-oriented workflow suggests that patients (as opposed to the clinician) are the foci of workflow. Organizational routines focus on repetitive patterns that allow care delivery settings to accomplish their goals. Researchers and practitioners can choose to utilize any of these four frameworks depending on their needs and objectives.

One methodological challenge of workflow is the differences between the perceived workflow (by clinicians or health IT users), actual workflow, and the predetermined/designed/ideal workflow [32–34]. Workflow design and redesign studies should focus on minimizing the differences [35].

The comprehensive examination of the workflow may require interdisciplinary expertise, including industrial engineering, human factors, sociology, psychology, and organizational theory, combined with domain knowledge and perspectives of patients. Therefore, a workflow study starts with establishing a team with complementary skills. Missing expertise can lead to incomplete modeling of workflow or incomplete interpretation of it. Xie et al. [36] examined multi-stakeholder collaboration in redesigning the family-centered rounds process, which involved four human factors engineering researchers, three attending physicians, a parent, a medical administrator, two nurse managers, two nurses, and two residents. Each participant's contribution was essential for the redesign. For example, the parent participant provided feedback and gathered feedback from other parents. Researchers played a vital role in the collaboration process within the team. Clinicians and hospital management provided their perspectives during the redesign.

Methods to Develop a Better Understanding of Workflow

Healthcare-related workflow is complex and highly adaptive; any single approach to studying workflow will likely capture only a tiny fraction of this complexity. A wide range of methods helps capture workflow data, including qualitative, quantitative, and mixed methods. No single "right" approach to studying workflow exists. The selection of a method is dependent on underlying theoretical frameworks, research questions, implementation goals, project aims, available resources, contextual constraints, to name a few.

Qualitative Approaches

Qualitative study designs for workflow research are typically more open-ended and iterative than study designs using quantitative methods. Qualitative methods are more suited towards generating hypotheses rather than testing them. Two crucial components of qualitative workflow studies are carefully setting study boundaries and a rigorous approach to sampling. Due to workflow complexity, it is impossible to gather data on all contexts and people involved, so identifying reasonable boundaries for data collection (e.g., specific units, organizational boundaries, community versus healthcare system) is needed to capture data at essential points within resource constraints. Although qualitative research does not have statistical power calculations to determine the sample size, defining a rigorous sampling plan that will gather data reflective of the phenomena and roles of interest is critical.

Observation, or *naturalistic observation*, is the systematic study of behavior and activities in context. When studying healthcare workflow, context refers to locations where work occurs, such as an ambulatory clinic, ED, hospital unit, or community setting such as someone's home or school. Subjects for naturalistic observation could include anyone participating in the workflow of interest, such as nurses, physicians, patients, caregivers, administrative staff, and ancillary professionals. During naturalistic observation sessions, a researcher shadows a subject as they participate in routine work activities. The researcher may focus on specific activities during these sessions, such as observing how a subject interacts with technology. Researchers conducting naturalistic observations typically record free-text notes, which are later transcribed and analyzed.

Two methods that are particularly useful as supplements to naturalistic observation are artifact collection and spatial analysis. Artifacts are any items an individual uses in work activities. Examples of artifacts collected with health infor-

mation technology include paper forms, sticky notes, printouts from electronic health records (or other technology systems), lists of contact information, and written descriptions of procedures. The heavy use of artifacts can indicate workarounds and gaps between existing technology systems and user needs. The spatial analysis involves studying the physical environment in which work is occurring. This method can include photographing the work environment, drawing sketches of physical space, or obtaining blueprints of the environment. Spatial analysis can assist with uncovering how the physical space constraints and enables workflow. For example, the spatial layout of an exam room can create barriers between computer use and physician-patient interaction that directly impact workflow.

The use of interviews is also a well-established method for workflow data collection. Interviews are often used in combination with *naturalistic observation*. For example, informal interviews can be conducted during observation periods to clarify observed behavior and understand the rationale behind specific actions. Interviews can also take on a more formal structure, with one or more researchers interviewing either an individual or a group using a semi-structured interview approach. Semi-structured interview instruments provide a standard set of questions for all subjects but allow the flexibility to add or alter questions based on the subject's response. Focus groups could be considered a group interview, with several subjects asked to respond to identical questions. Group interviews have limitations related to the potential for dominant personalities to steer the discussion without including other perspectives. Additionally, there may be difficulty sharing potentially sensitive information in a group setting. Participatory design workshops could be considered a more active group interview, with participants, asked to contribute to the design of an experience or technology.

Patient health management work continues to be an important area of research outside of the healthcare system. Methods such as home visit interviews with video walkthroughs of home settings have generated insight into the work activities that patients and their families do to manage health outside of the healthcare system. Recent situations have led to an increase in remote home visits through tools such as videoconferencing software.

Quantitative and Statistical Approaches

As data collection methods advance and more data are available to examine workflow (e.g., data extraction from EHRs, sensors), sophisticated quantitative data analysis techniques powered for large sample sizes become possible. Quantitative data analysis techniques are helpful because they can establish statistical relationships between process and outcome variables. In this chapter, we describe three quantitative techniques: (1) Markov Chains, (2) Pattern mining, and (3) Discrete Event Simulation. We selected these techniques from many available models in operations research because these techniques (1) represent workflow graphically and (2) have strong mathematical foundations. The main disadvantage common to all such models is that they are time-consuming to apply.

Markov Chains

A Markov Chain (MC) is a stochastic (random) process that is characterized by a set of discrete states and transitions between these states. The simplest form of the Markov Chain can be defined as a triplet (Q, A, π), where Q is the number of states, A is the matrix of transition probabilities, and π is the initial distribution accounting for the probability of being in one state at time t = 0 [37]. **Q** is a set of patient care events (e.g., triage started, physician assessment). **A** is a matrix of probabilities associated with transitioning from one of these patient care events to another. Finally, $\boldsymbol{\pi}$ is the probability of being in the initial patient care event. MC is a probabilistic modeling method used for temporal sequence analysis [38]. MC has been shown to work with EHR data to model workflow patterns quantitatively [26, 39]. The analysis aims to identify MCs representing sequences of high-probability clinical actions or chains of states in MC terminology.

Pattern Mining

Pattern mining studies assume that several possible sequential patterns are hidden in an extensive amount of time-stamped data extracted from EHR or other resources. Then a mining technique should (a) find the complete set of patterns that satisfies the minimum frequency threshold. In a study conducted in an ED, pattern mining was used to identify the most frequent sequential pattern in a network graph for each clinical role [40]. The mining demonstrated that clinicians with different roles had different and more frequent patterns in their activities. In another ED study, glucocorticoid administration earlier in treating a pediatric asthma population was associated with a shorter length of stay and lower hospital admission rates [41]. Petri-Nets (i.e., a collection of directed arcs connecting places and transitions) can also provide a beneficial template to identify workflow patterns [42].

Discrete Event Simulation (DES)

DES refers to codifying the behavior of a complex system as an ordered sequence of events. It imitates the "real world" operations of a system over time using queuing theory. The inputs of a DES are statistical distributions for the behaviors of the system elements, such as the arrival rate of patients and clinicians' service (encounter) time. Simulation is helpful to illustrate how the performance of multiple events affects each other and the overall performance of the delivery of care. One advantage of DES is that it allows testing the performance of a planned intervention in a care delivery setting. The results

will inform changes to the intervention before implementing any changes. For example, Zhou et al. [43] used simulation to estimate the impact of the electronic health record with various levels of interoperability on day-to-day tasks in primary care settings. Once data is collected to run a DES, a wide range of software packages can process the data and simulate the care delivery setting. Hoot et al. [44] used DES to forecast overcrowding in EDs. In a recent unpublished study, the first author (MO) was a part of the team who simulated EKG technicians' work in inpatient settings under various policy options. The primary outcome was EKG time.

Visualizing Workflow

In general, visualization supports researchers and practitioners by providing cognitive support by exploiting human perception advantages, such as parallel visual processing, and compensating for cognitive deficiencies, such as limited working memory [45]. Specifically, visualizing workflow facilitates examining patterns and variations in practice. In this section, four different visualization techniques will be discussed.

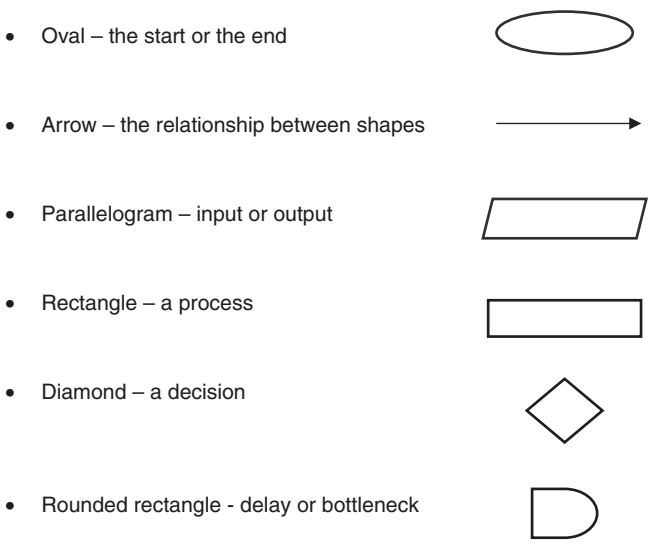

Fig. 8.3 The six basic symbols of a process map

Process Map/Flow (Process) Charts

Although the terms flow (process) chart and process maps will be used interchangeably in this chapter, there is a slight difference in these terms. The basic diagram is the flowchart, while process mapping involves the creation of the diagram. The overarching goal of a process map is to graphically represent a set of associated processes [46].

The idea of process mapping is not new. Process mapping, as described in the early 1920s [47] as "*a device for visualizing a process as means of improving.*" Every detail of a process must be presented in such a form that it can be visualized all at once before any changes are made to its subdivisions. Any changes made without considering all the decisions and motions that precede and follow that subdivision will often be unsuitable to the ultimate plan of operation in any subdivision of the process under examination. Moreover, creating a process map is an iterative process. Key stakeholders should be involved in the review and subsequent reviews until consensus is reached that the process has been wholly and correctly mapped.

Creating a process map entails the use of symbols, as shown in Fig. 8.3. Significantly, standardization of symbols is maintained by the International Organization for Standardization. ISO 5807: 1985 "defines symbols to be used in information processing documentation and gives guidance to their use in data flowcharts, program flowcharts, system flowcharts, program network charts, and system resources chart" [48].

Data Flow Diagrams

A data flow diagram (Fig. 8.4) is defined as "a graphical representation of the flow of data through a system" [49]. Like the process map, creating a data flow diagram involves using symbols [50]. The data flow diagram includes what information is exchanged, but it does not show when or in what sequence the information is exchanged. Data flow diagrams can be classified as

- Logical—the emphasis is on the organization and how the organization functions
- Physical—illustrates how the system will be implemented

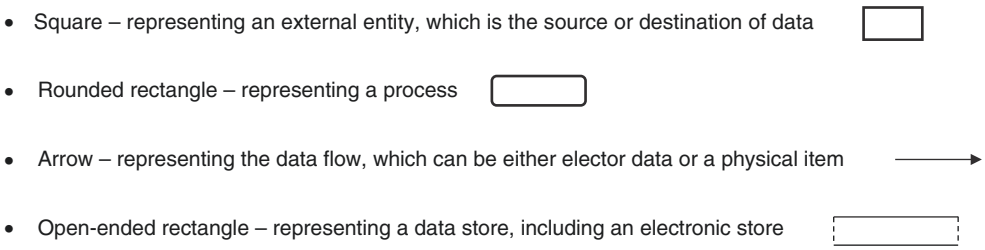

Fig. 8.4 The four major symbols of a data-flow diagram

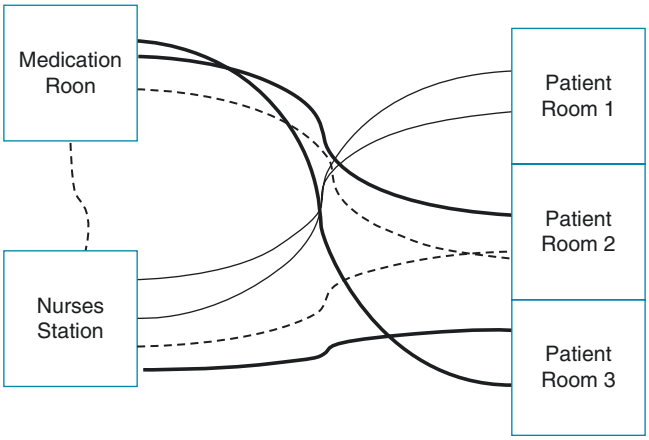

Fig. 8.5 An example of a spaghetti diagram that shows the movement of three nurses in a clinical setting. The type of line (regular, thick and dashed) shows the movements of a nurse in a pre-defined time frame

Notably, the data flow diagram differs from a flowchart diagram. Sharp and McDermott [46] explain that "on a data flow diagram, a data flow line between the steps indicates that the receiving step uses the data produced by the originating step." A merged diagram can become highly complex, resulting in a loss of explicit detail visualized in individual diagrams.

Spaghetti Diagrams

The spaghetti diagram is a visual illustration of the work unit running through a process, including the flow sequence of the information. The spaghetti diagram relies on the use of lines. The lines are often very squiggly rather than straight, color-coded to visualize the various workflows (Fig. 8.5). The spaghetti diagram documents the functional dependencies and responsibilities for each step in the process. The name "spaghetti" is derived from the representation that often resembles a plate of spaghetti. The diagram helps determine the current state for the specific path through a process. The spaghetti diagram helps determine the efficiency of a space by making it easier to visualize wasted motion. It is easier to quantify the impact of a layout on a process over time through spaghetti diagraming.

A spaghetti diagram can be created by

- Diagramming a layout of the facility
- Indicating what task is completed, at what step, as well as the person or department involved in each step.
- Documenting the time to move from one step to the next.
- Documenting the travel time and distance from the map into a table and calculating the opportunity to shorten the distance.

Like other diagrams, the spaghetti diagram uses symbols. However, the notation is not as extensive as many other diagrams.

Swimlane Diagrams

Another visualization of workflow is the swimlane diagram. A swimlane diagram looks akin to a swimming pool that has been divided into "swim lanes" (Fig. 8.6). In a swimlane diagram, each actor is assigned to a lane. Swimlane diagrams are meant to visualize a complete process from start to finish and show what is done, by whom, and in what sequence and dependencies and time [46]. An actor can be either a person, a group, or another process. All the work performed by an actor will be visualized in their specific swimlane. Each lane will visually depict the steps and decisions for a specific process performed by an actor. The swimlanes can be depicted either horizontally or vertically.

Swimlanes can depict different types of workflow [46]:

- **Sequential**—a simple, orderly step by step workflow
- **Conditional**—in which a decision is involved and determines the subsequent workflow
- **Parallel**—in which one step is followed by two or more steps, each of which stands alone

Various software applications can create the four diagrams (process map/flowchart, data flow, spaghetti, and swimlane diagrams). For example, Microsoft Visio offers features and functionality for drawing and inserting shapes to create these figures.

Selecting Appropriate Methods

Multiple considerations go into the selection of analytic methods for understanding workflow. Research questions and study aims, along with practical consideration of resource availability and constraints, should drive the selection of methods. Quantitative methods are generally most appropriate for answering questions related to the frequency of events or actions, amount of usage of a technology system, and workflow-related metrics. Qualitative methods are typically better suited for study aims related to underlying reasons for workflow choices, the rationale for usage or non-usage of technology, and the impact of technology on collaboration and teamwork. While qualitative and quantitative methods require substantial expertise in methodologies, qualitative methods also require significant resources (time, people) and access to clinical settings and research subjects.

The complexity of workflow demands multiple methods to gain a deep and accurate understanding of workflow. Applying a single research method to a workflow research question will rarely result in a comprehensive understanding of workflow. Whether the selected methods are qualitative, quantitative, or mixed methods, by combining methods, gaps in the understanding of workflow can be filled, unlike when a single method is applied.

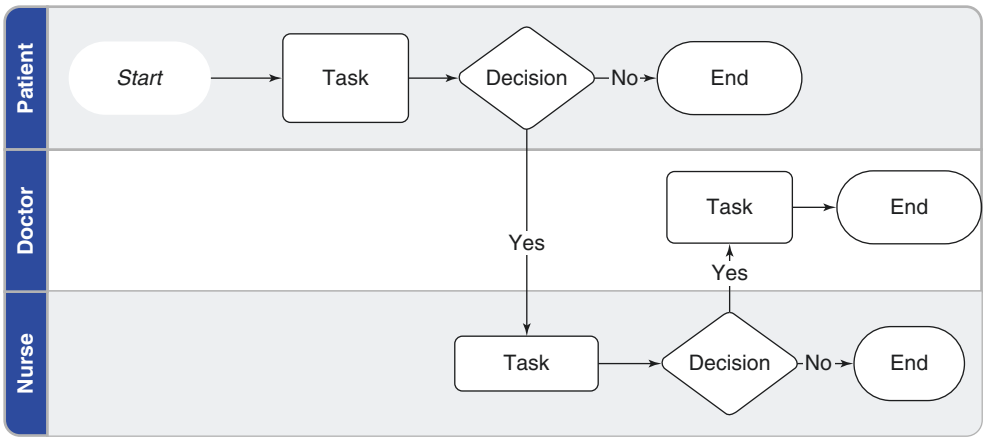

Fig. 8.6 The symbols that comprise a swimlane diagram

The symbols that comprise a swimlane diagram

- Circle – the start or endpoint
- Arrow – the flow of a process
- Cylinder – stored data
- Rectangle – a process
- Diamond –a decision

When designing a workflow study, a critical consideration considers the unit of analysis and the study boundaries. Depending on the study aims, the unit of analysis can range from a subset of roles within a workgroup (e.g., nurses within a single clinic), a specific workgroup of various sizes (e.g., staff, nurses, physicians, and other healthcare team members within a single hospital unit), different groups within one organization (e.g., emergency department and inpatient unit within the same hospital), or multiple organizations (e.g., health information exchange among different hospitals).

Because work crosses many boundaries, once the unit of analysis is established, the study's boundaries also need to be considered. For example, when studying workflow related to care coordination for individuals with diabetes, will a study focus on workflow within a clinic, or will it also consider the individual's home/community? Will aspects of workflow that cross into environments like schools or community pharmacies be included in the data collection and analysis? Accounting for study boundaries is an important aspect of the study design and aids in establishing study transparency.

A final consideration when selecting methods for the study of workflow involves balancing available resources against project aims. Methods such as observation and one-on-one interviews yield a wealth of data and require a significant investment in time and personnel. Methods such as extraction of workflow data from health IT require appropriate technological resources and training on analysis. Workflow studies need to consider what methods contribute to understanding workflow and identify whether adequate resources are available to meet the requirements of specific methods.

Process Redesign

Process redesign opportunities arise due to performance gaps and changes in technology, physical space, or personnel. Process performance can be examined regarding clinical outcomes, patient satisfaction, or operational measures such as utilization and patient waiting time. Performance gaps may be identified based on complaints, compared with similar processes in other units or organizations, or identified as part of a continuous process improvement plan culture. As more data are collected and analyzed in IT systems, new measures can be tracked, yielding additional opportunities

and ideas for process redesigns. For example, by collecting data across different organizational units, Kaiser Permanente discovered that sepsis was the leading preventable cause of mortality. This set forth new clinical guidelines to standardize care, resulting in significant quality improvements [51].

Process redesign can be accomplished by (1) designing interventions (e.g., supportive, social, and technical infrastructures) or (2) changing the building blocks of the process [35]. In this section, we will focus on the latter. Changes to the building blocks of a process include: tasks, people, physical environment, and information (other technologies,) create the opportunity and often a need for process redesign. For example, a move to a new clinic space may be designed to support group visits for patients with common chronic diseases or improve access by providing more examination rooms for additional providers. New information technologies (e.g., new electronic health records (EHR), telehealth, mobile applications) are currently vital drivers to the process of change. Because EHR systems encode specific workflows (e.g., specifying what information needs to be recorded and in what order), those implementing such systems must work with providers to ensure consistency with best practices. In addition, EHR systems support new capabilities, such as tracking and supporting all patients with specific chronic conditions or giving providers access to patient data anytime, anywhere [52]. Patient portals and mobile applications often seek to engage patients more in their health. This means that processes need to be redesigned to support this engagement.

Three process redesign frameworks will be described: (1) System Analysis [53]; (2) Sociotechnical Principles for Redesign [54]; and (3) Systems Engineering Initiative for Patient Safety (SEIPS) [55]. These frameworks overlap with each other but also have different areas of focus.

Karsh and Alper [53] suggest a ten-step work system analysis (Table 8.1). This analysis is based on systems engineering principles. Clegg [54] proposed 19 principles of redesign based on sociotechnical principles (Table 8.2). The SEIPS model highlights five components of a working system and their interplay (Fig. 8.7).

Table 8.1 Ten steps of process redesign as suggested by Karsh and Alper [53]

Step-1: Decide what system will be the subject of the analysis
Step-2: Produce a preliminary workflow map
Step-3: Use the preliminary workflow map to determine who should be represented on the team that will carry out the analysis
Step-4: Conducts an initial scan of the system with the team
Step-5: Put boundaries on the system under study
Step-6: Performance expectations for each step determined
Step-7: Formal data collection to revise and update the workflow map. Gauge the current performance of the system, and determine baseline measures that will be used to evaluate the effectiveness of the redesign
Step-8: Analysis of the data
Step-9: Once hazards (i.e., causes of failure modes or variances) have been identified, control strategies should be developed
Step-10: Analyzing redesign ideas. Deciding on a redesign idea, pilot testing and implementation

Table 8.2 19 principles of redesign by Clegg [54]

1. Design is systemic
2. Values and mindsets are central to design
3. Design involves making choices
4. Design should reflect the needs of the business, its users and their managers
5. Design is an extended social process
6. Design is socially shaped
7. Design is contingent
8. Core processes should be integrated
9. Design entails multiple task allocations between and amongst humans and machines
10. System components should be congruent
11. Systems should be simple in design and make problems visible
12. Problems should be controlled at source
13. The means of undertaking tasks should be flexibly specified
14. Design practice is itself a sociotechnical system
15. Systems and their design should be owned by their managers and users
16. Evaluation is an essential aspect of design
17. Design involves multidisciplinary education
18. Resources and support are required for design
19. System design involves political processes

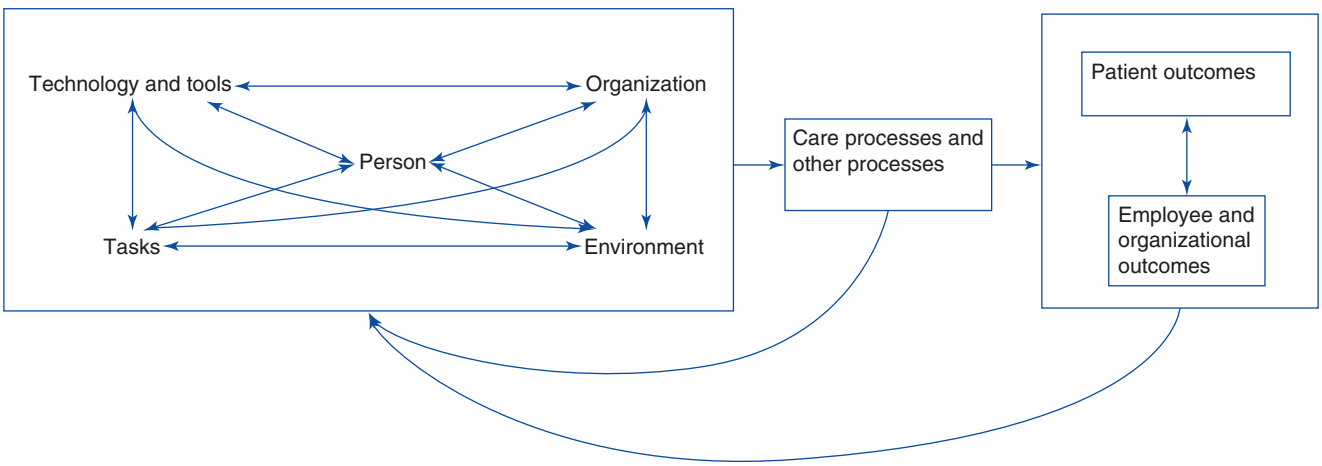

Fig. 8.7 The Systems Engineering Initiative for Patient Safety (SEIPS) model

Applying systematic approaches to process redesign increases the likelihood that desired goals will be achieved. These guidelines can mitigate the following common problems that can occur. First, the solutions implemented may not address the real cause of a process issue. Second, the scope of the change may not be significant enough to achieve the desired goals or so broad as to be unwieldy (or outside the control of those seeking to make the change) [56]. Third, efforts at redesign (which often focus primarily on tasks and activities) may not address the need to redesign roles and incentives or provide sufficient infrastructural support [56]. In particular, the resources provided for implementation may not consider ongoing investments needed to sustain a new process, such as the need for additional training or refining a new EHR feature. Finally, process redesign requires the commitment of leadership. Leadership must recognize participants and support the time and effort to develop a redesign, and be willing to consider implementing suggested changes. Lack of leadership commitment is often cited as a critical element of implementation failure. Several process redesign and quality improvement approaches have been used to address these problems.

Quality Improvement in Health Care

Quality improvement (QI) encompasses methods grounded in the concepts of continuous process improvement and workforce engagement and is used extensively in healthcare to enhance process delivery and performance. Quality in health care has been defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [57]. In a landmark publication in 2001 that developed an expanded concept of quality, the Institute of Medicine outlined six aspects of the healthcare system that could be improved to create a higher quality system, including safety, effectiveness (defined as providing services based on scientific knowledge and refraining from providing services that are not likely to add benefit), patient-centeredness, timeliness, efficiency, and equitability [58].

Defined in this context, QI encompasses clinical outcomes and patient satisfaction, and access to care. Donabedian [59] theorized a three-part approach to quality assessment and improvement, suggesting that (1) an appropriate structure (the attributes of the setting in which care occurs) increases the likelihood that (2) good processes for giving and receiving care will yield (3) better outcomes. Workflow and process redesign efforts seek to create the structure and processes that improve performance, build an understanding of the relationship between process and outcomes, and thus support QI. Informatics and process interventions can reinforce one another, creating new capabilities that can yield better outcomes. The increasing amount and variety of data available can be harnessed to boost quality management efforts.

Important Quality Improvement Frameworks

Several types of QI models are used in healthcare settings. They share several standard features, including iterative cycles of improvement, an emphasis on data-based decision-making, quality tools (such as flow charts or other visual process descriptions), active engagement of frontline staff, and the need for leadership commitment [60].

Plan-Do-Check-Act

One of the most popular methods to guide quality improvement cycles in clinical settings is a Plan-Do-Check-Act (PDCA) or a Plan-Do-Study-Act (PDSA) approach. This approach is also known as the Deming Cycle or the Deming Wheel, named after W. Edwards Deming, a leader in the field of QI. As with all QI methods, the PDSA cycle encourages a methodical approach that emphasizes understanding issues before jumping to potential solutions [61]. For example, a problem is identified in the "Plan" phase, and potential solutions are developed. For example, a solution might involve a change in process design. Fishbone diagrams, also cause-and-effect diagrams, might be used as a starting point for root-cause analysis to understand how potential system elements (e.g., personnel, technology, environment, methods) might contribute to the problem. In the 'Do' phase, potentials solutions are developed, and pilot testing may be carried out. During the 'Study' or 'Check' phase, the proposed change is undertaken to determine success. In this step, qualitative and quantitative evidence is gathered to evaluate the change. In the final 'Act' phase, the proposed solution is either adopted into routine work, abandoned, or adjusted (after going through another PDSA cycle).

While the PDSA cycle forms a foundation for continuous quality improvement, it is focused on testing changes. It is more effective in an infrastructure that ensures that significant problems are addressed, and QI efforts are sustained. For example, the PDSA cycle is one component of the Model for Improvement [62], which includes a second component that requires understanding the overall aim for the project and defining how a "successful" change will be determined. Other studies have found that one PDSA cycle is often used in isolation [63] rather than in a sequence of iterative cycles and that sustaining and spreading changes is difficult.

Lean and Six Sigma are two additional, commonly used QI methods that build from and use the PDSA cycle. These approaches include other philosophies and structures that support problem definition, measurement, and sustainability. Table 8.3 compares the Lean and Six Sigma approaches described in more detail below. Many health care organizations blend these approaches as part of an overall Lean Six

Table 8.3 Lean and six sigma comparison

	Lean	Six Sigma
Goal	Eliminate waste, improve flow	Reduce variation, eliminate defects
Methodology	A3 problem-solving, which involves: 1. Defining the problem or gap in performance 2. Understanding the current process 3. Determining the root causes of the problem 4. Developing actions to address root causes 5. Implementing the plan 6. Collecting follow-up data Steps 2–6 are carried out as a series of cycles until the desired target is met.	DMAIC Problem-Solving: D—Define M—Measure A—Analyze I—Improve C—Control
Underlying principles	Define value and the value-stream, eliminate or reduce activities that hinder process flow, pull work through a process based on customer demand, seek perfection	Six Sigma emphasizes continuous improvement, but is also a toolkit and a measure of quality Data and numbers are valued
Tools and methods	Process mapping, spaghetti diagrams, identifying 7 types of wastes, 5S (workplace organization), root cause analysis/fishbone diagrams, standard work definition, results boards	Similar tools to lean, but emphasizing more statistical and quantitative approaches such as statistical process control and failure modes and effects analysis (FMEA)
Infrastructure	Kaizen events—a short-term event that brings stakeholders together to understand root causes and develop responses Lean management system—a management approach that focuses on alignment with organizational goals (called the *True North*) and understanding the daily work of frontline staff	Dedicated improvement team, with black and green belt personnel trained in six sigma methods to support project

Sigma program, employing the most appropriate frame depending on the issue being addressed.

Lean Methods

Lean is a QI strategy that emphasizes value and process from a customer perspective, respect for people, and continuous improvement [60, 64]. The **Lean** philosophy and its supporting principles originated with Toyota in the automotive industry [65]. These principles have been employed extensively to improve process performance in a variety of industries and include: (1) identifying the value a process provides; (2) mapping the value stream, or the set of activities and tasks making up the process; (3) improving process flow, by eliminating activities that do not add value, standardizing work, or removing disruptions from the process (such as an error, which must be reworked); (4) creating pull so that the process produces what is needed by the customer when it is needed; and (5) achieving perfection, by continuously improving the process [65].

The use of **Lean** in healthcare settings has grown dramatically in the past 10 years. It is one of the most widely used QI models in the US **Lean** is used in healthcare both as a strategy for improvement across the entire organization and an effective approach for supporting the implementation of specific practices and activities within a practice setting [66]. Several healthcare organizations have used **Lean** to achieve significant operational improvements, including Thedacare, Virginia Mason, Cleveland Clinic, and Intermountain Healthcare [67, 68]. At Thedacare, Touissant and Berry [69] augmented traditional **Lean** philosophies to include unity of purpose or tie individual projects' goals to broader organizational goals and visual management.

Lean includes a diverse range of tools that are used to implement the underlying principles. These tools include methods that support process design and management approaches that provide infrastructure for ongoing improvement. One commonly used tool is an A3, or A3 problem-solving [61, 70]. A3 is a plan for solving an identified problem and a structure for moving through continuous improvement cycles (PDSA cycles) to achieve the desired goal (Table 8.3).

The A3 problem-solving process is often facilitated through workshops that bring together relevant stakeholders to understand a problem and generate solutions. These are called *Kaizen* events or rapid process improvement workshops [71].

Other tools support specific problem-solving steps. For example, *value-stream mapping* or other process mapping approaches can be used to identify the specific activities in a process, to understand how each contributes to providing value [72]. Often both the current state of the process and a desired future state are mapped. Tools such as fishbone diagrams are also commonly used to explore the underlying causes of issues. In developing solutions, creating a standard approach to carrying out a process (i.e., *standard work*) is often used to reduce variation [65]. As solutions are tested and measured, a *results board* is updated to visually display the outcomes in a prominent location [61].

To support sustainability and a culture of continuous improvement, healthcare organizations may use **Lean** to guide their overall management approach, defining organizational goals and seeking to align activities with these goals [61]. Such systems also define standard work for managers, including activities such as:

- *Gemba walks*: where the redesign team travels on-site to see the actual process and understand issues by talking with those who do the work; and
- *Huddles*: daily, brief meetings that often occur in front of a results board. This brings staff together to keep them up to date on the activities of their work area and enables them to raise and address issues as they occur, preventing more significant problems from developing [61].

Six Sigma

As with Lean, **Six Sigma** has elements focused on problem-solving at the project level and infrastructural elements that support sustaining a QI effort and impacting organizational performance. In terms of infrastructure, Six Sigma programs include rigorous training for Six Sigma practitioners, called Green Belts and Black Belts, who support project teams engaged in QI efforts [61]. Teams include a champion who sponsors the project and ensures there is management support and commitment for projects.

At the project level, problem-solving is guided by a process that involves [61] five phases or stages:

1. Define—spell out the goal of the project and determine who will be part of the project team
2. Measure—collect data to determine how the process or system is currently operating
3. Analyze—examine the data to understand what underlying factors may influence measures and current process performance
4. Improve—based on the analysis, develop potential solutions and test them, which is often done using a PDSA cycle, measuring improvements and comparing them to the baseline performance captured in the Measure phase
5. Control—implement changes and monitor them to ensure that they are sustained.

In a **Six Sigma** project, QI tools such as process mapping are often employed. However, the Green or Black Belt experts assigned to the project also know how to design more sophisticated experiments to test and analyze results. As increasing amounts of data are collected through EHR systems, sensor-based devices, and patient-facing applications, new analysis methods and data science experts are likely to be part of lean six sigma projects [66].

Important Components of Quality Improvement

Learning to deliver existing therapies and care more effectively can improve patient outcomes more shortly than new treatment discoveries [73, 74]. Therefore, improving quality is a critical aim for most health care delivery organizations, and they have initiated QI studies using various approaches. The impact of such programs often yields different levels of success [75]; common challenges include sustaining changes, focusing on piecemeal projects that are not linked to system-wide efforts, and emphasizing tools with less emphasis on culture and behavioral change [71]. The unique features of organizations make it impossible to develop prescriptive rules for success [75]. However, there are five principles common to successful projects:

1. Participation and teamwork
2. Leadership
3. Being data-driven/data monitoring and dashboards
4. Focusing on value-added activities and
5. Embracing continuous improvement

Emerging Trends

We identified two significant emerging trends that will be central to workflow, process redesign, and quality improvement: (1) Workflow in the era of data science and artificial intelligence; (2) Workflow for patients.

Workflow in the Era of Data Science and Artificial Intelligence

Recent developments in data science and artificial intelligence (AI) provide new opportunities and challenges for informatics researchers and practitioners [76, 77]. These opportunities are better leveraged with the availability of new data sources, including sensors and EHR. State-of-the-art AI applications, however, will not reach their full potential unless they are integrated into clinical workflow [78]. However, multiple barriers include data privacy concerns, algorithm transparency, data standardization, interoperability, and patient safety concerns. Workflow studies that consider the fragility of AI models in real-world, heterogeneous, and noisy clinical environments are critical to integrating AI systems into clinical decision-making.

As the use of AI becomes more mature in health care settings, it can also improve clinical workflow by providing predictions (e.g., whether the patient in ED will be admitted or discharged [79]) to users or auto-configuring information systems by sensing the current situation.

Workflow for Patients

As more health activities are conducted in the home and community settings, health systems require a better understanding of how these and traditional care settings (hospitals

and clinics) are connected [19, 20]. Capturing daily living as a workflow can inform consumer informatics interventions [80, 81].

Summary

Workflow can be defined as the flow of work through space and time. Workflow is a crucial component of the design and implementation of health informatics interventions. Therefore, a misfit between workflow and the intervention will lead to inefficiencies and potential patient safety concerns. To better understand the term workflow, we provided a survey of methods to capture and analyze workflow. These methods include qualitative, quantitative, visualizations, and statistical approaches. We further provided a survey of process redesign, which included three process redesign frameworks. A survey of quality improvement in health care with three frameworks for performing quality improvement was provided.

Application Exercise/Questions for Discussion

1. What is the difference between the ostensive and performative aspects of routines? How do these differences impact workflow?
2. What kinds of workflow questions are suited to study qualitatively versus quantitatively?
3. What are some barriers to using data generated routinely through work activities (e.g., EHR usage logs) in understanding workflow? Why might this type of data analytics still help study workflow?
4. How can workflow-related analysis be used in a Learning Health System? Is workflow an essential consideration in a Learning Health System?
5. Could you give an example from your clinical expertise in which
   (a) Designed workflow
   (b) Actual workflow and
   (c) Are perceived workflow different? How are they different?

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9 Human Factors Engineering and Human-Computer Interaction: Supporting User Performance and Experience

Richard J. Holden, Ephrem Abebe, Jordan R. Hill, Janetta Brown, April Savoy, Stephen Voida, Josette F. Jones, and Anand Kulanthaivel

Learning Objectives

- Understand how human factors engineering (HFE) and human-computer interaction (HCI) are defined and why they are essential to the success of clinical informatics.
- Identify models, theories, and principles of HFE and HCI that can design and evaluate various clinical informatics systems.
- Describe the processes or practices used by HFE and HCI professionals to design and evaluate a system for usability (including effectiveness, efficiency, and satisfaction).

Practice Domains: Tasks, Knowledge, and Skills

- K033. User-centered design principles (e.g., iterative design process)
- K034. Usability testing
- K065. Models and theories of human-computer (machine) interaction (HCI)
- K066. HCI evaluation, usability engineering, and testing study design and methods
- K067. HCI design standards and design principles

Case Vignette

Dr. Davis is a primary care physician whose clinic recently implemented the HiTech electronic health records (EHR) system, a product billed as "fast and powerful," and housing "all the features you need." HiTech representatives claim that their EHR system is "user-friendly" because it is "aesthetically pleasing and intuitive"; after all, its look and feel were designed by an artistically gifted graphic designer.

Dr. Davis appreciates a stunning display but notices a slowdown in her work as she starts to use the system. She has trouble finding information, especially past medications, which she has to find by scrolling and advancing the page ("Next"). Allergy information is available but only by clicking another tab. Another click shows the severity of each, one by one. Nurses' notes cannot be read side-by-side with the discharging physician's note or laboratory values. The lab values themselves can be plotted over time, but only one at a time, which sometimes leaves Dr. Davis switching back and forth between graphs. The graphs can be saved to be retrieved from a screen inaccessible during order entry. She would print the lab values and charts, but her clinic has disabled printing to "go fully paperless." Dr. Davis has also stopped using the graphic icons for shortcut commands after having clicked one (a computer with a green checkmark) that logged her out of her session and another that looked like a standard web browser "refresh" but-

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ton, but that wiped and restarted her complex clinical note. The buttons are meant to save time, leading to actions directly, without a confirm-or-cancel prompt.

When entering orders, Dr. Davis finds herself doing a lot of typing. The autocomplete feature under medication orders is helpful. Still, it often defaults to the first few items on the list, and the list of options is long, with subtle variations between options depending on dose, route, and timing of administration. A tentative typist, Dr. Davis, looks at the keyboard when typing. She remembers once entering the wrong vowel and then selecting the wrong medication. Luckily, she caught it when the medication was flagged in a drug-drug interaction alert. However, instead of editing the order, she had to delete it and start over.

In some cases, especially for radiology orders, the names of options are so long and detailed that they are truncated. The display is designed so that hovering over the order with the mouse cursor provides the full name, but Dr. Davis does not know this, as intuitive as it was for the designer. Instead, she uses trial and error: clicking on the truncated option, look at the readout, delete if wrong. Deleting for her means hitting the backspace key to wipe the whole line of characters, one by one. This leads to a lot of eye-rolling by her younger patients.

As frustrated as she is, Dr. Davis most regrets the uneasy feeling that she will make a mistake. Already, she knows she once failed to fill a checkbox because she did not click close enough to the box, chose the wrong patient from an alphabetically sorted list (and began to write an order for the wrong Mr. Smith), duplicated a radiology order because she failed to scroll far enough, entered 20 packages instead of 20 pills under quantity, saved a draft note but was never alerted to return to it after being interrupted, and missed an electronic message from 5 days ago about a patient's upcoming surgery. Dr. Davis fears that as her work pace increases, she will make more mistakes and be blamed for it because the system is supposedly "user-friendly." "Well, it's not my friend," she laments as she spends her evening at home reviewing the day's orders for mistakes that could have been avoided with better interface design.

Introduction

Human factors engineering (HFE) and **human-computer interaction (HCI)** are scientific and professional disciplines with shared histories and practices that aim to *support people's performance and experiences by optimizing human-system interactions*. An important application of HFE and HCI is the design and evaluation of interactive computing technologies across domains, including healthcare, to ensure their **usability**, defined as "the extent to which specified users can use a product to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [1].

The principal HFE/HCI approach for achieving system usability is **user-centered design (UCD)**. National reports and regulations promote HFE, HCI, and UCD for electronic health record (EHR) systems and other clinical informatics systems. They argue that doing so will increase the likelihood that EHR system use will improve healthcare quality [2], prevent rather than promote errors and harm [3] or healthcare disparities [4], and facilitate the adoption, diffusion, and successful implementation of EHR systems [5], while yielding a positive return on investment [6]. After many years of EHR system usability being disregarded or deprioritized [7], it is now at the forefront. The Final Rule of Meaningful Use Stage 2 (45 CFR Part 170) requires that EHR system vendors demonstrate a UCD process in ensuring their product's usability and safety-enhanced design. In 2014, the American Medical Association released a statement expressing concern over EHR system usability and listed eight usability priorities toward achieving high quality and affordable healthcare [8] (see Box 9.1). The growing need for the usability of health information technology (IT) such as EHR systems is echoed by national entities and individual clinicians, many of whom have experienced the kind of issues described in Dr. Davis' case vignette. Fortunately for Dr. Davis, others like her, and their patients, health IT usability is the product of good design and testing, achieved through UCD principles and processes that have been developed and described by HFE and HCI professionals. Further, the emerging literature offers guidance for applying these principles and techniques to health IT [6, 9–11].

Box 9.1. Eight EHR Usability Priorities

As proposed by the American Medical Association [8], usable EHRs should:

1. **Enhance physicians' ability to provide high-quality patient care.** EHRs should be designed to promote effective communication between patients and physicians and not distract physicians from patients.
2. **Support team-based care.** EHR design should facilitate clinical staff to perform work as necessary and allow the dynamic allocation and delegation of work to appropriate care team members.
3. **Promote care coordination.** EHRs should automatically track referrals/consultations and ensure the referring physician can follow the patient's progress and activity.
4. **Offer product modularity and configurability.** EHR design should be flexible to meet individual practice requirements.

5. **Reduce cognitive workload.** EHRs should support medical decision-making by providing concise, context-sensitive, and real-time data.
6. **Promote data liquidity.** EHRs should be interoperable across different venues (e.g., hospitals, ambulatory care settings, laboratories, pharmacies, etc.). Users should export data, and external data should be properly incorporated into the patient record.
7. **Facilitate digital and mobile patient engagement.** EHRs should be interoperable with a patient's mobile technology.
8. **Expedite user input into product design and post-implementation feedback.** Incorporate the feedback of end-users to improve the design of the product.

Putting HFE and HCI in Context

Table 9.1 presents formal definitions and key attributes of HFE, HCI, and related concepts. Of note are HFE/HCI's person-centered, systems-oriented perspective and the dual goal of improving human performance and experience (or, more broadly, wellbeing). In this chapter, we focus on HFE and HCI contributions to enhancing clinical information system usability; however, there are numerous other applications of HFE and HCI in healthcare in areas such as process mapping and redesign, cognitive task analysis, technology implementation, and change management, patient and employee safety, risk assessment, workload measurement, teamwork training, and simulation [12].

Table 9.1 Definitions of key terms and concepts

Human factors engineering (HFE) aka ergonomics—"the design and engineering of human-machine systems for the purpose of enhancing human performance" [13]. HFE is systems-oriented, design-driven, and has a dual goal of improving performance and wellbeing [14]
Human-computer interaction (HCI) aka Human-centered computing—"a discipline concerned with the design, evaluation and implementation of interactive computing systems for human use and with the study of major phenomena surrounding them" [15]
Usability—"the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [1]. Nielsen [16] decomposes usability into the system's learnability, efficiency, memorability, error avoidance and recovery, and satisfaction of use; others add usefulness, effectiveness, and accessibility [17]. Usability is the primary goal of professionals known as usability engineers
User-centered design (UCD) aka human-centered design—an iterative, multidisciplinary process of product design and evaluation that considers and designs to support people's tasks, skills, abilities, limitations, creativity, needs, and preferences [1, 18]. UCD is based on a clear understanding of users and actively involves them or their representatives in the evaluation of products (user testing) and sometimes in their design (participatory design)
Human performance—the physical, cognitive, and social-behavioral transformations that result in outcomes to the patient, clinician, organization, and beyond [19, 20].
User experience (UX)—"a person's perceptions and responses that result from the use or anticipated use of a product, system or service" [1]. User experience often refers to characteristics of a computer or device beyond the strictly functional aspects of the system (e.g., aesthetic concerns) [21]
User interface (UI)—the objects, individually and in aggregate, with which a user interacts, primarily the system's display that users perceive and the controls with which users manipulate the system

HFE and HCI Models

A general type of contemporary HFE/HCI conceptual model is a **sociotechnical systems model** or **work system model**, depicting interactions between people and other social, technical, and environmental elements. Figure 9.1 illustrates one such model [22], SEIPS 2.0 (SEIPS originally meant Systems Engineering Initiatives for Patient Safety); for other such models, see Carayon [23], and for a simplified version called SEIPS 101 and seven accompanying tools for its use, see Holden and Carayon [24]. Four main points regarding technology can be gleaned from the SEIPS 2.0 model in Fig. 9.1:

- **A system is comprised of many components**: technology use occurs in context [25].
- **The elements interact**: the person-technology interaction is vital, no person or technology alone.
- **The person is in the center**: technology should be designed to fit people, not the other way around.
- **The system produces and shapes work processes, which shape outcomes**: achieving improved outcomes requires that technologies support work performance [19].

Following the dictate "know thy user," early HFE and HCI models attempted to understand how people think and process information to design technologies that "fit" their users [26]. Drawing on approaches commonly used in engineering psychology, these early models applied the concept of **task decomposition** to break down complex information process activities into their constituent parts and then to experimentally determine people's capabilities and limitations related to these atomic operations—characteristics such as working memory capacity and average memory retrieval times [27]. Based on these models, techniques like the keystroke-level model [27] and the GOMS ("*G*oals, *O*perators, *M*ethods, and *S*election rules") family of analysis techniques [28] were developed to enable usability engineers to decompose a person's use of an interactive system into the smallest possible

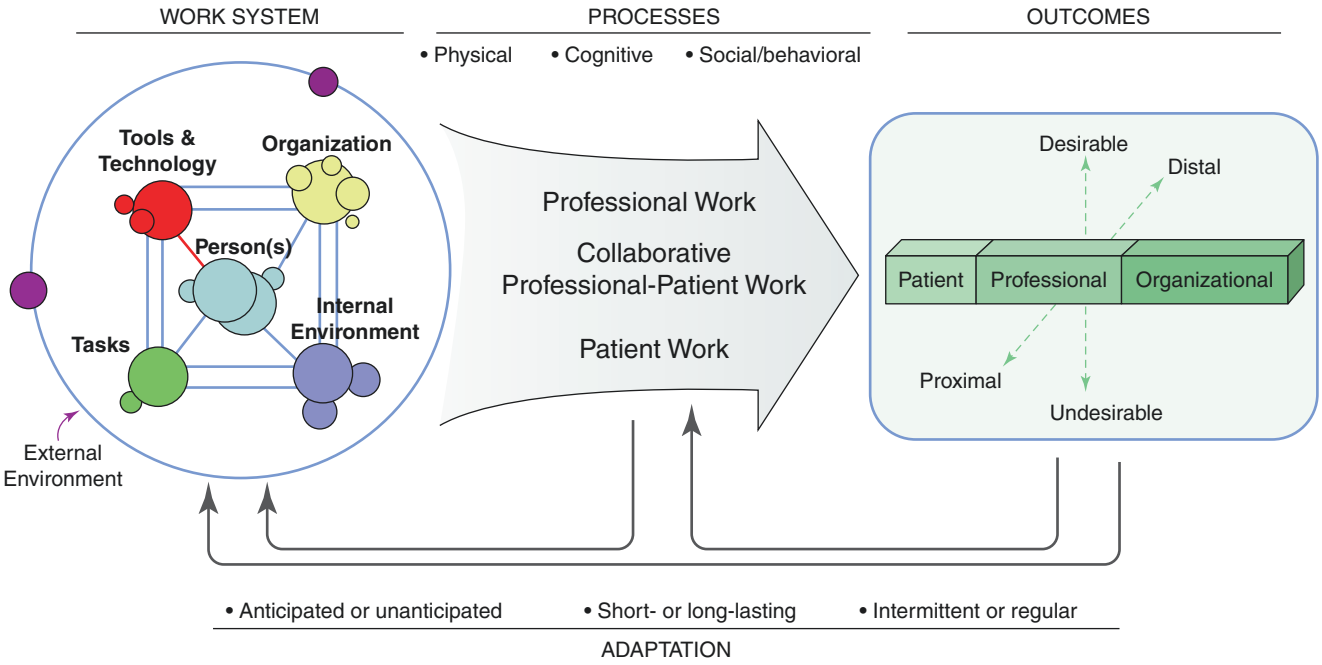

Fig. 9.1 SEIPS 2.0, a sociotechnical systems model developed for healthcare (adapted from Holden et al. [22])

units and uncover the trade-offs of taking different actions to achieve the same outcome, e.g., Dr. Davis in the vignette deletes a line of text character-by-character; Dr. Davis might use the mouse to highlight and delete. The keystroke-level model approach and automated GOMS tools can calculate the time and accuracy for different system use; the outputs from these techniques can be used to compare different use strategies or designs quantitatively.

Among models attempting to understand human cognition, i.e., how we perceive, think, and remember, some of the most commonly used depict humans as information processing systems [29, 30]. These Information Processing Models often describe how inputs, or stimuli, are processed through stages such as sensation, perception, cognition, and action, thus resulting in some kind of output such as a decision or behavior. Short-term and long-term memory and systems are described as supporting these stages, and a limited pool of attention resources is said to exert executive control over them [30]. Figure 9.2 depicts this model as applied to a clinical decision support warning. Of note:

- Sensation is not the same as perception. Perception involves processing raw sensory stimuli or "knowledge in the world" into something meaningful, based on existing "knowledge in the head." Thus, perception is both a bottom-up *and* top-down process, meaning that a given stimulus can be interpreted differently based on prior experiences, expectations, amount of attention allocated to the task, and users' mental models [30]. Mental models are relatively stable individual people's representations of how the world works or how specific objects in the world work [31]. Even if the actual stimulus is not consistent with one's mental model, humans sometimes process it as if it is and perceive things differently from how they are.
- Perceived items are mapped onto and interpreted against existing knowledge stored in long-term memory. Again, one's mental model influences how one interprets perceived objects or situations. Importantly, when a user interface or its behavior (e.g., flashing text means that something is "ready") is inconsistent with one's mental model (e.g., flashing text implies that something is "loading/not ready"), confusion ensues, and usability suffers [32].
- Information being processed can be incompatible with one's memory, for example, because it does not match any prior experiences or knowledge in long-term memory or exceeds the finite and time-limited short-term memory capacity. This can result in errors in cognition and is prevented by presenting familiar information, reducing memory load, or not requiring memory use and instead of making more accessible any information that needs to be used. Furthermore, cognitive processes, especially short-term memory, are susceptible to failure when attention is drawn away or "depleted" in a finite-resource depiction of memory.
- The last stage in information processing is usually the execution of a decision through action. Actions can be verbal or physical, the latter being the most common way to act on health IT. The time it takes to carry out an activity in a user interface is described by the Hick-Hyman Law and Fitts's Law. The Hick-Hyman Law states that

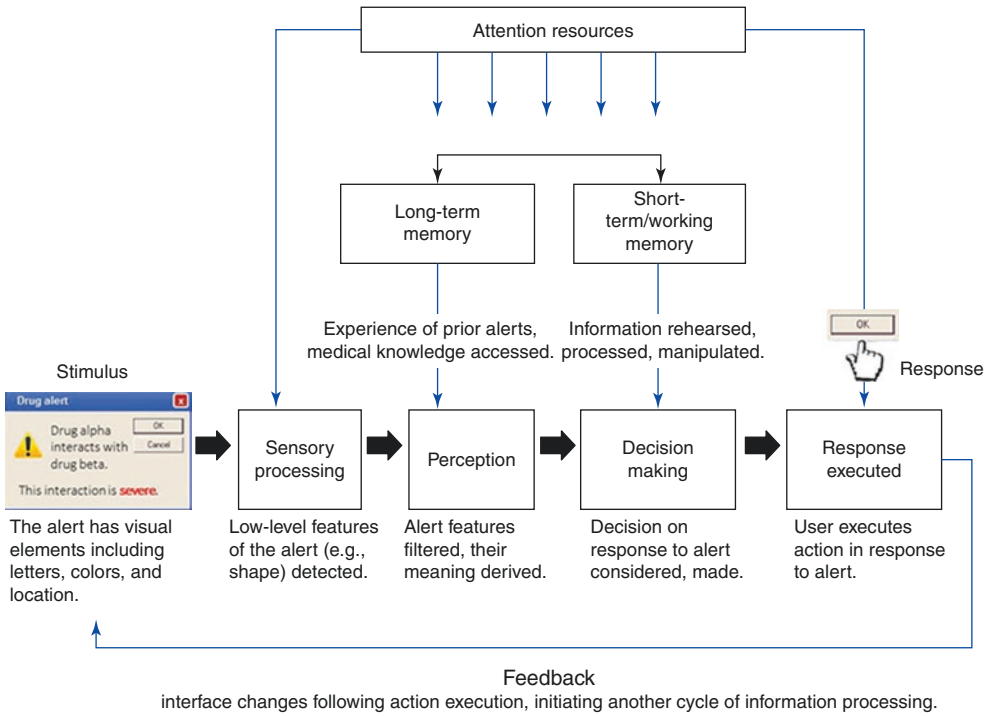

Fig. 9.2 Information processing model applied to clinical informatics (based on Wickens et al. [30])

given the rate of human information processing, the time to decide and act on something, T (e.g., click on the correct link), increases logarithmically with each added object, n (e.g., number of links on the page). Reaction time can be manipulated using, for example, color, highlighting, or reducing the set of objects under consideration.

$$T = b \cdot \log_2 (n+1)$$

- Fitts's Law states that the time to move to an object, MT (e.g., move a mouse cursor to the button), increases logarithmically as distance to the object increases, D, and the object's width decreases, W.

$$MT = a + b \cdot \log_2 \left(\frac{2D}{W} \right)$$

- In addition to these laws, which guide the design of user interface objects, a common principle of information processing is that there is a trade-off between speed and accuracy; however, despite the trade-off, proper user interface design can improve both speed and accuracy, for example, by optimizing the spacing between objects and using graphic elements to highlight items.

Other models focus more on how people interact or communicate with systems. Norman's [33, 34] *seven stages of action* are an HCI model that frames human-computer interaction as a dialog. This dialog encompasses two broad processes: first, the process by which people articulate their goals to a computing system, that is, how they translate their (mental) goals into actions that can be performed on (or with) the inputs, controls, or options offered by the system (e.g., what button to press to order a test). When this process breaks down, for instance, a user cannot find an appropriately labeled control or cannot click something on the main page when a pop-up comes up, Norman's model describes the breakdown as a failure of the system to bridge a "gulf of execution successfully." This situation suggests a careful re-examination of the controls or inputs that a system offers based on the anticipated tasks for which the system will be used. The second part of the model represents the other half of the dialog: how people perceive and interpret the feedback provided by a system, including whether or not they can determine if their goals have been met (e.g., whether the requested test was successfully ordered). When this pathway fails (e.g., the "gulf of evaluation" opens up), it suggests opportunities for re-examining the design of displays, system feedback, or the content of error messages.

Zhang and Walji's [10] TURF framework is grounded in HFE/HCI but explicitly created for EHR system usability. It defines EHR system usability as the degree to which an EHR system can be helpful, usable, and satisfying when used for clinical care. Usefulness refers to whether the EHR system has the functionality to support its users' work requirements. Usability refers to the EHR system's learnability, the efficiency of use (i.e., the effort to performance ratio), and error

tolerance. Satisfaction is the user's subjective evaluation of their EHR system use. All three components can be measured quantitatively and qualitatively through either assessment of the EHR system or self-report. Like the work system model, TURF posits that well-designed technologies are ones that efficiently and effectively support users' actual performance of work processes, not merely ones that are attractive or liked by users.

HFE and HCI Practices

The ISO standard defining human-centered design for interactive systems, ISO 9241-210 [1], is based around a series of UCD principles, including:

- Designs are based upon an explicit understanding of users, tasks, and environments;
- Users are involved throughout the design and development process;
- Designs are driven and refined by user-centered evaluation;
- The process is iterative;
- Designs address the complete user experience; and
- The design team includes multidisciplinary skills and perspectives.

The first four of these points define the *process* by which HFE and HCI practitioners structure their work. Other articulations of this process [30, 35–37] characterize the UCD design process as an ongoing cycle of three phases: study, design, and evaluation [38] (see Fig. 9.3):

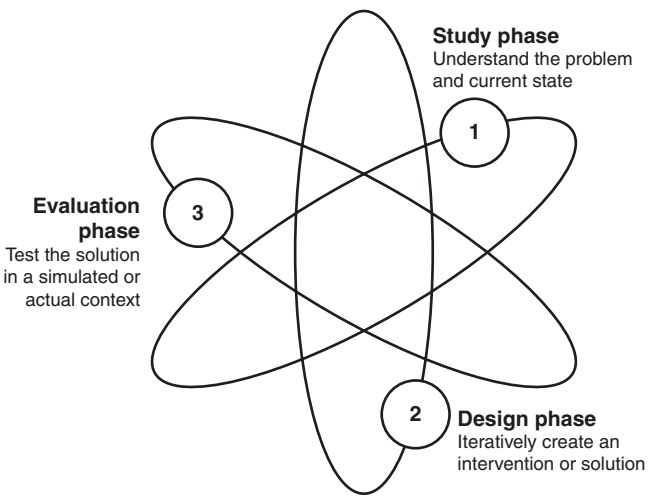

Fig. 9.3 The three iterative phases of human-centered design and evaluation (based on Holden et al. [38])

- First, HFE and HCI practitioners seek to *understand* the tasks the system will support, its users, their goals, and various aspects of the surrounding environment, including the social, organizational, technical, and physical context in which a system will be used. This part of the process is also called user needs analysis, requirements engineering, or, more generally, field study, and can be done in many ways [39]. It often requires that the members of the design team work directly with people who represent the system's anticipated user base, and can include face-to-face or telephone interviews and focus groups, surveys and questionnaires, in-person observation of a work environment, also known as a "contextual inquiry" [40], or—in many cases—some combination of these techniques [21].
- Based on this background research, practitioners then move into a *design* phase. The designs created during this phase can range from abstract representations, including personas reflecting key attributes and goals of anticipated stakeholders, descriptive use cases and scenarios, and detailed cognitive and behavioral models of users [40, 41], to more traditional artifacts, such as sketches, "wireframe" user interface mockups, storyboards, physical prototypes, video walkthroughs, simulations, or early system implementations [42–44]. During the early phases of a UCD design process, these designs can often be informal, "sketchy," or incomplete and are intended to serve as both evolving representations of the intended final design(s) as well as props that facilitate communication within the design team, with intended users of the system, and with members of the broader development organization (professional programmers, marketing and sales teams, and management executives) [45].
- Finally, practitioners transition to the *evaluation* phase for the designs. There are various approaches to evaluation, presented in summary format in Table 9.2 with suggestions on when each is generally used. Sometimes, HFE and HCI professionals carry out the evaluations themselves, called "expert review," assessing the usability of the designs based on established heuristics or principles [16]. Experts can also conduct low-level "cognitive walkthroughs" that model users' likely mental goals at each step of a system interaction [46]. In other cases, practitioners show the designs (or, in some cases, deploy the partially- or fully-implemented systems) to people who will represent the final system's users, intending to elicit more direct feedback about the designs' usability and usefulness. These usability tests can be controlled and formal (e.g., laboratory tests that assess the amount of time required to complete specific tasks and the number and types of errors made) or more qualitative and open-ended. For example, A/B user tests ask individuals to select from two or more design options they prefer or would most

Table 9.2 Summary of usability evaluation techniques

Evaluation technique/tool	Definition	Who	When
Ethnographic Studies	Researchers meet and observe end-users in in the environment in which they would use the product/service of interest. Data is used to gain information about the users, the tasks they need to complete, and the scenarios in which they will use the product/service	Researchers who are in the initial stages of (re)designing a product/service. As many members as possible on the design team should go on a "customer visit" during the design process to gain contextual information on their product/service	Used early in the (re)design of a product/service
Focus Groups	A group of end-users (generally 3–12) are led through a discussion on a topic of interest or to evaluate initial design concepts. Allows design teams to elicit in-depth feelings and judgements from a group	Design teams who want to elicit in-depth, qualitative information about design concepts. A moderator leads the focus group discussion	Used early in the design of a product/service
Surveys	Used to elicit responses on topics of interest from a broad base of users. Data is less in-depth than other methods, but larger samples can be used to generalize information to an entire population of users	Design teams or researchers who want data on a general aspect of their user population	Most used in the early design stages, but can be used throughout the design process
Participatory Design	A design team includes one or more end-users on the design team to leverage their skills, knowledge, and reactions to designs	Design teams, including one or more end-users	Throughout the design process
Cognitive Walkthrough	A design team follows a user's route through the use of a product or service. Can be done by the design team, or an end-user can be brought in to document any difficulties or concerns with the current design	Design teams who want to evaluate the steps required or workflow to accomplish a task using the product. A moderator may be used to guide an end-user through tasks	Used in the early design stages when an initial design/prototype is available
Heuristic Evaluation	Review of a product or system according to accepted usability principles, human factors literature, and the evaluators professional experience	Evaluation done by a human factors or usability specialist. It is preferable that this specialist has minimal involvement in the project	Used in the early design stages when a design/prototype is available
Usability Testing	Collection of empirical data through observation of end-users using the product in realistic ways. Exposes usability deficiencies in the product. Data collected can be both quantitative and qualitative	A moderator will guide participants through the performance of tasks. Both the moderator and other observers take note of usability issues encountered	Used in early stages to test prototypes and later in the design process when a more mature product/service is available to test

Source: Nielsen-Norman Group (www.nngroup.com) and Rubin and Chisnell [17]

likely use, then probe how they arrived at their choice. In tests of interactive systems, usability professionals can track eye movements and keystrokes. Software such as Morae (TechSmith; Okemos, MI) and Lync (Microsoft; Redmond, WA) allow evaluators to remotely monitor test users' actions, to take real-time notes and screen captures, and to manipulate the interface (e.g., to assist the user or introduce a new message). Due to the decrease in user burden for scheduling and travel, the remote usability testing option is gaining momentum in healthcare [47]. It allows users to participate in evaluations without leaving their desks and lets them use their hardware.

Of note, the National Institute of Standards and Technology (NIST) provides a template for reporting the results of EHR usability tests [48], based on the ISO/IEC standard industry format [49]. Furthermore, several measures for user-reported subjective usability, such as the System Usability Scale [50]. The evaluation phase's outcome often helps refine the practitioners' *study* of how people are likely to interpret, use, and appropriate the new technology or technologies, which then lead to further iterations of the *design* and *evaluation* activities.

The ISO standard also encourages UCD teams to incorporate diverse, multidisciplinary perspectives. Practically speaking, this is often a necessity, as few practitioners possess the full breadth of skills required to support an end-to-end UCD process: expertise in collecting and analyzing qualitative and quantitative user data, aptitude in behavioral and cognitive modeling, interface design, and technical communication skills, the ability to implement interactive systems, and knowledge of formative and summative usability evaluation techniques. Furthermore, when a diversity of viewpoints and backgrounds are brought to bear throughout the entire UCD process, it becomes more likely that usability problems will be identified earlier in the process and that issues related to social, cultural, and organizational assumptions can be effectively uncovered and addressed. This is important because several analyses have established that it is far more cost-effective to consider usability and involve usability professionals at the very beginning of the product lifecycle, or as early as possible,

compared to late in the cycle (e.g., after it has been engineered) [51]. However, a study of UCD practices among EHR vendors showed that while about a third involved usability/UCD professionals early and often, another third used usability expertise in a more limited fashion. A final third mischaracterized UCD as responding to post-market end-user requests for changes [52].

In some cases, the UCD team involves the end-users of a system. This approach, known as **participatory design**, originated in Scandinavia to ensure that users would be empowered in designing, developing, and deploying new workplace technologies [53]. In participatory design, users actively contribute as co-designers of a system, often through workshops and collaborative design sessions. While this approach can incur additional management and coordination overhead, the presence and voice of users or clients throughout the process can often help speed the overall development process by injecting the design team with a much higher degree of domain expertise. Over the years, examples of participatory design in healthcare include the design and development of a clinical protocol eligibility screening tool [54], technology-supported standardized nursing documentation [55], a web-based observational tool for detecting intravenous medication errors with smart infusion pumps [56], and public health informatics projects [57, 58]. Participatory design is a promising concept whose practices and challenges should be more systematically articulated for clinical informatics [59].

HFE and HCI Principles for Design

HFE and HCI experts have developed several principles or heuristics on an excellent design that apply across products and interfaces. Table 9.3 presents a collection of principles from several sources, all based on how people generally perceive, think, decide, act, and use technology. Violating these principles can result in a system being less usable or in errors and adverse events. IT is illustrated in a review of medication safety alerts [60]. Some of the principles are also clearly violated in the case vignette, particularly those concerning error management, workload, navigation, and compatibility with the user's mental model. In the case of Dr. Davis, it is clear that the design of the fictitious HiTech EHR violates not only the principles of how humans think and act but also clinical cognition, or how doctors think and act [61]. Health IT that does not accommodate clinical understanding or workflow can lead to workarounds. Although workarounds may reflect inventiveness and adaptation skills of clinicians and may be beneficial, they may also contribute to potential safety risks by eroding existing institutional safety guardrails [20, 62, 63].

Table 9.3 A compilation of HFE and HCI principles for good design

Consistency and standards in design. Use similar sequences of actions, terms, or commands across similar situations. Follow design conventions (e.g., tabs move between fields; "Yes / No" not "No / Yes")
Simplify the interface. Remove unnecessary information. Users should have only what they need for their task, with links to more as needed. Related data (e.g., height and weight, allergy and its severity) should be placed together, nested, or integrated
Navigation and visibility. Users should be in control of the system and their navigation. The sequence of actions should be clear and have a beginning, middle, and end. Feedback should be given on the completion of actions and stages through a process. During the process, users should be informed of what is going on and where they are, using appropriate and timely feedback or indicators
System should resemble the user's world and mental models. The system should use concepts and terms that the user uses and understands. Familiar frameworks and metaphors are used (e.g., objects are read left-to-right, dragged-and-dropped items are moved, larger things are more important, items in sequence are related but not used simultaneously). Labels (e.g., 'Order') should reflect their functions. Objects should afford actions, e.g., clickable objects should look clickable—i.e., like a button
Reduce workload. Physical and mental steps to accomplish a goal should be minimized. Users should not have to recall information "in the head" but rather act on existing information "in the world," through recognition or clear instructions. Tasks that can be done by the computer such as calculations should be automated, without assigning the computer tasks at which humans excel such as pattern detection. Shortcuts should be available, particularly for frequent users and frequent commands. Users should be able to create their own templates, shortcuts, or automated action sequences to reduce burden. Provide default options when possible and order options in a logical manner, not just alphabetically
Informative feedback. Actions should produce immediate and apparent feedback, especially when the system state has changed or an important action was taken
Good error management. Design should seek to prevent errors, especially serious ones. If errors occur, this should be clearly indicated with clear alerts that describe the issue, the reason for the alert, and possible solutions. Erroneous actions should be auditable and reversible (undo, cancel). Judiciously use redundancy for important elements, e.g., combine color, text, highlighting, bold font, placement, and symbols to indicate something important such as similar or identical patient names
Help and documentation. Those who need it should be able to quickly access help and documentation, either in the current screen or separately in the software. The help documents should be searchable, logically organized, and present clear steps

Compiled and adapted from multiple sources [10, 16, 64–67]

HFE and HCI Challenges Specific to Clinical Information Systems and EHRS

The models, practices, and principles described above are believed to be universal and applicable to clinical informatics as much as to any other interactive technology [30, 68]. Nevertheless, healthcare delivery involves goals, actors, procedures, and constraints that pose particular design challenges discussed elsewhere [61, 69]. Healthcare delivery and clinical informatics have standards, requirements, terminolo-

gies, and regulations, the various formats for interoperability and data exchange, regulations over patient data privacy and security, and requirements for data (e.g., for rural or federally qualified health centers). For example, while the principles of good design might urge quick access to systems without the onus of extra clicks or keystrokes or the redundant use of patients' pictures, names, and other identifiers on every digital or printed document to avoid wrong patient selection errors, doing so requires careful consideration of patients' privacy and HIPAA regulations.

Another notable aspect of clinical informatics is that users span multiple professions and roles, including patients or family members, with numerous functions, sometimes using a single system. Users also tend to be professionals and may have been trained in different institutions with different IT systems. The working conditions of clinician users are also unique. Learning is often practice-based, residents' duty hours are restricted, time pressure can be very high in specific settings, and co-workers are often separated by time and space. The same clinical informatics systems are also used for daily, high-frequency, low-risk activities and infrequent and high-risk scenarios. Thus, they must be designed to balance efficiency with preventing, detecting, and remediating errors. Other chapters in this volume deal with other unique features of clinical informatics systems, including their regulation (see Chap. 3) and the sociopolitical and organizational climates (see Chaps. 8 and 22) in which they are deployed. In terms of the latter, we hasten to acknowledge that for successful human use of IT, one must go "beyond usability" and consider change management issues, implementation planning, and the interaction between social and technical aspects of usability [70–72].

Clinicians are all too familiar with the challenges of the adoption and spread of evidence-based practice guidelines. The oft-cited paper by Balas and Boren [73] described a nearly 17-year lag for translation of new evidence into routine clinical practice. Barriers to evidence implementation and organizational contexts are now the subject of inquiry within a developing field of study known as the science of knowledge translation or implementation science, primarily known in the US. In some respects, clinical informatics systems came to the fore to help with these gaps in evidence translation. However, in parallel to clinician adoption of new evidence, their deployment has suffered from a lack of attention to unique organization-wide, department and unit level, contexts, and implementation barriers. Fortunately, these factors are receiving increased attention. The field of implementation science has begun to mature, offering various frameworks and strategies that can be leveraged during the implementation and evaluation of clinical informatics systems. The field also draws from ideas and principles already established in HFE (e.g., complex sociotechnical systems theory). It can be combined with HFE and related fields (e.g., organizational behavior, decision science, behavioral economics).

Additional HFE and HCI Resources

The history of HFE and HCI and its products spans over 75 years, and interested readers will find many excellent accounts of these fields' history, science, and practice [16, 30, 74–76]. Table 9.4 provides further guidance, particularly for those seeking to apply HFE and HCI to healthcare and clinical informatics.

Emerging Trends

Several emerging trends should be noted that make it more challenging to apply standard HFE, HCI, and UCD approaches to improve clinical informatics usability and healthcare performance. The first is the notion of *team-based, collaborative informatics*. Team-based care models such as the patient-centered medical home (PCMH), coordinated care, and team-based primary care are widely promoted but variably applied [84, 85]. Most of these team-based models are described as requiring multiple professionals to use a single information system (or set of systems) across time and space [86–88]. However, design and testing for usability usually consider individual needs and involve individual end-users instead of teams. Clinical informatics systems are often designed for physicians *or* nurses *or* pharmacists *or* technicians; future design and evaluation should consider clinical information systems and usability for physicians *and* nurses, pharmacists, technicians, *and* others. This will mean more consideration of *shared* and *collaborative* tasks, workflows, technologies, training, infrastructures, and policies. With the evolving notion that patients and families can be part of the care team, collaboration increasingly means healthcare professionals working with patients and other nonprofessionals synchronously and in sequence [89]. UCD to support patients, families, and other nonprofessionals in concert with or independent of healthcare professionals is the domain of the emerging subdiscipline of patient ergonomics—i.e., the science and engineering of patient work [90]. Whoever the team is, designing for collaboration requires solving communication challenges, multiple and sometimes shifting user roles, and responsibility for shared data [20, 91].

Similarly, clinical informatics systems must also support the evolving role of healthcare professionals concerning the scope of practice, place of work, and new types of relationships and collaborations being forged. Designing and implementing information systems with traditionally assumed roles can create challenges and lead to inadequate support

Table 9.4 Selected additional resources on HFE, HCI, UCD, and usability.

Websites, primers, and reports
• Usability.gov, a website for design guidance and additional resources on usability
• Healthcare Information and Management Systems Society (HIMSS) usability primer: http://www.himss.org/content/files/himss_definingandtestingemrusability.pdf
• National Center for Cognitive Informatics & Decision Making in Healthcare (UT Health), a large repository of resources, products, tools, guidelines, and links: https://sbmi.uth.edu/nccd/index.htm
• User Interface Design for EHR resources and product demonstrations from the SHARP-C group at University of Maryland: http://www.cs.umd.edu/hcil/sharp/
• NIST usability documents, http://www.nist.gov/healthcare/usability/index.cfm
• EHR design and usability toolkit by Westat: http://healthit.ahrq.gov/ahrq-funded-projects/electronic-health-record-information-design-and-usability-toolkit
• Agency for Healthcare Research and Quality (AHRQ) reports related to usability by Armijo et al. [77, 78] and McDonnell et al. [79]
Books and journals
• Books on EHR usability [11, 80]
• Books with comprehensive content on usability and HCI [64, 81, 82]
• "How-to" books to guide usability testing [16, 17]
• Journals: *Human Factors, Applied Ergonomics, Ergonomics, ACM Transactions on Computer-Human Interaction, International Journal of Human-Computer Interaction, Behaviour & Information Technology*
Education (for a comprehensive list, including massive open online courses, see Franklin [83])
• Short courses at the University of Wisconsin (http://cqpi.wisc.edu/seips-short-course.htm) and University of Michigan (http://www.umich.edu/~driving/shortcourse/)
• Training on usability from the Nielsen Norman Group: http://www.nngroup.com/training/
• HFE Conferences: Human Factors and Ergonomics Society (HFES) Annual Meeting, HFES International Healthcare Symposium, International Ergonomics Association Triennial Congress
• HCI Conferences: http://www.sigchi.org/conferences
• For HFE educational resources and list of degree programs: https://www.hfes.org//Web/EducationalResources/educresourcesmain.html
• American Medical Informatics Association (AMIA) 10 × 10 Course on Healthcare Interface Design

for the work of clinicians. For example, clinicians working in the transitional care setting may need to visit patients in their homes to provide support and ultimately prevent readmission. In this context, using information systems primarily designed for formal healthcare settings can present unique challenges to the clinician operating in the home environment. With the explosion of telehealth services, a new generation of clinical informatics systems must also account for new norms and roles that will inevitably develop as this technology finds a firm footing and widely spreads across healthcare organizations.

The second trend can be called *personal and connected health informatics*. With the increasing involvement of patients and families in their care [92], there has been a rise in and need for patient and caregiver use of information and informatics systems [93]. For additional detail on the evolving role of patients in their health and emerging patient- and caregiver-facing information systems, see Chap. 24. Unfortunately, few technologies of this kind are developed using UCD practices and HFE/HCI principles, which jeopardizes their usability and results in a lack of overall use and system abandonment after an initial period of use [94]. Not only can HFE and HCI play a role in ensuring that the technology that patients use is safe, effective, efficient, and satisfying, but the data generated through this technology must be usable to clinicians.

Furthermore, collaborative activities performed by patients and clinicians, such as shared decision making or patient-clinician communication, must be supported by usable collaborative technologies, such as in-room monitors for clinics and hospitals, remote telemonitoring/telemedicine interfaces, and interactive personal health records [95]. The recently announced alliance between Apple, Epic Systems, and Mayo Clinic notwithstanding, personal technologies are not currently integrated into clinical care. Therefore, a significant future challenge will be to meaningfully integrate personal technologies into robust models of care in which patients and clinicians are connected without either becoming overburdened.

A third trend is the growing burden of multiple chronic conditions and an increasing number of people with complex and life-threatening conditions now living longer due to advances in medical technology. That means these individuals are interacting with the healthcare system with high frequency. Using information systems designed with the traditional, episodic care delivery as the dominant paradigm will thus be inadequate in delivering safe and high-quality care. Envisioning clinical informatics systems that support whole-person centered care that incorporates the longitudinal healthcare experience of patients and their family caregivers will be required. New approaches and methods that capture the patient journey (e.g., patient journey mapping) are now being introduced in healthcare [96, 97]. This will create opportunities to develop information systems that capture and visualize the patient experience over a period of time, enabling better decision support for clinicians, patients, and caregivers.

The fourth trend is that of *mobile health (mHealth) and ubiquitous health (uHealth) informatics*. Trends in mHealth, in particular, can influence usability, as clinicians are now using EHRs and other informatics systems on laptops and other mobile devices such as smartphones and tablets. Compared to the desktop computers for which many clinical informatics systems were initially designed, mobile technologies have different input modalities, operating systems, connectivity options, and contexts of use, requiring additional usability considerations. The mHealth trend coincides with a rising "app culture," highlighted by Epic Systems' 2015 announcement of its "app store," App Exchange, and their newest version, Applied Epic, the world's leading enterprise cloud marketplace. The introduction of mobile devices and clinician-facing apps in healthcare has great potential to enhance provider effectiveness and satisfaction. Smartphones and tablets can improve access to patient information and clinical decision support tools at the point of care. The effectiveness of population health management is significantly increased with the help of mobile health.

For instance, virtual visits are a practical option within clinical care. They have become a critical component to maintaining patient access to healthcare professionals, spurred on by emerging needs such as those witnessed during the COVID-19 pandemic [98]. Clinicians' decisions to use remote methods of communication should be in part based on the suitability for the individual patient, including the need for a personal connection to the patient's level of disability or technology access [99]. Many recent concerns with integrating mobile devices and apps in the clinical workflow have focused on infrastructure and security. Beyond those concerns, there are challenges to understanding the impact these technologies have on provider mental models, patient expectations, and workflow. Mobile systems also create challenges related to power (battery life), Internet connectivity, physical environment (e.g., lighting or glare issues), and data entry speed and accuracy. Due to the demand for these devices and the flood of new apps, it will be tempting for medical facilities to choose technology-driven solutions based on availability instead of usability.

The fifth trend is *data analytics and learning health system informatics*. In brief, with multiple sources of big and small data, informatics systems are being harnessed to draw connections, identify patterns, and empower quality improvement efforts. This calls for expertise from data sciences and HFE and HCI to optimize visualization and end-user interaction with data displays. For example, a dashboard used for quality control would need to follow principles from Table 9.3 in the use of colors (e.g., red = bad, green = good; darker = more, lighter = less), graphic features (e.g., geospatial information should be plotted on x-y coordinate space), and information (e.g., hovering over data points provides further data). HFE principles about function allocation, i.e., tasks to be done by computers vs. humans, must be practiced so that computers are assigned heavy data computation. Still, humans are responsible for evaluating patterns and making decisions [100]. Furthermore, the integration of informatics systems into processes for improving quality, operational efficiency, and rapid improvement efforts (e.g., using lean) will benefit from expertise from professionals who practice human organizational factors or "macroergonomics" [101, 102].

Summary

If the purpose of clinical informatics is to improve clinical care, then it must provide support, be usable, and be satisfying to the individuals who perform that care [2]. Furthermore, both existing and future technologies must ensure that care is performed safely and by no means should increase the risk for error or harm [103]. However, various health IT systems, including EHRs, have criticized usability problems, reduced efficiency, and productivity, and disrupted established workflow patterns. What is more, some systems appear to introduce safety hazards and may be ill-equipped to detect and handle errors once they occur. Fortunately, entire disciplines such as HFE and HCI have developed over many decades a collection of theories, models, tools, methods, practices, and guidelines to evaluate and ensure the safe and successful performance of people using technologies in sociotechnical systems. Increasingly, designers, administrators, clinicians, and other stakeholders are becoming aware of opportunities to apply HFE, HCI, and other human-centered approaches to improve clinical informatics systems' usability and identify and correct usability flaws.

Furthermore, resources are increasingly being made available to and adapted for these stakeholders. As a result, there is reason to believe that future iterations of clinical informatics systems will be superior in usability. Future generations of health IT users will enjoy improved performance and user experience.

Questions for Discussion

1. Can usability, as defined by HFE and HCI, be achieved simply through displays pleasing to the eyes, or must goals besides aesthetics be met?
2. How do the implications of a systems approach to health IT compare to those of an approach that considers either people or technology in isolation?
3. A hospital wants to create a dashboard to track the recommended care that patients have received versus the pending care. Apply the three phases of the UCD process, including specific steps, to the design of this system.

4. What are the HFE and HCI considerations for a new implementation of a suite of desktop and mobile technologies to improve collaboration between nurses, physicians, retail community pharmacists, patients, and their family caregivers to manage chronic disease?
5. Given that UCD requires designers to consider the needs of end-users, what are the approaches to ensure that user needs are appropriately understood and addressed?
6. Examine a user interface and identify how elements of the interface comply with or violate HFE and HCI principles for good design.
7. What are the main challenges for applying HFE, HCI, and UCD to health IT, given that healthcare delivery is collaborative and involves patients and caregivers?

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Part III

Health Information Systems

Information Technology Systems

10

Shawn N. Murphy and Jeffrey G. Klann

Learning Objectives

At the end of the chapter, the reader will be able to:

- Describe the difference between structured and unstructured data
- Understand how data typically need to be changed to fit into a database
- Define the ACID concept of a database
- Describe the differences and tradeoffs between relational and non-relational systems, as well as cloud vs. on-premise databases
- Discuss the essential components of data interoperability, including Common Data Models and Health Information Exchange
- Identify the basic concepts behind Knowledge Discovery and Data Mining
- Cite various types of network topology
- Understand how a system architecture is represented
- Describe a three-tier software architecture
- Explain the design considerations in choosing a programming language, including compiled vs. interpreted and object-oriented vs. procedural
- List three software design considerations
- List four safeguards that HIPAA describes
- List three types of security attacks
- Describe how FISMA moderate compliance helps prevent security attacks

Practice Domains: Tasks, Knowledge, and Skills

- K006. Computer programming fundamentals and computational thinking
- K007. Basic systems and network architecture
- K060. Enterprise architecture (databases, storage, application, interface engine)
- K062. Network communications infrastructure and protocols between information systems
- K076. Approaches to knowledge repositories
- K077. Data storage options and their implications
- K089: Data life cycle
- K090. Transactional and reporting/research databases
- K091. Techniques for the storage of disparate data types
- K092. Techniques to extract, transform, and load data
- K094. Data management and validation techniques
- K096. Types and uses of specialized and emerging data sources (e.g., imaging, bioinformatics, internet of things
- K098. Information architecture
- K099. Query tools and techniques
- K100. Flat files, relational and non-relational/NoSQL database structures, distributed file systems

Case Vignette

Jane is the CMIO of a large healthcare system and wants her enterprise to invest in a new electronic medical record (EMR) system. She will need to make a convincing argument, hoping to keep the technically-oriented CIO happy by showing the new system will indeed scale to the requirements of an upcoming merger with another health system. She would like to justify some of the claims made in the sales-oriented, splashy presentations of the EMR companies with her hard-hitting, factual presentation. It turns out the EMR companies are different in several ways. First, they use different types of databases. The first company uses a MUMPS hierarchical database, while the other companies use relational databases. The first company also uses a waterfall programming methodology, while the other com-

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panies use agile programming methodologies. One of the EMR companies is pushing a novel NoSQL-based system as part of its platform, but she doubts it can handle the transaction flow and wants to make that point to the CIO. Ultimately, Jane would like her health system to adopt an EMR with agile programming practices and a standards-based Application Programming Interface that uses a relational database system. How could she best present her arguments to the CIO? See if you can help Jane build her presentation as you navigate this chapter.

Introduction

The events of clinical practice can be represented in an Information Technology (IT) system. Medical software is at the pinnacle of all IT system development in many ways, because these systems have a great responsibility towards the patient. Therefore, systems must be carefully designed to embody the following characteristics: sharing, proper formulation, quality measures, and fulfillment of use cases. Sharing includes proper authorization practices for those assessing the system, distinctions between data types that can be shared, and harmonization methods that allow sharing. The proper formulation includes focusing on data sources and data types, accounting for temporal aspects of clinical data, and accounting for various levels of data granularity and missingness in IT systems design. Quality measures for IT systems include working under many failure situations regarding data, code, and system security. This chapter will introduce practical decisions that must be made to formulate the components of a health IT system, including data, networks, and programs. We will carefully consider these characteristics as we discuss each component.

Data and Databases

Data is at the heart of every health IT (HIT) system. The purpose of all HIT systems is gathering, storing, sharing, and utilizing data. This section will discuss the data itself, which will allow us to dive into further topics on building HIT systems, such as programming and system architecture, in later sections.

Getting Data

Data Sources

HIT systems constantly generate data, which in the context of medical practice are pieces of information, especially those that are part of a collection to analyze a problem. In HIT parlance, these data fall into three broad categories:

- **Structured data** make up most of the information clinicians, and technicians enter into electronic health record (EHR) systems for record-keeping and billing purposes. Structured data are stored in various standard formats and terminologies (as discussed in Chap. 13) that computers can interpret and manipulate. As a rule, structured data come at the cost of clinicians' time and effort; these are not part of normal communication between clinicians that normally occurs with written unstructured discourse. However, structured data are much more useful to HIT systems for data processing.
  - *Examples of structured data:* billing data (e.g., diagnosis codes, procedure codes), demographic data, laboratory results, vital signs, and coded medication and problem lists.
- **Unstructured data** refer to data not stored in an easily computable format. Primarily this includes all the notes about a patient—from reports to discharge summaries, including data that may not be stored in a computer system at all (such as, in many environments, daily nursing notes). Images are often considered unstructured, as well as lab results that are supplied as fax documents. This category also includes some financial and legal data that are not readily available in computable format (such as consent forms, DNR orders, etc.). Unstructured data tend to be much richer than structured data, but they usually cannot be used directly in a computable environment such as a decision support system. Natural language processing (NLP) [1] is a way to extract computable meaning from this text. However, due to the many variations of how things can be said in human languages and how text is structured, NLP is fraught with difficulty and error-prone.
  - *Examples of unstructured data:* patient notes, financial and legal documents.
- **"Big" data** is an emerging category of data that are generally unstructured but is put in this separate category because it is difficult to process [2]. It is difficult, because the data has either an extremely large storage footprint (like radiology images or genomics from sequencing machines) or is so extraordinarily complex that it takes enormous computing resources. Sometimes these are data collected by continuous-monitoring machines. Home health monitoring (such as home blood glucose monitors) is an example of continuous monitoring data working into medical records.
  - *Examples of "big" data:* radiological images, genomic, and exomic data.

Another source of data besides HIT is patient-reported data and community information, as elaborated in Chaps. 24 and 25. Patient-reported data is used to reconcile the medical record with patient experiences and collect subjective information on patient perception of disease burden. Community information (such as public data about the number of parks in

a city) is becoming more important as medical data is used for public health. Understanding local health policy, regional socioeconomic statuses, communicable diseases, and disease trends are becoming integrated into health data analysis.

Interoperability: Mapping and ETL

Data are stored in many different systems throughout the hospital. To be retrieved or used for analysis, data must be extracted from their source system. Typically, when data are retrieved on a single patient, software interfaces exist that allow the clinician to browse their patients' information using a combination of proprietary and standard solutions. Many of these interfaces are based on standards developed by Health Level Seven (HL7). Data retrieval becomes more difficult when gathering cohorts of patient data for research or quality improvement. Data retrieved for this purpose undergo a three-step process known as Extract, Transform, and Load (ETL). Chapter 14 discusses interoperability in more detail. Here, we provide a brief overview of the ETL steps and major stumbling blocks [3].

- **Extract**. Data must be retrieved from the source system using available programming interfaces. The biggest stumbling block in this step is knowing what data resides where and what it means. For example, an ambulatory EHR system might be separate from billing systems, and thus the data from these systems must be merged to understand patient encounters. Diagnosis codes that represent billing diagnosis might not represent a patient's actual disease, so these would need to be stored separately from the problem list. For example, the billing diagnosis code for a visit to rule out diabetes is the same as a billing diagnosis code to manage diabetes.
- **Transform**. Because data are stored in various proprietary formats, it is necessary to align all these formats so that the data can be analyzed together. This task, known as data mapping, is often quite complex and is discussed at length in Chap. 13.
- **Load**. This step involves transferring data in large quantities into a data warehouse, which requires careful attention to some of the performance concerns discussed in "storing data" below.

Data Representation

When data is in transit or being processed, structured data is often represented in one of the following formats: XML, JSON, or CSV [4]. These are largely interchangeable ways of organizing data. Text data (notes) often also have some structure in the header section, which defines to whom the note belongs, who transcribed it, and on what date, among other "metadata" fields (data about the data).

- **XML** uses tags, or text within brackets, to separate pieces of the document. Tags can be embedded in other tags, thus creating a hierarchy of information with a document.
- **JSON** is a similar format that uses colons, commas, and tabs instead of brackets and has become popular as it is generally more readable.
- **CSV** is a nonhierarchical structured format that essentially represents data as a spreadsheet, with columns and rows—commas separate columns, and each row appears on a separate line. A simple example of information in all three formats is below.

A sample data structure represents a patient's weight at an encounter as XML, JSON, and CSV in Table 10.1.

Chapter 13 will discuss data exchange standards, which define the specific tags, element names, and headings used to transit various data in these three formats. These data exchange standards build on the underlying structures of XML, JSON, and CSV. Most notable among these are the Fast Healthcare Interoperability Resources (FHIR), which describe EMR data in a standard way using these data structures [5]. FHIR's use is being accelerated by the 21st Century Cures Act, which mandates that EMR vendors support this standard in some circumstances [6]. These include serving Medicare patients and getting a certification from the US Office of the National Coordinator for Health Information Technology (ONC).

Storing Data (Databases)

In enterprise systems, data are stored in databases.

Table 10.1 Data representation of patient's weight in XML, JSON, and CSV

XML	JSON	CSV

<encounter id='111'>
<vitals>
<weight units="lbs">140</weight>
</vitals>
</encounter>
	{
	"encounter": {
	"id" : "111",
	"vitals": {
	"weight": {
	"units" : "lbs",
	"weight": "140"
	} } } }
		(This "vitals" csv would be one of several csv files needed to represent these data.)
		Encounter,weight,units
		111,140,lbs

Relational Databases

The gold standard for database storage is the **relational database** [7]. These are also known as SQL databases because database programming is done in the Structured Query Language (SQL) [8]. SQL 92, the version of the language released in 1992, is a standard across most database systems. Since then, many changes have been made to the standard language, but there is incompatibility across database platforms concerning features introduced since SQL 92. Although database platforms implement the features introduced in SQL 99 and some features found in even more recent versions, they all do so slightly differently. Therefore, database programmers tend to become experts in one platform, such as Microsoft SQL Server or Oracle.

The most common relational database brands used in HIT systems are those from Oracle and Microsoft. They have a reasonable equivalence of features, though, as mentioned, their SQL dialects are quite different. Postgres is a popular open-source database used in smaller health IT projects (such as for research systems), which offers many of the same features as the commercial equivalents but without the same level of support or guarantee of functionality.

Database Schema Design

In SQL databases, data are stored in *tables* where each entry is a *row* with a predetermined set of *columns*. Conceptually, this is very similar to a spreadsheet. Like spreadsheets, various aggregate functions can be performed on tables to characterize the data. Unlike spreadsheets, tables can be *joined* to answer questions that cannot be gleaned from a single table. These joins are performed using the relationships between the tables, which is why these databases are *relational*.

The structure of the database tables for any particular application is known as the database *schema*. These tables are usually designed to store data so that information is not duplicated across tables. This is known as *normalizing* the data [9]. For example, a patient table might contain the patient's date of birth. A normalized schema would not duplicate the patient date of birth in, for example, the encounters table.

Structuring a database schema, so tables are normalized can be quite complex. Normalization should be done only up to the point that makes sense for the database application. There are more than six normal forms of data. However, the third normal form (3NF) is the level of normalization proposed by relational database pioneer EF Codd and is the general standard for minimizing data repetition [10]. 3NF specifies that every piece of data in a row only depends on the information in the primary key (the primary identifier for the table, such as a patient id or encounter id). For example, an encounter table might have a provider identifier. The encounter table should not also have the provider's name and address, as these are properties of the provider and not the encounter. These should go in a separate provider table.

To understand how joins are used, consider how many encounters occurred in 2014 involving patients born in the 1960s. A database programmer would issue a query that "joins" the patient and encounter tables. The power of relational databases is that these joins are dynamic and ad hoc and do not require a priori definition of relationship hierarchy. To join two tables, a common column must exist between these two tables. This is an exception to the "do not duplicate data" rule of normalization. These two columns are the *primary key* (the column[s] of the primary table to be joined) and the *foreign* key (the column[s] of the secondary table to be joined). In the above example of the patient and encounter table, both tables would include some type of patient identifier. More technical details of SQL joins can be found in the section "Programming" below.

Schema designs are frequently visualized with an Entity Relationship Diagram (ERD). These simple diagrams use boxes to represent each table in the schema. Each box lists the columns in the table and their data types. Usually, the keys of the table are demarcated by boldfacing or otherwise highlighting them. Lines are drawn between boxes where a relationship exists (i.e., indicating that the two tables can be joined). The lines are annotated with the type of relationship: one-to-one, many-to-one, or many-to-many. The patient-to-encounter relationship would be one-to-many because a single patient can have many encounters, but each encounter is about only one patient. A many-to-many relationship might be a provider and patient table. A provider has many patients, and a patient likewise has many providers. Many-to-many relationships are often shown on ERD diagrams as a pair of one-to-many relationships, with an intermediate table in the middle that provides the many-to-many linkage. In this case, the encounter table might be the intermediary table for the many-to-many linkage (assuming that a patient can have only one provider per encounter). A variety of schemes for annotating the relationship exists. An ERD diagram based on this discussion that uses the popular "crow's foot" annotation method is shown in Fig. 10.1.

One complexity to consider when defining a database schema is balancing usability with resilience to future changes in that schema. It is generally faster and easier to access data with predefined columns (such as columns in a patient table, e.g., gender, race, and ethnicity). Still, suppose the available data could change dramatically over time. In that case, it is often better to use an entity attribute value (EAV) format, a special way of normalizing the data that provides great flexibility for schema changes [11]. In pure EAV format, a table has only three columns. In a patient table, the Entity column would be a patient identifier. The Attribute column would define what is being measured in that row (e.g., birthdate). The Value column would have the value of the measurement (e.g., January 1, 1960). Thus each patient's data in the patient table would take up many rows. Without careful indexing, this can have poor performance.

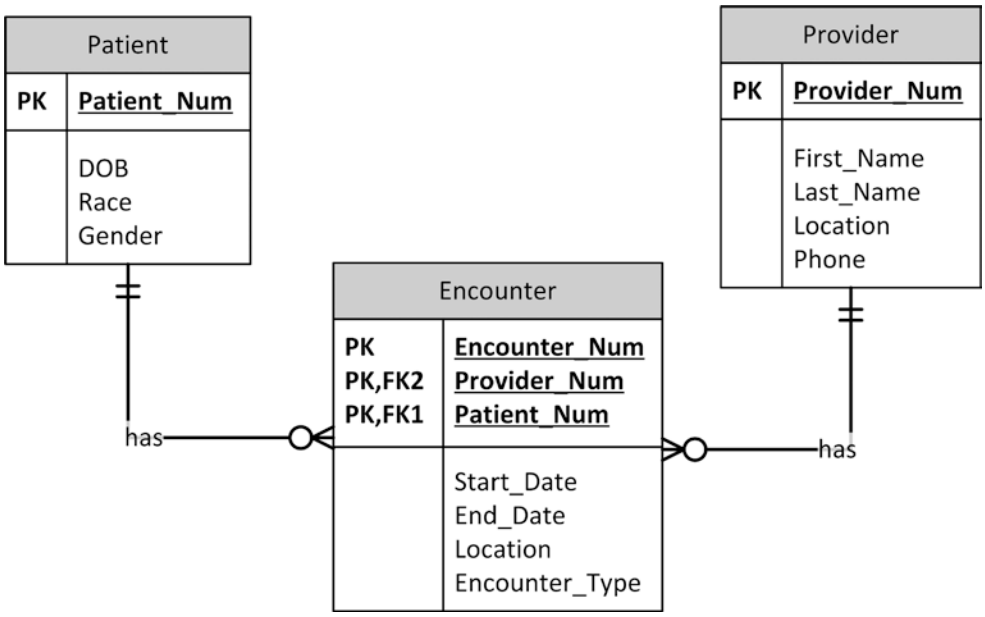

Fig. 10.1 Entity relationship diagram for a simple database schema

Furthermore, it is not particularly human-readable. However, it is immediately adaptable to new data types without changing the underlying database schema. Because of this, EAV is used in many data warehouses. In practice, schema styles are used that combine EAV and standard tables. The star schema and the snowflake schema prototypes are most common, both of which involve one or more EAV tables and *dimension* tables that define additional attributes using standard normalized data. The dimensions are linked to the EAV table through additional columns (foreign keys). The Informatics for Integrating Biology and the Bedside (i2b2) database framework for clinical data warehousing, free and in use at over 200 sites worldwide, uses a star schema format [12].

Cloud Database Providers

Of increasing importance are cloud-based data storage providers. Although due to security concerns around clinical data, such data are traditionally stored on-premises ("on-prem") on an institutionally managed database server, the flexibility of storing data in the cloud is attractive. It does not require institutional investment in and maintenance of database servers, and database size can be "elastic" and dynamically allocated by the hosting provider. All major cloud providers support healthcare data in some way, and it is becoming more commonplace for major institutions to sign BAAs (business associate agreements) with commercial cloud providers.

New variants of SQL and other query languages come with these cloud providers that informaticians must become familiar with. Google provides an implementation called BigQuery, which is compatible with SQL 2011 standards [13]. Amazon promotes a scalable database solution called RedShift, which implements its own dialect of SQL to support very large datasets and high-performance analytics [14]. Microsoft Azure suggests using Azure SQL, which uses a SQL language like Microsoft SQL Server [15]. Although all these companies offer more traditional databases on the cloud, they claim that the highest performance is achieved with one of their cloud-native approaches.

There are many cloud-based NoSQL solutions (i.e., databases that provide programming interfaces not based on SQL). See the next section for a discussion of NoSQL.

Database Integrity and Performance

Because databases are often accessed by many systems simultaneously, it is critical that no two systems modify the database simultaneously. Furthermore, databases must be resilient to failures (such as power or hardware). Data integrity in relational databases is achieved through the ACID principles [3]. In this framework, database operations that must occur together are said to be a single *transaction*. The elements of ACID are:

- **Atomicity**. If one part of a transaction fails, the entire transaction is reversed.
- **Consistency**. No transaction will violate the rules of the database (such as the schema and other constraints).
- **Isolation**. If transactions are run concurrently, the database and results must be the same as if they were run consecutively. This can be achieved by configuring the system to run all transactions consecutively. Still, in practice, complex database scheduling programs determine which transactions can be run simultaneously (for example, read-only transactions can always be run simultaneously).

- **Durability**. Once a transaction succeeds (is *committed*), the changes are resilient to failures and visible to all other running transactions. Database designers must balance this requirement with performance because true durability means that committed database changes must be immediately written to permanent storage (i.e., they cannot be stored in memory), which is much slower than using memory.

Columns on tables can be *indexed*, which speeds up searches significantly. Defining indices depends on the intended application and the database's *query optimize*r, which maximizes the performance of index use. Every database engine (e.g., Oracle or SQL Server) has a unique query optimizer, so index designs must be tweaked for each database engine supported. As a rule of thumb, the performance of a database table will not degrade until the relevant parts of the index are too large to fit into memory. Therefore, it is possible to have tables with hundreds of millions of queryable rows in milliseconds if the query optimizer uses indices. At that scale, index design and query optimization become very important, and there are many tutorials and technical documents on this subject. Unfortunately, the optimal query design also varies between database platforms. For example, Oracle often excels on complex, large queries, whereas SQL Server tends to do better when each step is computed separately and stored in a temporary table.

Non-relational Databases (NoSQL)

Non-relational databases (collectively called NoSQL) are becoming popular for some specific tasks, although relational databases remain the highest performing systems for general use. However, NoSQL databases can be very powerful for in-memory and distributed querying (i.e., when there are extremely large amounts of memory and many compute nodes).

Popular NoSQL approaches include:

- ***Massachusetts General Hospital Utility Multi-Programming System (MUMPS):*** MUMPS is particularly important to the medical informatics community [16]. This is a database format developed in the 1970s at the Massachusetts General Hospital before relational databases. It is still widely used in medical informatics. It is both a programming language and a database, and all data are stored in *sparse matrices* rather than in tables. (See the section "Knowledge Discovery and Data Mining (KDDM)" below for more information on sparse matrices.) It is very efficient at complex data manipulation. Because MUMPS was developed when memory was costly, it tends to be very terse—all MUMPS commands can be reduced to a one-to-three letter abbreviation.

  Additionally, spaces are important (which is not true in most languages). A space is used to separate commands, for example. Therefore, MUMPS programs tend to be more cryptic than SQL. Entire systems have been written in MUMPS, but many modern systems (such as Epic's EHR platform) use MUMPS similarly to SQL and use a more traditional language for user interaction (see the section "Programming" below). MUMPS implementations include M and Caché®. The latter is the most popular MUMPS implementation, sold by InterSystems, Inc. Caché® is now part of the company's suite of tools called IRIS, which exposes a multi-model datastore built on MUMPS and provides an approach to use SQL and no-SQL in the same environment [17].
- **MapReduce databases**: MapReduce is an algorithm developed by Google that allows optimized querying in "massively parallel" environments [18], where hundreds of computers execute portions of queries simultaneously. Each query is split into many small subtasks. When the hardware is available, parallelizing complex computing tasks into inexpensive computing nodes is very appealing. Hadoop is a popular open-source MapReduce database [19].
- **Document databases**: Whole-document storage and processing is a feature of many NoSQL databases that support MapReduce. This simplifies the Load process of ETL because the data can be stored and queried as structured documents. Thus, the transformation from the transport format (e.g., XML) into a database schema becomes unnecessary. Document databases are computer-processing intensive, but in a massively parallel environment, this can be mitigated.
- **Graph Databases**: In cases where the relationships between tables can be predefined into a schema of linear relationships (such as "patients have encounters" and "encounters have data on medications"), a graph database allows such data to be traversed faster than the dynamic data relationships of a relational database. The difficulty is that the data relationships are static and must be traversed linearly. In this example, it is not possible to directly join patients and medications. This can create performance problems and limit query design when the data are not used as anticipated. On the other hand, the performance is very good if the schema fits these constraints. Neo4J is a popular open-source graph database [20].

NoSQL databases frequently relax some of the constraints of ACID to achieve high performance. Therefore, in many cases, NoSQL is better at analytics on massive, slow-to-update datasets than live systems that are continuously updated (e.g., an EHR).

Examples of NoSQL Databases Neo4J [20] (a popular open-source graph database); MongoDB, CouchDB, and Hadoop [19] (MapReduce Document databases); Caché® and Iris (a widely-used MUMPS database and its successor).

Many NoSQL databases are open source but frequently provide recovery and support contracts for commercial use. Additionally, cloud providers offer many NoSQL solutions, such as Amazon's DynamoDB and Google Firestore (both document databases).

Using Data

Data serve no purpose without a reason to use them. Here we briefly discuss some important uses of data in HIT systems.

Health Information Systems

Health Information Systems (HIS) are the clinical systems used to retrieve patient data for review by their caregivers [21]. Structured data are presented in easy-to-understand formats such as flow sheets. The data sometimes power useful applications that run alongside the health record, such as decision support systems, which provide helpful suggestions to improve patient care (e.g., reminders about vaccinations). Most systems can search within a patient chart to find keywords in unstructured data or draft a patient note for a visit based on the structured data entered for that visit. Many innovations continue to emerge. Homegrown HIS used to be common. Commercial systems have largely replaced these. Still, recent government initiatives, such as the 21st Century Cures Act, are encouraging open standards for integrating smaller, single-purpose "apps" with larger HIS [22–24].

Data Warehouses

Data warehouses are increasingly used within hospital systems for, among other uses, quality improvement, public health reporting, research, and clinical trial recruitment. The ETL process described earlier copies data into data warehouses out of production systems. These data warehouses may be refreshed as frequently as daily, or they might be created on a one-off basis (for a research project, for example), depending on the applications for the warehouse and the amount of data. The COVID-19 pandemic motivated many healthcare organizations to develop faster data warehouse refresh pipelines. Daily or weekly updates on COVID patients could occur to speed up research on the disease. This will have the effect of faster ETL pipelines post-pandemic.

Data warehouses define a Common Data Model (CDM) and may offer various data analytic tools that will run on the CDM. Several open-source clinical data warehouses are in widespread use. The most widely used freely available platforms are i2b2, OMOP, and PCORnet. Additionally, EHR vendors frequently offer a data warehouse (Epic Caboodle), and home-grown data warehouses built by individual hospital systems are still widely used. Here we will briefly introduce the freely available platforms.

Informatics for integrating biology in the bedside (i2b2) is the oldest, freely available data warehouse system, first developed over a decade ago and used at over 200 sites worldwide. It is also used in large data research networks, including NCATS's national Accrual to Clinical Trials (ACT) network. In addition to a data model, it provides an Application Programming Interface (API) for query and data retrieval, supporting database-independent app design. It also offers a client tool for developing queries and viewing results [12, 25, 26]. i2b2's greatest strength is its flexibility and ability to ingest and analyze new types of data without changing the core data model. Besides EHR data, i2b2 is used in many other unique domains, including patient-reported outcomes, genomics, and social determinants of health.

The **Observational Health Data Sciences and Informatics** (or OHDSI, pronounced "Odyssey") Collaborative provides a CDM known as **Observational Medical Outcomes Partnership** (OMOP). The collaborative offers a variety of analytic tools, from cohort design to regression analysis to data sharing. However, the platform's greatest strengths are probably its well-specified data model and comprehensive, regularly updated data dictionary of curated terms from many standard terminologies. These make OHDSI/OMOP very appealing for data analysts because SQL queries are readable and relatively easy to write. As of this writing, OMOP is implemented at over 100 organizations worldwide [27, 28].

The Patient-Centered Outcomes Research Network develops the PCORnet CDM, an OMOP-like relational data model representing EHR data. It is used at PCORnet sites in the US, which currently encompasses 70 million patients' data. Network participants gain access to data characterization and quality checking programs that run on the commercial SAS analytics platform and produce reports used for quality improvement [29].

Health Information Exchange

Many initiatives to share information across health systems are collectively dubbed "health information exchange" or HIE. This can be as small-scale as electronically transferring a single patient's records to a new hospital system, such as the Direct project from the National Coordinator's Office for Health Information Technology [30]. HIE can also be as large-scale as distributed analytics across an entire state or country.

Early efforts in HIE took data from local sites and built regional data repositories (Regional Health Information Organizations, or RHIOs) for analytics. Several of these projects were successful, such as the Indiana Network for Patient Care operated by Indiana Health Information Exchange, which aggregates data on millions of patients from dozens of hospitals, as well as independent laboratories

and insurance companies for a comprehensive record of the patient's medical history [31].

In general, however, regulatory issues around sharing patient data hamper the success of this approach. Therefore, in the past decade, the "federated network" has emerged as the most prominent modality of health information exchange. In this model, data stay at home institutions. Rather than creating central repositories of data, the "questions are brought to the data"—queries are distributed across networks of health systems, and only the results are aggregated. This solves a variety of privacy and security problems at the expense of performance. Many large government-sponsored national networks take this approach, such as PCORnet [32], the NIH ACT [25] network, and the Mini-Sentinel network [33]. The new NIH "Long COVID" research network (RECOVER DRC—Researching COVID to Enhance Recovery Data Resource Core) is also planning to use a federated approach [34]. Emerging advancements allow much more complex distributed analysis, taking advantage of new technologies like homomorphic encryption to exchange patient-level information while ensuring patient privacy [35].

Knowledge Discovery and Data Mining (KDDM)

KDDM refers to using statistical methods on data to discover patterns that are not intuitively obvious upon inspection [36]. In practice, preliminary knowledge discovery frequently occurs through simple searches in databases of patient data (such as keyword searches in notes or "cohort finding queries" on data warehouses). Still, KDDM can also be much more complex [37]. One popular use of KDDM is for *predictive analytics*, such as predicting 30-day hospital readmissions or risk of heart failure. This type of KDDM uses *classification* algorithms, such as *regression analysis* or *support vector machines* [38]. Classification algorithms are known as *supervised learning* because the correct outcome is known and *supervises* the algorithm as it trains its parameters. Supervised learning involves a *training set* of data, meaning that the final statistical model is developed from a set of data where the true positives are known. Then the model is tested on a *test set*, where the true positives are unknown to the algorithm, and the algorithm's accuracy is evaluated by how closely the algorithm correctly labels the test set.

A popular approach for robust testing involves repeatedly splitting the data into different training and test sets and comparing performance across all parameterizations of the algorithm. This is known as *cross-validation*. A related technique, *bootstrapping*, creates additional training data by resampling the existing training set (i.e., creating additional simulated data based on the statistical properties of the training set). For algorithms where sensitivity can be varied, the algorithm's output is often presented as a *Receiver Operator Curve (ROC)*, which is a plot of sensitivity against one-specificity for each parameterization of the algorithm.

Unsupervised learning is also becoming popular in medical KDDM. Unsupervised learning looks for patterns or relationships in data where there is no known "goal". The most popular example of unsupervised learning is recommendation algorithms used in consumer e-commerce platforms such as Netflix and Amazon to suggest purchases to customers based on the previous purchase history [39]. This type of algorithm has been used, e.g., to generate drafts of decision support, suggest ontological relationships among data elements in standardized vocabularies, and find the most important variables in a dataset (feature selection) [40–42]. One of the most recent popular unsupervised techniques is the autoencoder, which essentially uses a single dataset for training and testing. The goal is an algorithm that can efficiently reproduce the input data from a smaller set of parameters. These smaller representations of the original data can then be used in a variety of ways, such as data compression, noise reduction, synthetic data creation, etc. [43] Autoencoders are a form of Deep Learning, which is becoming an important term of art in medical informatics [44]. Deep Learning networks are essentially complex, multilayer neural networks (a classic machine learning technique that dates back to the 1960s). However, today's extremely powerful computing resources allow very complex networks, inspiring a revolution of new KDDM tools and applications.

The data format required for KDDM is somewhat different than data transport or storage. Whereas databases store information in normalized tables and transport formats tend to store data hierarchically, KDDM usually requires data in a *sparse matrix*, in which there are perhaps hundreds of columns, each representing a parameter that could be predictive of the desired outcome. This is the same format used by MUMPS. These matrices are known as sparse because most of the entries in the matrix are empty.

Data Quality

It is important to remember that representing data efficiently and with semantic standards does not guarantee sufficient quality to be used in KDDM algorithms and large-scale HIE. Because EHR data are entered by busy humans whose primary goal is to *provide* healthcare, the *documentation* of such healthcare can at times be lacking. Moreover, EHR documentation is largely driven by billing needs, so information needed for analytics (a secondary use of the data) is often inadequately recorded. A range of problems are possible, from the use of unexpected (albeit standard) codes to information not being present at all. The core elements of data quality are: *conformance* (does data adhere to the required standards?), *completeness* (are data present?), and *plausibility* (are data believable?) [45]. It is possible to ensure conformance through well-written ETL, but completeness and plausibility are much more difficult. For this reason, CDMs like OHDSI and PCORnet have made quality checks

a cornerstone of their tools. Still, data quality is a major limiting factor in the use of EHR data for research. It is, therefore, very important to validate the accuracy of algorithms and data-based discoveries across multiple locations to detect potential differences in information entry and coding [46]. Data Quality is covered in more detail in Chap. 16.

Networks and Network Architecture

In this section, we will discuss how computers communicate with each other and with various devices that may be instrumental in collecting medical data, such as imaging and laboratory machines.

Networks

Computer systems connect to each other via *networks*. Networks operate over various physical media, including copper wire, fiber optic cable, and wireless radio transmission. Networks convey various information, including text, sound, and video, over the Internet, medical orders within a health care system, and the exchange of medical data between care providers.

Enterprise networks, sometimes called corporate networks, link computer systems within an organization to support the organization's business processes. Networks or subnetworks within a building or campus are known as Local Area Networks (LAN). The characteristics of a LAN include high network speeds, routing at lower layers of the network, local ownership, and a high degree of trust between nodes.

LANs contrast with Wide Area Networks (WANs), which employ different technologies than LANs to connect campuses or buildings across longer distances. *Telecommunications* refers to the technologies employed to send data, voice, or video over distances of more than a few hundred meters. Telecommunication technology is highly specialized, and most organizations rent either shared or private long-distance connections from telecommunications companies.

As one might imagine, a private telecommunication connection is more secure than a shared connection. However, a Virtual Private Network (VPN) achieves something similar to a private connection by encrypting all communications between two locations over a shared network.

Network Topology

Network topology is an abstract representation of the way computer systems connect. Computer systems are visualized as nodes on a graph in network topology and network connections as lines between nodes. Simple network topologies in include:

- **Point-to-point**, in which two computers connect directly to each other.
- **Star topology**, a central system such as a large computer or router connects to each of the other computer systems. The satellite systems communicate with each other through the central node.
- **Backbone topology**, in which a shared communications channel such as an Ethernet cable serves as a backbone linking nodes at multiple drop points. The Internet Cloud is a variant of a Backbone topology—the essential feature being multiple drop points from a communication medium into which we have no visibility.
- **Ring topology**, a backbone circles around to connect its ends to form a large ring. The ring topology provides increased reliability since cutting the ring at any point produces a backbone that can continue communications.
- **Hybrid topology**, in which multiple backbones, stars, and rings connect. An enterprise network is likely a hybrid.

In a hybrid topology, the constituent network segments connect via specialized network devices. Network devices may boost the physical signal to allow networks to extend over longer distances.

Seven-Layer Network Model

Another way to think about networks is by looking at how atomic data (binary 0's and 1's) are organized and transferred. We categorize network devices as hubs, switches, routers, and firewalls by the *network layer* at which the device connects subnets. Table 10.2 shows the network layers of the seven-layer Open Systems Interconnection (OSI) network model [47] of the International Standards Organization (ISO). Note that HL7 was aptly named as it focuses on the 7th layer of the OSI model.

Firewalls are a special case in that they are security devices that operate at multiple network layers. The firewall passes approved network packets, and it blocks unapproved or suspicious network packets, per a list of approved network addresses, application port numbers, and network protocols. Firewalls may also scan network traffic for known viruses or leaks of confidential information.

Network Speed

As any user of the Internet knows, network speed matters. Several factors affect network speed. *Network speed* is the time it takes for a fixed amount of data, such as a message or a file, to cross the network from one computer system to another. The raw network speed, known as *bandwidth*, is the rate at which binary 0's and 1's (bits) cross the network (bits per second). Modern networks transfer megabits (millions of bits per second) or gigabits (billions of bits per second).

Table 10.2 Network layers of the International Standards Organization (ISO) model

Layer	Name	Description and examples
7	Application	The application layer defines the message format between computer systems or the human-machine interface. Examples are HTTP for web browsers or HL7 for communicating health information between servers
6	Presentation	The presentation layer handles encryption and compression of data packets. Examples are SSL encryption, ASCII text or JPEG images
5	Session	The session layer performs authentication, authorization and session restoration. An application connects to a session via a socket, which is assigned by port number
4	Transport	The transport layer provides end-to-end error control, since data may pass over many physical layers and routers between ends. TCP is a common transport layer protocol. When combined with an IP Address, TCP/IP is the transport method used by the Internet
3	Network	The network address is an external (unique globally) or internal (unique within the enterprise) address assigned by the network, such as an Internet Protocol Address (IP Address). The network layer connects via routers
2	Data Link	The data link layer performs error detection and flow of control on the physical link, i.e. controls which end is transmitting and which is receiving. This layer uses physical device addresses known as Media Access Control (MAC) addresses. Each networked device has a unique MAC that does not change if you move the device to a different part of the network. Ethernet is a common data link protocol. The data link layer connects via switches
1	Physical	Physical medium, such as copper wire, optical fiber or wireless radio transmission. Physical segments connect via hubs

However, there is much more to network speed than bandwidth. Any modestly large data set, say a web page, is broken down into smaller data packets to cross the network. A packet header of routing information is added to each data packet for the network to correctly route and reassemble the packets at the destination. Therefore, the actual number of bits transferred increases by some amount, typically in the 5–10% range.

In addition to the packet-header overhead, there will be some delay in getting the first byte of the packet transferred, called *network latency*. Network latency usually results from (1) the time it takes a network device (hub, switch, router, or firewall) to receive the packet, process its header for the relevant routing information, and then retransmit the packet toward the appropriate target; and (2) waiting time due to competition for network resources from other computer systems using the network.

Networks are fundamental to any modern enterprise computer application, with LANs connecting local computer systems and WANs connecting the enterprise to other organizations. Network topology affects the reliability, scalability, maintainability, and cost of a network. Network speed is influenced by different types of network devices (hubs, switches, routers, and firewalls), which operate at different network layers to route data packets and reassemble them at the correct destination.

Network Architecture

Architecture is about the big picture—how the parts relate to the whole. In *systems architecture,* we break the computer system down into *components* and *relationships* among these components. There are multiple ways to divide a system into components, depending on what aspect is most important to the analysis or the target audience. The most common of these are network topology, application structure, the flow of data among components, and a summary of the most important features of each breakdown.

Architectural Diagrams

Let's consider a hypothetical obstetrics system as an example. This system collects and manages pregnancy information during clinic visits, makes that information available to the hospital at the time of delivery, and eventually sends the data to a data warehouse for research.

Architectural diagrams are the most common way to represent a system of components and relationships. The ability to read and understand common architectural diagrams is a key to communicating with IT professionals.

Figure 10.2 shows a *Network Architecture Diagram* of the network used by our hypothetical system. This diagram conveys information about the hybrid network topology at the lower layers of the OSI network model:

- A star topology centered on the Internet cloud, connected via Firewalls to the Clinic, Hospital, and University networks
- A single Ethernet backbone at the University, connecting servers, data storage, and user devices
- Two Ethernet backbones connected with a (Layer 2) switch at the Clinic
- A wireless network at the Clinic, connecting to a wireless table for user interaction,
- A ring network connected to a (Layer 3) router at the Hospital

Note that a Network Diagram shows how the servers, data storage, and user interface devices are connected but doesn't show what is happening at the application level (Layer 7).

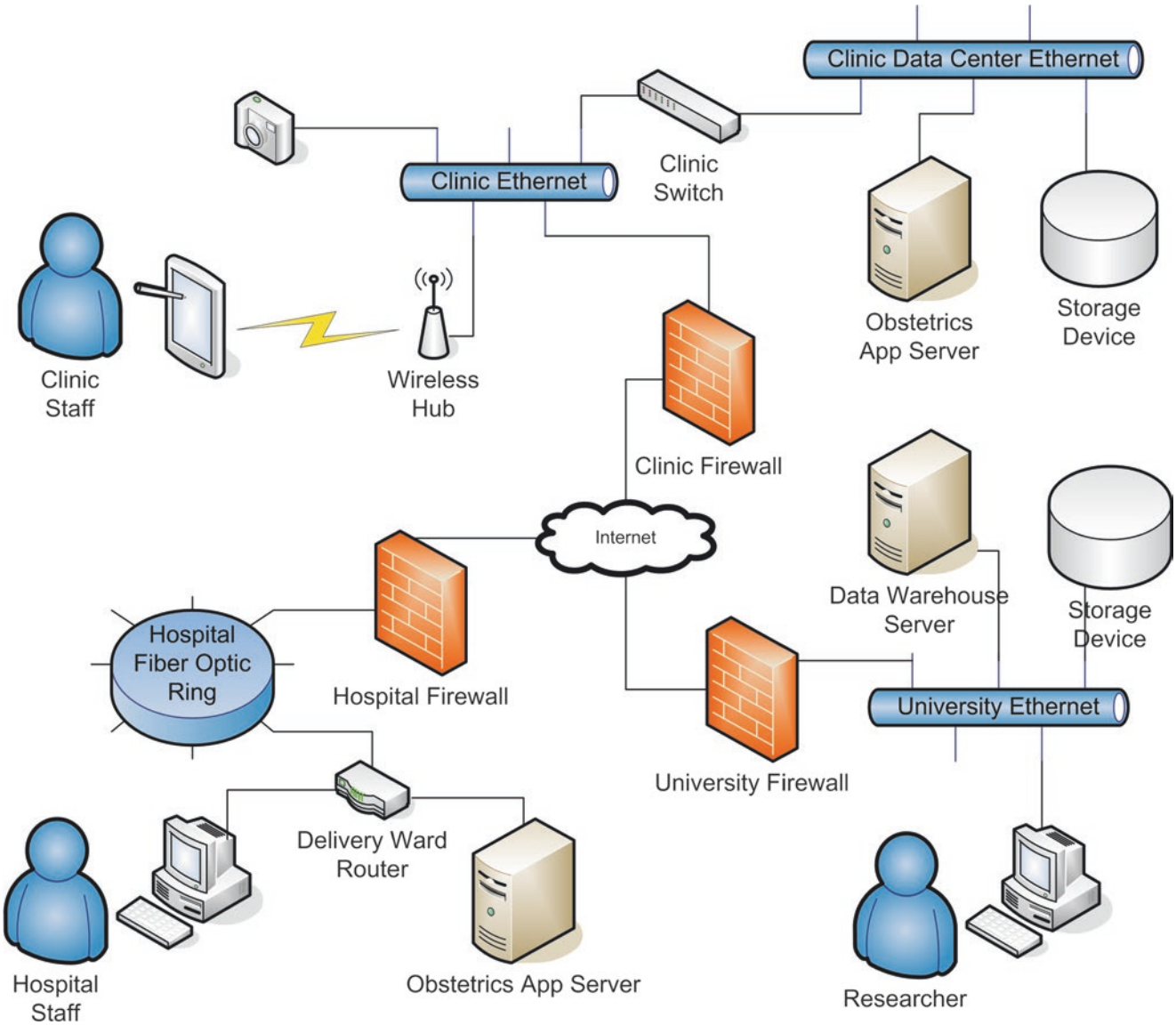

Fig. 10.2 Network architecture diagram of sample obstetrics system

In Fig. 10.3, a *UML Activity Diagram* shows how the application logic works at Layer 7. The major features of the UML Activity Diagram are:

- Swimlanes are vertical boxes that group the activities according to who and where the actor is (Clinic Provider, Obstetrics Application, Hospital Provider, Data Warehouse, or University Researcher)
- Processes, boxes with rounded corners
- Datastores, boxes with less rounded corners
- Flow of control, represented as solid arrows
- Flow of data, represented as dashed arrows
- Split and join operations on the flow of control, shown as dark bars. In our system, this occurs where the clinic provider performs the sonogram and note & observation entry

UML stands for Unified Modeling Language, which Grady Booch, Ivar Jacobson, and James Rumbaugh developed in the mid-1990s [48]. In 2000, the ISO adopted UML as a software design standard. An activity diagram is only one type of diagram in the UML family, including many other diagrams for software structure, behavior, and deployment.

A *Data Flow Diagram* describes the movement of data through a system, with emphasis on data transformations. Circular nodes represent data transformation processes, and labeled lines show data flow from one process to another. The Data Flow Diagram in Fig. 10.4 shows:

- A starting point at a double circle
- Every line is labeled with the data elements in motion

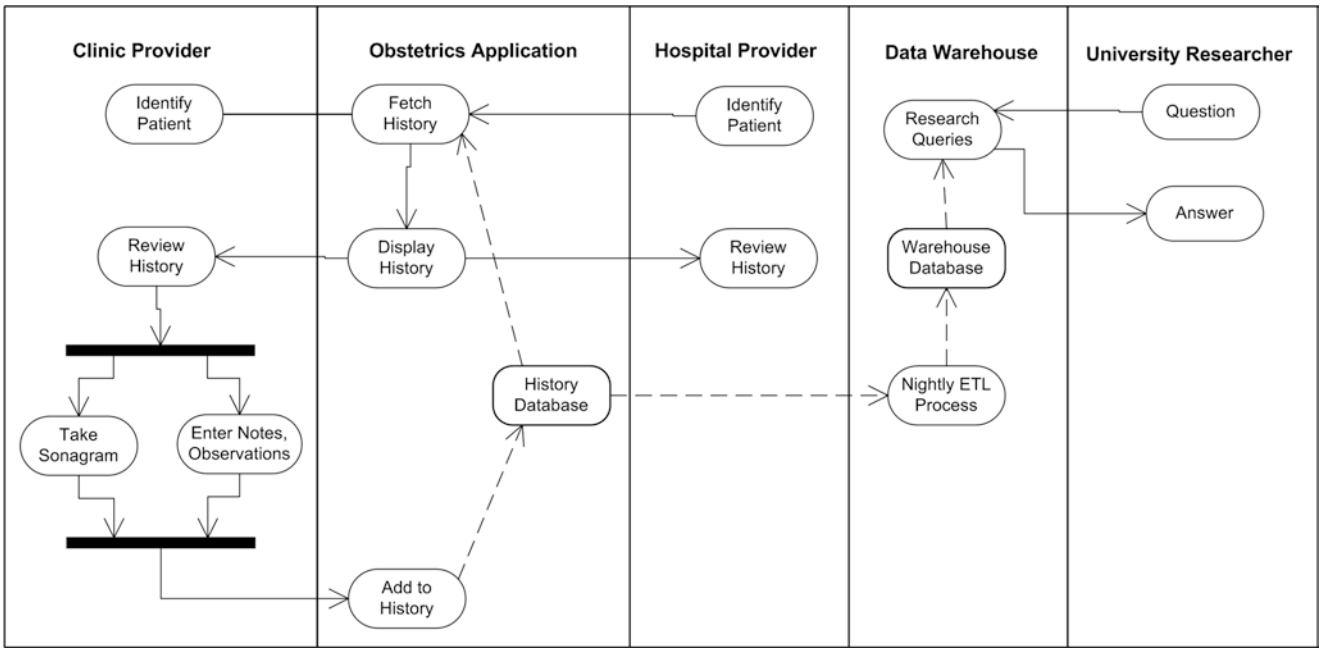

Fig. 10.3 UML activity diagram of sample obstetrics system

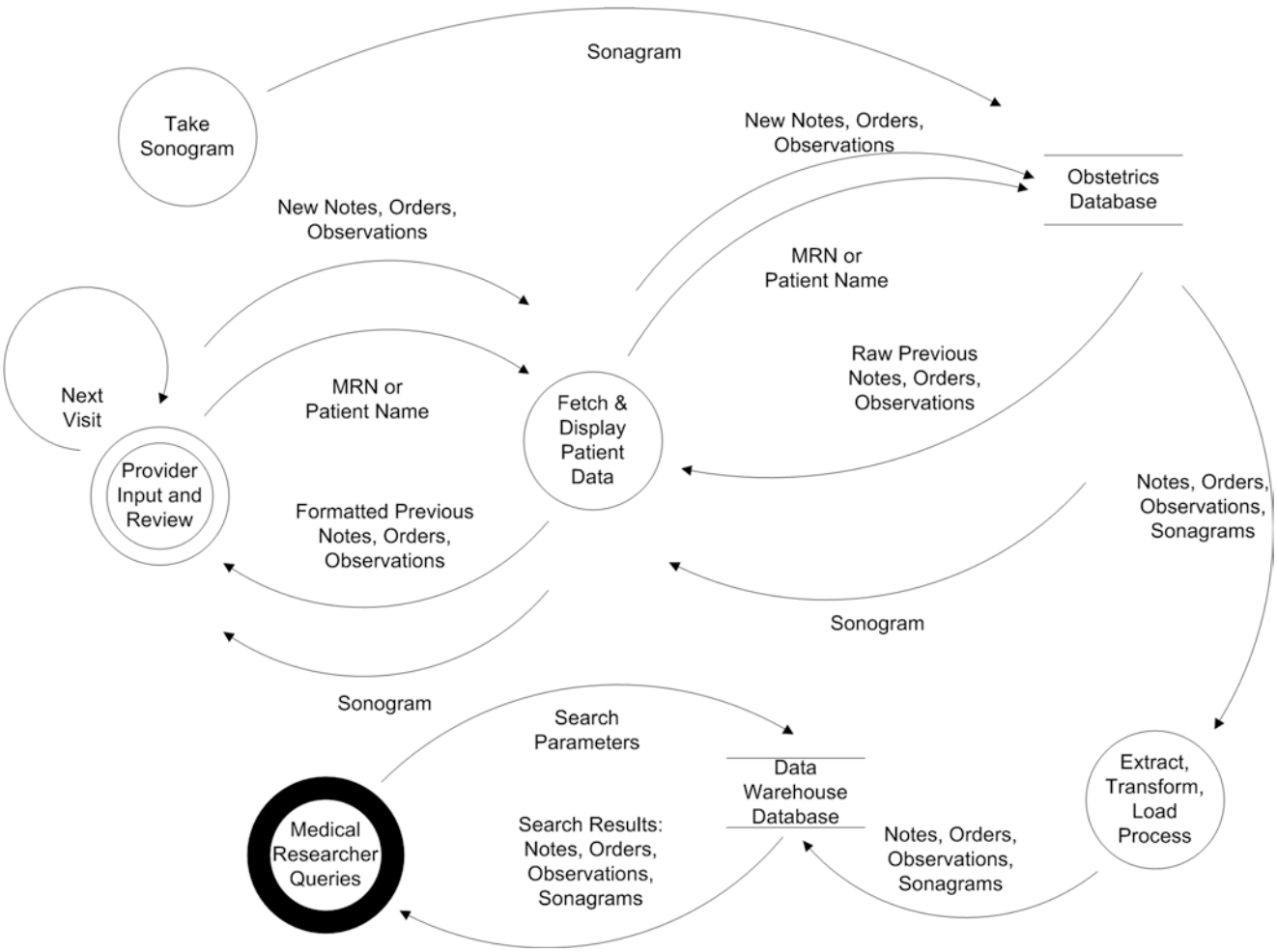

Fig. 10.4 Dataflow diagram of sample obstetrics system

- Every circle is labeled with a data transformation process
- Permanent data stores (obstetrics and data warehouse databases) are represented as open rectangles
- An ending point at the darkened circle

Sometimes the goal is to communicate the overall structure and behavior of a system with only the main features of each aspect of the system. An *Enterprise Architecture Diagram*, as in Fig. 10.5, shows how to accomplish this.

- The main feature of the network shown is the Internet cloud
- Additional network connections are shown as arrows labeled with the data elements being transported, emphasizing the data flow at the application layer (Layer 7) and not the underlying network topology, protocols, and physical structure
- The system users, Clinic Providers, Hospital Providers, and Researchers appear in all types of architecture diagrams. This is appropriate because these actors are essential in defining how the system interacts with the real world
- Computer servers and PCs show how the application is divided and distributed
  - The application displays information on PCs and tablets, organizes information on application servers, and stores data on database servers.
  - The obstetrics application runs on two servers, one at the clinic and one at the hospital, and on multiple user workstations.

Application Architecture

Application architecture refers to the way the software is broken down into components, especially on different servers. *Software tiers* are the layers from user interaction to the database and back. A three-tier architecture is common: (1) user interface (front end) on a PC or tablet, (2) application server, which may serve multiple users, and (3) database server, which may serve multiple applications.

If the user interface layer is simple, such as a web browser, we call it a *thin-client* application. We call it a thick-client application if some or all the application logic is encoded in the front-end tier. If the application resides on multiple servers, then it is called a *distributed application*, and similarly,

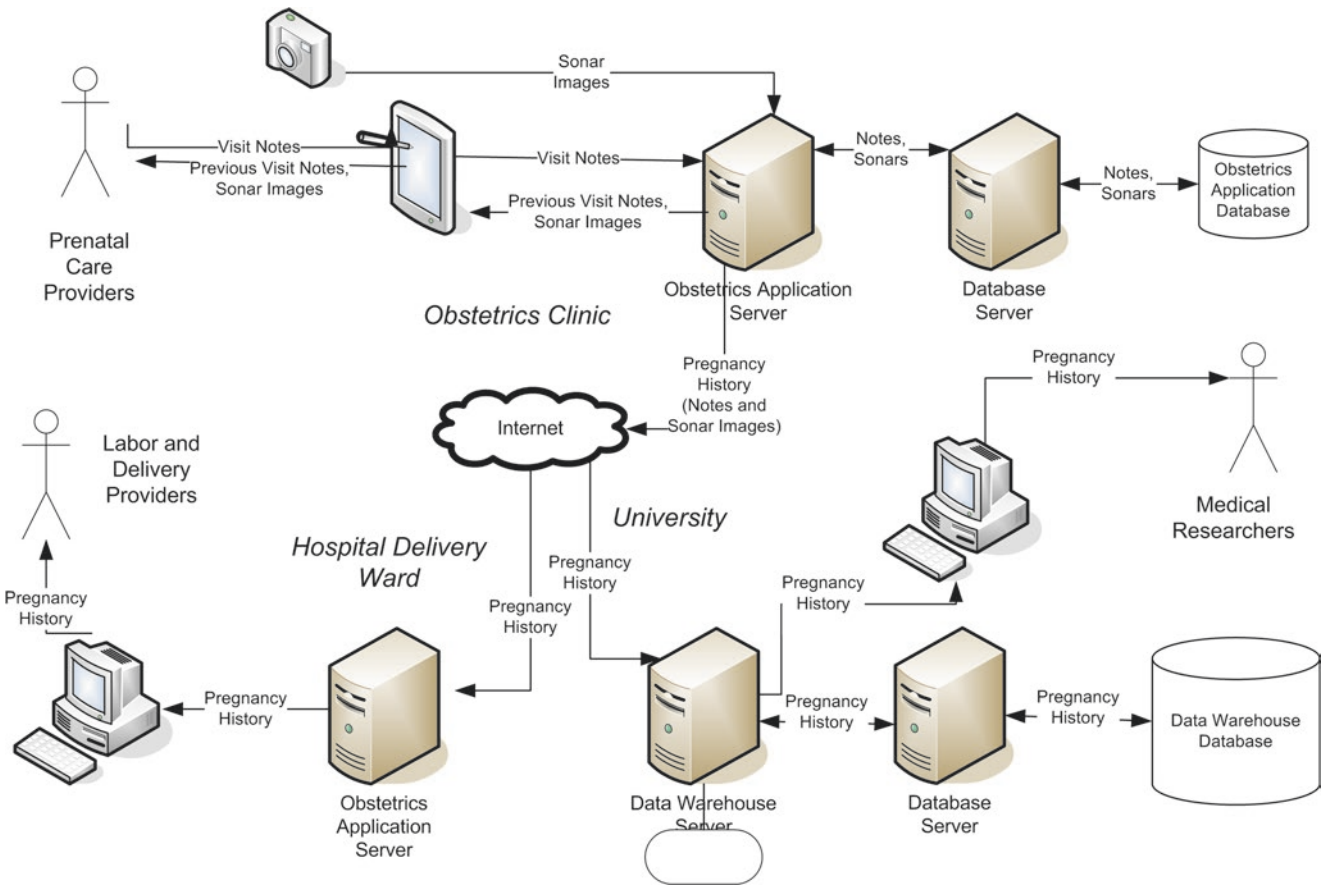

Fig. 10.5 Enterprise architecture diagram of sample obstetrics system

if the database resides in multiple locations, it is called a *distributed database*. Distributed systems are more reliable and scalable, but they come at a greater cost and add complexity to maintain and support.

Non-functional Requirements

The decisions embodied in selecting system architecture have a significant impact on meeting *non-functional requirements*. Non-functional requirements are not features but things like usability, reliability, response time, maintainability, security, disaster recovery, and system cost.

For example, in our diagrams, we represented *servers* as individual computers. This was always true when computers first came into wide use in the 1900s, but it is often no longer the case. *Virtual servers,* or, more precisely, *guest virtual servers,* are emulations of *physical servers* on a larger *host virtual server*. Virtual servers do everything a physical server does, but because they share resources with other virtual servers on the same host, they are more economical and maintainable. *Cloud computing* places the host virtual server on the internet, where a third party manages the host and sells guest computing capacity, capitalizing even further on economies of scale.

Other extensions of the simple physical server include *parallel computing*, in which multiple processing units share the computational load. This is very common in recent years, even on inexpensive PCs. *Grid computing* extends the parallel computing notion to groups of physical servers, such as all the PCs in a building or all servers in a data center. Some applications can leverage parallel or grid computing to speed themselves up many times (such as MapReduce discussed earlier in this chapter) [18], but other applications may be a series of sequential steps that cannot benefit from parallel computing.

Integration and Interfaces

Another key aspect of application architecture is whether the relationship between two components is tight and private (*integrated*) or loose and public (*interfaced*). Interfaced components allow for interoperability. This is especially true for interfaces defined by public standards. For example, the World Wide Web (WWW) depends on two public standards: TCP/IP for transport and HTTP for formatting data for use by web browsers.

When computers provide services to other servers on a network via a standard application interface, it is sometimes called a Service-Oriented Architecture (SOA) [49]. Some common frameworks for general-purpose SOAs include SOAP (Simple Object Access Protocol) [49], REST (REpresentational State Transfer) [50, 51], CORBA (Common Object Request Broker Architecture) [52] and ICE (Internet Communications Engine) [53].

REST is heavily used in medical informatics, as it builds on Internet motifs and is simple to implement and operate. Many of the systems discussed in earlier sections utilize REST, including FHIR, i2b2, and OHDSI tools. Other communications standards that typically rely on REST include HL7, CCD, and standard terminologies like ICD-10, LOINC, and RXNORM (detailed in Chap. 13).

Software, Computer Languages, and Programming

Software is the command center that controls the components in the system architecture. Like spoken language, the software can be written in a variety of programming languages. These vastly differ from one another. Most programming languages are extensively documented in other reference books and online [54–57]. Here, we will cover the most important approaches from the perspective of medical informatics, focusing on data.

Data Types

In programming languages, data are stored in *variables*. Variables are temporary holding cells for data that *vary* as a program executes. Data can be stored longer-term in files on disk or in relational database tables. In MUMPS, this distinction between database and variable is blurred—variables can be either in-memory holding cells or locations in a database.

No matter where data are stored, each variable or database column has a specific *data type* that constrains the data type that can be stored. Languages can be *strongly typed* or *weakly typed*, depending on the degree of computer verification that variables correctly match their defined data type. Weakly typed languages, which do not enforce such checks, are harder to debug and run less efficiently. Still, they offer more flexibility and the potential for data types to change as the program is running. Common data types include:

- **Numbers**: usually defined as integers or floating-point numbers (numbers with decimals)
- **Letters**: single characters and strings (sequences of characters, or what we commonly think of as text)
- **Dates and times**: specialized storage of these temporal data, which supports computer interpretation and manipulation
- **Lists and sets and other collections**: groups of numbers or letters stored in a way conducive to performing iterative operations
- **Binary data**: information such as image data that is not meant to be directly manipulated by a programmer but transported to specialized software. In databases, columns of this type are known as *blobs*. In programming languages, the name for binary data varies widely.

Programming

In informatics, a distinction is frequently made between "software development" and "database programming". The former are programs run directly on the computer and correspond to either the user interface or application server layers in the three-tier architecture. In, for example, an EHR system, the software development component provides the user interface and control structure that guides the system's functionality. The database programming involves subprograms that process data, such as loading a patient's record, pulling up today's appointments, or analyzing quality deficits in the treatment of diabetic patients.

Database Programming

As discussed previously, relational database programming is done in SQL.

The core of all SQL code is the SELECT statement, which implements set theory to ask questions about the data. If we wanted to ask questions about the PATIENT table with one row per unique patient, we would use this format: SELECT <data elements> FROM PATIENT WHERE <constraint>. We can use aggregate functions, such as

```
SELECT avg(income) FROM PATIENT WHERE birth_
date>'01/01/1979'
```

This will return the average income of all patients born after January 1, 1979. We would use a join with a common column between the tables known as a "key" to answer questions involving multiple tables. A full discussion of SQL SELECT statements, including more complex joins and aggregate operators, is out of the scope of this chapter, but excellent online tutorials are readily available. SQL commands can be collected into small programs that are more complex than a single statement. These are called *stored procedures*.

Software Development

Traditional software development is done through imperative languages, which issue a series of commands to the computer. There are a variety of styles, each with advantages and disadvantages. Broadly, these can be grouped into object-oriented and procedural styles.

Object-Oriented vs. Procedural Programming

In **object-oriented programming**, data structures can be built to have *properties* and *methods*. Properties are variables that the object holds, and methods are actions that one can perform on the variables. For example, there might be objects named Patient and Appointment. Patients could have a method named hasAppointment, which verifies whether the patient has a given appointment. This method would take an *argument*, a piece of data upon which the method operates. Our hasAppointment method's argument is an appointment object. The appointment object might have various properties such as date, time, clinic, and physician ID. The object definitions are templates for actual appointments and patients. These object definitions are *instantiated* for each specific case.

Java is a very popular object-oriented language. The language and many tools associated with it are freely available. Also, it is a cross-platform language, meaning that it will run on many types of machines. This is because Java runs on a *virtual machine* that interprets the Java program when it is run and converts it to the machine language of that particular machine.

Other notable object-oriented-only languages include: C++, which is the grandfather of all object-oriented languages and continues to remain the most efficient due to its native compilation; C#, Microsoft's virtual-machine Java-like language, which is easier to develop in but only runs on Windows; Ruby, a popular more recent language which also improves upon Java and is popularly used for web applications using the "Ruby on Rails" framework.

Procedural programming is more straightforward: entire programs share methods and global variables, and there are no objects. This structure has a significant disadvantage: the object paradigm makes it easier to organize and conceptualize large programs. Therefore, most languages that support procedural programming also support some type of object-oriented programming. Procedural languages are particularly useful as scripting languages. *Scripts* are short programs that control the functionality of other computer programs, most frequently webpages. Popular procedural languages that also support object-oriented programming and are widely used for scripting include Python (widely used in scientific programming), PHP, JavaScript (which powers the world wide web), and R (which is widely used in statistical modeling and data visualization).

A notable exception is the language C, a procedural language that does not support object-oriented programming and is also not well suited to scripting. Many of today's most complex software underpinnings (e.g., most operating systems) are written in some variant of C. C was developed long before object-oriented programming was invented or scripting was envisioned. Because it continues to be the most powerful and efficient high-level language available (despite its complexity), it is still widely used today.

New languages continue to appear to address the problems of the modern era. For example, Google's Go language (sometimes called Golang) is built around concurrency—executing multiple tasks simultaneously. This is in many ways a response to the growing popularity and prevalence of parallel and grid computing.

Other programming paradigms, such as functional programming, are of primary interest to mathematicians and computer scientists and are therefore out of the scope of this chapter.

Control Structures

Programs don't just issue commands in order. Most imperative languages make extensive use of *control structures* to manipulate the flow of commands. SQL is an exception; SQL has control structures, but control structures are not a central component of the language because the primary motif is set theory. In imperative languages, control structures are central to the design of the program. Broadly, control structures can be broken down into *looping* and *branching*. A variant of looping is *recursion*, but the differences between these are out of the scope of this chapter.

A common programming design is to repeat some operation until a condition is true. This is done with a loop. A list of names could be looped over until all the names are processed. This is known as a *for* loop because operations are performed for all elements in a collection. There are also other types of loops, such as *while* loops, which operate while a certain condition is true (such as accepting new patients until the clinic closes). Branching occurs when the program takes a different direction depending on the value of a variable. This is done through an *if… then* statement.

Compiled and Interpreted Languages

Languages are either *compiled* or *interpreted*. Compiled languages are converted into code that the computer can understand before running the program. Interpreted languages are converted to this machine language from scratch each time the program is run. Languages that run on virtual machines are a special case. A language run on a virtual machine is first compiled to *byte code*, a pseudo-machine language that is quickly translatable into machine language.

Therefore, a performance hierarchy emerges among programming languages: the fastest languages are natively compiled, the second-fastest languages run on virtual machines, and the slowest languages are interpreted. Of course, this hierarchy has some exceptions because of how specific features in the language are implemented. For example, Jython, a version of Python that runs in the Java virtual machine, is generally slower than the interpreted language Python. As computer speeds increase, this hierarchy is becoming less important, at least for high-level application development. Although an operating system or other core computer code that is run constantly should be written in a compiled language, many of today's user-facing applications are written in Java or Python. It is typical in scientific code to use an interpreted or bytecode language for most of the application and then write core functions (like image processing) in a compiled language for speed.

Software Design Considerations

Code Modularity, Reuse, and Performance

Code Reuse The ability of a programmer to understand the programming code she or others on a team have written is imperative to the success of a project. Therefore, many software development methodologies highly emphasize software documentation. Also, there are frequently multiple approaches to solving computational problems. In a team-based environment, frequently, the approach that is most easily understood by others (the most readable approach) is preferred.

Modularity Self-contained software code can be distributed in "libraries" that other software developers can use. Thousands of these libraries exist for any given language; they provide the functionality to the programmer quickly without the programmer having to dive into the source code of another developer. Because the libraries do not require source code, many commercial products provide libraries while retaining the confidentiality of their proprietary software code. Examples of libraries include packages to manipulate Microsoft Office documents from within a software program, packages to perform statistical analysis of data, or packages for animation and visualization. One well-known source for quality, free libraries is the Apache Software Foundation at www.apache.org.

Performance Often code readability is more important than performance, but for computation-intensive tasks (such as KDDM), performance is very important. The performance of computer algorithms can be determined mathematically through *complexity analysis*. The practical performance of computer programs is often judged through *profilers*, which are special programs that measure the speed of software under a variety of conditions.

Methodology and Quality Assurance

Software Development Methodology A variety of organizational designs for developing software have been proposed. These tend to be combinations of two overall types:

- **Waterfall**: this is the traditional method of software development. A phase of requirements gathering occurs before any software is developed and requirements documents are assembled. Then the software development commences, followed by testing. This is a very robust and thorough method, but the final product is often either not

what was envisioned by those providing the requirements or changes during the product cycle.

- **Iterative**: This is the antithesis of the waterfall model, in which a minimum of planning occurs at the beginning of the project. Rather, the software is developed in short cycles of planning, development, and testing. The iterative approach offers closer alignment with shifting user needs and complex changing environments. However, it also tends to focus on immediate needs instead of long-term goals. This can tend to make the developed software less thoroughly developed and less modular.

The two overall types are combined in many methodologies. The **spiral** method directly combines these two types. Each project is defined as a collection of many development cycles, some of which use more of a waterfall approach, and some are more of an iteration.

Agile methodologies collectively refer to a variety of rapid cycling software development, in which development, testing, and requirements gathering revision are closely fused [58]. Agile methodologies use the same approach as the spiral method (shifting between iterations and planning phases). Still, they try to be more flexible by doing less pre-planning of cycles and being more able to change as a project moves forward.

A popular agile approach is the **scrum** methodology, in which work is broken down into 30-day **sprints**, which begin with planning and requirements gathering and end with a new release of the product. The sprints are not defined before the sprint's beginning, making this approach very resilient to changing needs. All these methods still have the danger of focusing too heavily on short-term development goals, however.

Quality Metrics and Testing Many methodologies exist for ensuring quality software and for subsequently testing that software. Popular methods to build software with quality from the outset include *pair programming, code reviews, and software documentation before writing the code* [58]. Also, there is some evidence that more readable languages tend to lead to higher-quality software. Software testing is fundamentally important, no matter how much a development methodology emphasizes up-front quality. One robust approach is that the software developer creates *unit tests* as they develop their software. Unit tests are tests of an individual function of the software for a specific combination of inputs. A finished piece of software might have thousands of unit tests. If these tests are written as the software is developed, it is simple to perform *regression testing*, or running all the old unit tests, to verify that new features have not broken any old features. If a test that used to work no longer does, it becomes straightforward to find the change that broke that particular test.

Verification and Validation Software *verification* testing, like unit tests, compares the software to what it was designed to do and may be performed by the software developers or by dedicated testers. The end-users and requirements gatherers perform software validation testing. Validation makes sure that the software performs the function that it was originally intended to. Whereas verification finds bugs in the software, validation finds problems in design or requirements gathering.

Other Considerations

Open-Source Much commercial software is closed source, meaning that the programming code used to develop the software is not available to the licensees. In open-source software, the code *is* made available [59]. However, the code could still be copyrighted and might have restrictions on changing or using it. Dozens of open-source licenses define exactly how to program code that can be used, changed, and redistributed in open-source software. Because the program code in commercial applications is often a trade secret, commercial software is more frequently closed source. The commercial software that is open source tends to have restrictive licenses to protect the copyright holders. For products where the goal is that their code is used for further innovation, licenses tend to be less restrictive, and the vendor company's main financial gain is through support contracts.

Platform The computer platform on which the software runs is another important consideration in choosing or developing software. As discussed previously, software written in some languages, such as Java, can be run on multiple computer platforms. Generally, however, the software is written for a particular operating system (such as Windows, Macintosh, or UNIX), a particular database platform (such as Oracle or SQL Server), or a particular web browser (such as Google Chrome or Microsoft Internet Explorer).

Security

Computer security is a balance of two things: (1) preventing misuse of computer systems and data, and (2) enabling proper use of computer systems and data. We could ensure no misuse by turning off a computer and locking it in a vault, but that would defeat the second objective. The goal must be a balance of usability and minimal risk of misuse.

This section will frame the discussion of computer security in terms of the HIPAA Security Rule, which is the law for all computer systems containing patient-specific medical

data. Still, the principles embedded in these regulations are good security practices for any type of data. Chapter 17 goes into much more detail on all the various considerations around cybersecurity.

The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes a Security Rule section to establish security standards for the protection of *Electronic Protected Health Information* (*e-PHI*). The HITECH Act of 2009 extends HIPAA with additional penalties for e-PHI security breaches and additional rights for patients to view and limit access to their own data. The latest "Omnibus HIPAA Final Rule" was published in 2013 [60]. Many states have additional patient privacy regulations.

Here is the core of the Security Rule:

The HIPAA Security Rule [60] addresses the confidentiality, integrity, and availability of e-PHI on any computer system that creates, receives, maintains, or transmits such information. Organizations handling e-PHI (referred to as *Covered Entities* and their *Business Associates,* with whom they exchange e-PHI) are required to

1. Ensure the confidentiality, integrity, and availability of all e-PHI the covered entity creates, receives, maintains, or transmits.
2. Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.
3. Protect against any reasonably anticipated misuses or disclosures of such information.
4. Ensure compliance by its workforce.

There are four types of technical safeguards to ensure the security of e-PHI: (a) access control, (b) audit controls, (c) integrity controls, and (d) transmission security. We will discuss each of these in turn.

(a) *Access Control* determines who has access to the data and consists of two parts: authentication and authorization.

Authentication ensures that the user is who they say they are. Usually, this is by a username and password. Other options include smart cards and biometrics, such as fingerprint readers. Physical security, such as limiting access to selected workstations or smartphones, also aids authentication. *Two-factor authentication* means that two types of authentication are required in combination, such as a smart card plus a PIN (Personal Identification Number) or a password plus a controlled network location.

The second component of Access Control is *Authorization*, which enables the user to access the computer systems, applications, and data necessary for their job function. A researcher is authorized to access data only for patients in their study. A physician is authorized to order lab tests and medications in a CPOE (Computerized Physician Order Entry) system for patients under his care.

(b) *Audit Controls* require computer systems to log activity, such as who viewed or modified a patient record, protect the audit logs from alteration and make the audit logs available for inspection.

(c) *Integrity Controls* consist of implementing policies and procedures to ensure that e-PHI is not improperly altered or destroyed.

(d) *Transmission security* refers to measures taken to prevent unauthorized access to e-PHI when transmitted over a network. Data encryption is a must, either by using a VPN (Virtual Private Network) or a point-to-point protocol such as SSL (Secure Sockets Layer). Computer systems first exchange encryption keys and then use those keys to scramble the data during transmission. Firewalls between organizations ensure that only authorized computer systems of Business Associates can receive e-PHI.

The Common Rule

The Common Rule is a 1981 rule of ethics (revised in 2018) regarding biomedical and behavioral research involving human subjects in the United States [61]. It establishes the regulations governing Institutional Review Boards for oversight of human research through the Department of Health and Human Services Title 45 CFR 46 (Public Welfare) Subparts A, B, C, and D. The Common Rule is the baseline standard of ethics by which any government-funded research in the US is held; nearly all academic institutions hold their researchers to these statements of rights regardless of funding.

The main elements of the Common Rule [62] include requirements for assuring compliance by research institutions, requirements for researchers' obtaining, waiving, and documenting informed consent, and requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping. The Common Rule includes additional protections for certain vulnerable research subjects: for pregnant women, in vitro fertilization, and fetuses, plus additional protections for prisoners and children.

Malicious Attacks

The HIPAA Security Rule obligates the organization to protect e-PHI against reasonably anticipated threats. One such threat is a *brute force attack,* which consists of the attacker trying to guess an encryption key or a password by trying many different combinations until one works. The length of the key or password determines how long it will take an unauthorized party to guess correctly—the longer the key, the better.

In the *Man-in-the-middle attack*, the attacker inserts a malicious computer system on the network somewhere between two systems exchanging data. The system in the middle acts as a router, receiving and retransmitting data, but it also copies or even alters the data packets as they pass through, potentially compromising e-PHI or stealing passwords, without either legitimate computer system realizing that anything is wrong.

Malicious actors may exploit weaknesses in computer applications and operating systems to place their own software on a computer, which can open e-PHI to the intruder. Two of the most common exploits, buffer overflow, and code injection, are described below.

The *buffer overflow attack* sends the target system a larger data packet than it expects. The computer system accepts the packet into a reserved area of memory, called a buffer. The extra data in the super-sized packet exceeds the buffer size, writing the extra data past the end of the buffer into an area of memory used by executable code. Later, the computer executes the attacker's code, thinking it is the original code that was overwritten, and the attacker's code can do anything it wants to on the target system.

In the *code injection attack*, the malicious actor puts executable code into the input data fields of an application. The attacker surrounds the code with special "escape characters" that cause subroutines within the computer application to end their intended operation prematurely and misinterpret the rest of the input as code to execute. For example, an application might insert user input directly into an SQL statement sent to the database for execution. An *SQL injection attack* might answer an MRN prompt with "; SELECT * FROM ALL_USERS;" The ";" tells the database query engine to start a new command, and the select statement returns a list of all database accounts to the attacker.

The Federal Information Security Management Act (FISMA)

The Federal Information Security Management Act (FISMA) is a United States federal law passed as part of the E-Government Act of 2002 [63]. It set the requirements for each federal agency to create, document, and implement programs that ensure security for the agencies' data and the systems that support the agencies' operations and assets, creating documented programs to use for securing said agencies' data and the systems they use for their operations and assets. Many federal research programs must obtain FISMA Authority to Operate (ATO) when participating in government Contracts or "Other Transaction" funding mechanisms. FISMA aims to prevent unauthorized access, use, disruption, modification, or destruction of information and information systems and requires a "FISMA boundary" around the software systems managing the data for the federal research program. By preventing misuse or attacks on the data and software, confidentiality, integrity, and availability are ensured. These systems must obtain an ATO to authorize system processing before and after operations begin, signifying the systems have detailed security plans, assigned security responsibilities to appropriate officials, and regularly reviewed the systems' security mechanisms.

De-identified Data

The HIPAA Security Rule only applies to e-PHI, namely data that a third party can identify as belonging to a specific individual. HIPAA specifies 18 identifiers of an individual, such as name, social security number, address, certain dates, and implanted device serial numbers. You can *anonymize* or *deidentify* e-PHI by removing all of these identifiers. The modified data set is not e-PHI and is not subject to HIPAA regulations. As discussed in the HIE section earlier, this allows organizations to share de-identified data sets for research purposes.

When in doubt, seek out the advice of your organization's HIPAA Compliance Officer or IT Security Officer. They can help interpret and advise on security regulations for e-PHI. The consequences of a mistake can be devastating. The HITECH Act of 2009 provides penalties for negligence leading to an e-PHI breach that can add up to millions of dollars. Major breaches of security, defined as unauthorized access to 500 or more unencrypted patient records, requires notification of the local media and reporting the breach to the HHS, where the breach will be listed on the HHS public internet site, sometimes referred to as "The Wall of Shame" [64].

Emerging Trends

As this chapter is being written, four emerging technologies appear to capture the most press and excitement. Only time will tell if they prove to be fruitful. The NoSQL database is

considered to be a cheap, scalable solution that will become highly competitive with the relational database that is currently the mainstay of data analytics. Although that destination is premature, it clearly will open new worlds for extracting data from documents that could not be performed in a scalable manner 10 years ago.

The "App store for health" is another emerging trend that holds promise for opening the user interface of the electronic healthcare system to novel ways of presenting data and providing decision support. Such marketplaces allow Apps to be bought and sold to accommodate niche needs throughout the system by a large workforce of developers.

Big Data represents a third emerging trend, with sensors on the body collecting massive amounts of data. The ability to sift through the data to extract insights will define much of how we view physiology in the future.

Data Enclaves, especially on the cloud, is a fourth emerging trend [65]. The Data Enclave provides a release of data, often with PHI, into a computing environment that has been pre-loaded with programming tools and libraries. However, the networking configuration does not allow the data to travel out of a firewall boundary around the Enclave. The data can be viewed (often on a Virtual Machine) but not removed.

Summary

Information technology is how all clinical informatics is ultimately expressed. The knowledge one has on the details of IT will figure into many implementation decisions. Data optimization, program efficiency, and attention to security will contribute greatly to the success of the informatician.

Query Tools and Techniques: Resources

We have attempted to include relevant resources (including websites, articles, and books) in the References section when possible. However, we also wanted to highlight the following resources for query tools and common data models:

- **Patient-centered Outcomes Research Network:** https://pcornet.org/resources/
- **National COVID Cohort Collaborative:** https://covid.cd2h.org/n3c
- **Informatics for Integrating Biology and the Bedside:** https://www.i2b2.org/software
- **Observational Health Data Science and Informatics:** https://www.ohdsi.org/software-tools/

Questions for Discussion

1. Clinical Data Warehouses store structured data in various Common Data Models (CDMs) and homegrown data models. What data models have your organization adopted or considered, and what economic and data considerations led to that decision?
2. If you were an informatics director tasked with developing software to build interactive reports on the various data facts in the hospital clinical data warehouse (e.g., the prevalence of uncontrolled diabetes over time), what programming language and software development methodology would you choose? Would you instruct your team to write the program as a series of SQL queries or use a higher-level language like Java?
3. In designing a physical network for a new informatics research lab, what key decisions must be made around network topology and network architecture? Draw several possible network architecture diagrams and discuss the pros and cons of each.
4. Imagine your organization wants to join a popular clinical data research network and participate in federated queries. What do you think are the most important considerations in ensuring that the shared data are appropriately de-identified and patient identity remains protected? What data sources would you use (e.g., notes, flowsheets, problem lists, etc.), and how would you think through designing an ETL process?
5. You have been awarded a federal contract to manage the data from a new clinical study sponsored by the NIH. What are the expected FISMA requirements you will need to adhere to within your "FISMA boundary?"

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Clinical Information Systems and Applications

11

Caitlin M. Cusack, Veena Lingam, Christoph U. Lehmann, and Rachel Wong

Learning Objectives

- Understand settings in which clinical information systems are used.
- Describe the key functionality of clinical information systems.
- Understand the role of telehealth as a tool for healthcare delivery and how it integrates into the health information system.
- Describe the spectrum of clinical communication channels, the flow of information between users, and best practices.
- Understand the reporting of data to clinical registries for secondary use.
- Identify key considerations around medical device management in health information systems.
- Gain insight into innovations and future directions of clinical information systems.

Practice Domains

- K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
- K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
- K068. Functionalities of clinical information systems (e.g., Electronic Health Records, Laboratory Information Systems, Picture Archiving and Communications Systems, Radiology Information System, vendor-neutral archive, pharmacy, revenue cycle)
- K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed-loop communication)
- K078. Clinical registries
- K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
- K085. Telehealth workflows and resources (e.g., software, hardware, staff)

Case Vignette

Ms. Jones was diagnosed with invasive breast cancer following a breast biopsy done in her rural community. Upon diagnosis, she is included in her state's breast cancer registry. Consultations, surgery, and follow-up care are 2 h from her home at the tertiary care center. Her care is documented in the local electronic health record, with data available to her care team electronically and to her primary care doctor via the regional health exchange. During her surgery, she suffers a cardiac event, resulting in post-op care in the cardiac care intensive care unit and a brief stay at a rehabilitation center. Imaging and post-op radiation therapy are completed at a radiology center closer to her home. Throughout her entire

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course for her breast cancer, from diagnosis, treatment, and post-recovery care, her care is facilitated by clinical information systems (CIS) that support all facets of her care. Throughout this chapter, Ms. Jones' journey and her interaction with CIS will continue.

Introduction

Just as technology has become an everyday aspect of our daily lives, health information technology (health IT) has become a ubiquitous tool in healthcare delivery and continues to gain importance. However, the path to today's health IT state has been long. By 1965, electronic health records (EHRs) were used in 70 hospitals, and it wasn't until 1971 that Lockheed Corporation produced the first computerized provider order entry (CPOE) system. In the 1980s, the Veteran's Administration's Veterans Health Information System Technology Architecture (VistA) system was ready. The Master Patient Index (MPI, see Chap. 14) was first introduced in the 1980s. Later in the decade, personal computers and the Windows operating system brought more computing power into physicians' offices. In 1990 the world wide web was invented, and by 2004 President George W. Bush had pointed out the importance of EHRs for healthcare. However, until 2009, with the 35-billion-dollar investment in health IT under the American Recovery and Reinvestment Act (ARRA), the EHR reached a penetration of physicians' offices and hospitals of over 90% [1].

Health IT is now ubiquitous. It reaches out beyond clinical settings throughout the community. Even patients now are familiar with EHRs and patient portals; smart devices such as scales, glucose monitors, and blood pressure monitors are all capable of feeding data back to the EHR. Thousands of apps on smartphones purport to manage health and well-being.

Enterprise Clinical Information System Settings

Not long ago, the task of describing healthcare settings where technology had penetrated would have taken a sentence: some hospitals, fewer ambulatory settings, a scatter of pharmacies. The Institute of Medicine's (IOMs) 2003 landmark book *Patient Safety, Achieving a New Standard for Care* [2] identified only four settings that contained electronic functionality: "…hospital, ambulatory care, nursing home, and care in the community".

As technology adoption has drastically increased, particularly since the Health Information Technology for Economic and Clinical Health Act (HITECH) Act and Meaningful Use incentive program sponsored by the U.S. Centers for Medicare and Medicaid Services (CMS), technology has penetrated every aspect of our healthcare system. Health care delivery settings go well beyond hospitals and ambulatory settings into our homes, long-term care, rehabilitation centers, and even in the ambulances that transport patients to acute care settings. Taking advantage of computing power, systems have been developed to support, enhance, and create efficiencies in every aspect of health and healthcare. As a focal point in the large scope of these systems, consider the patient, as the consumer of these services, at the center of these settings (Fig. 11.1).

During Ms. Jones' care, she interacts with numerous healthcare settings that take advantage of clinical information systems to support that care: her primary care physician's office, the community pharmacy, a commercial laboratory, the mammography center, the local surgeon for her breast biopsy, the Breast Care Center 2 hour from her home for her consult, definitive surgery, the rehabilitation center, and her home.

Seen at a high level, settings include the home and the patient's community. The community contains urgent care facilities, clinics, private physician offices, free clinics at charity organizations, free-standing radiology centers, laboratories, physical therapy, and surgery centers; large chain and small independently owned pharmacies; long-term care facilities; and rehabilitation centers. Entry into some settings requires that the individual be part of a group with access, for instance, school clinics, university health centers, and clinics embedded into companies that provide care only for their employees.

Many of the high-level care settings contain sub-settings, all supported by the software. Using the hospital as an example, each facility is a collection of individual settings. Some areas receive patients: hospital-based clinics, the emergency department, and admissions. While smaller hospitals may have single inpatient settings, larger hospitals begin to segment patients into dedicated inpatient areas: medical, surgical, cardiac, antepartum, neurology, pediatric, physical therapy, and many others. For those in critical condition, intensive care units (ICU) provide care: smaller hospitals may have a single ICU, while larger facilities may segment critical care into medical-surgical ICUs, coronary care units (CCU), pediatric intensive care units (PICU), neonatal intensive care units (NICU), trauma intensive care, neurological intensive care, and burn care units. Surgery is performed within hospital and outpatient surgical suites, including pre-operative areas, operating rooms, post-anesthesia units, and recovery. Obstetric labor and delivery units may care for both healthy laboring and critically ill patients. Many units also have dedicated

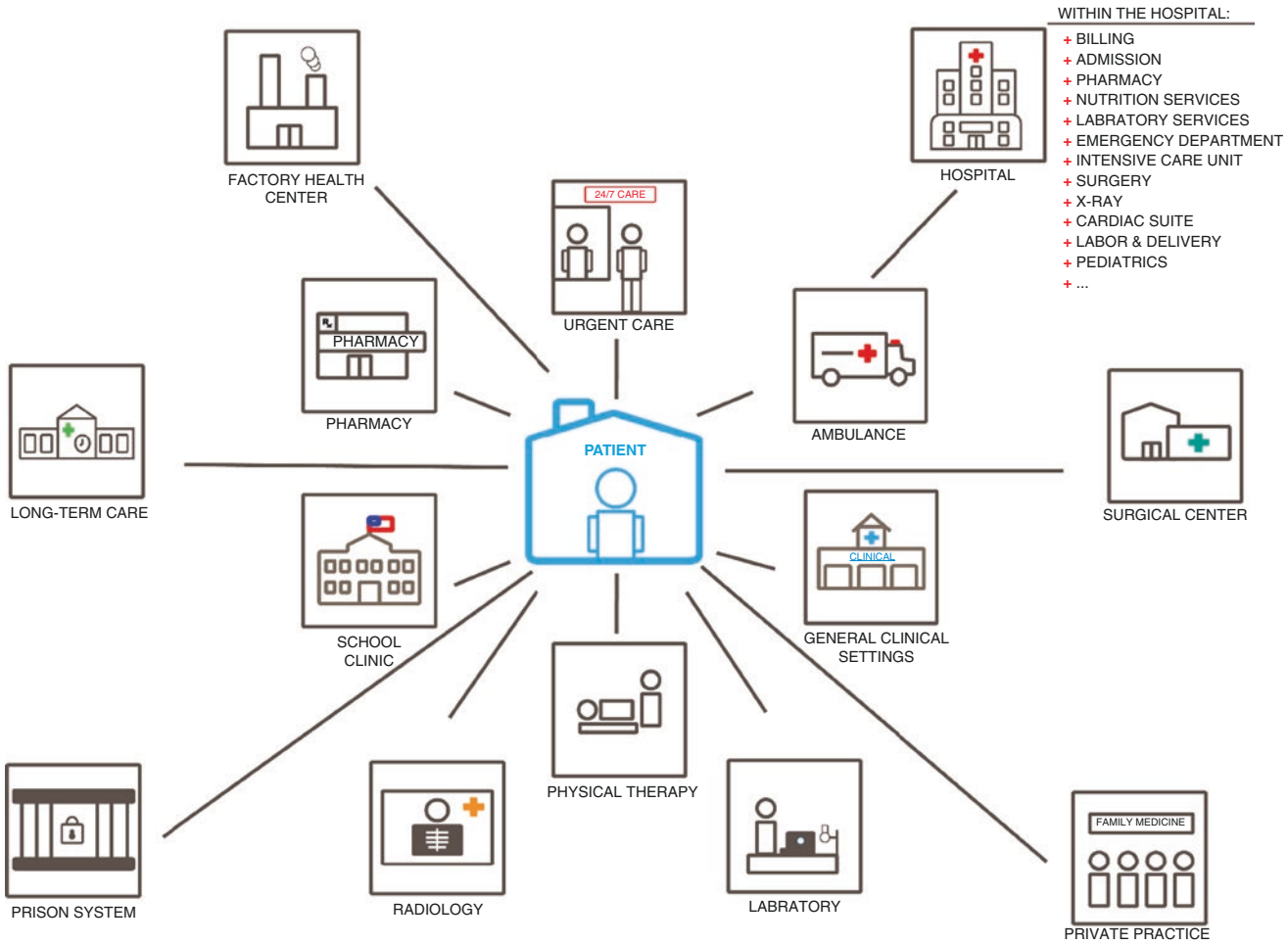

Fig. 11.1 Common settings for clinical information systems

surgical suites for cesarean deliveries, antepartum, and post-partum procedures. Cardiac suites may have capabilities to perform invasive procedures such as cardiac catheterization and relatively simple procedures such as echocardiograms and stress tests. Radiology suites include capabilities to perform x-rays, ultrasound, magnetic resonance imaging (MRI), computerized tomography (CT) scans, positron emission tomography (PET) scans, and more. Some also have active interventional capabilities that allow fluoroscopy guidance, vessels cauterization, and radiation treatment. Added to these settings are those that the patient may never physically visit but that are critical to care: pharmacy, laboratory, pathology, supply, and blood bank. Finally, there are the areas in the hospital that collectively ensure that the enterprise is functioning: the administrative suites, billing, medical records, pastor services, medical library, food and nutrition services, and housekeeping services. Today, many of these settings are computerized, with specialty software supporting unique needs and workflows.

Functionalities of Clinical Information Systems

Clinical information systems (CIS) are software systems coupled with necessary hardware that allow the capture, storage, and processing of clinical information to those making clinical decisions [3]. Considering the vast scope of settings highlighted above, the applications that make up a CIS have grown exponentially. Once the available range could be summarized into core functionality—electronic medical record (EMR), ancillary systems, scheduling, and billing—applications no longer fit into neat, discrete categories. To describe all that exists under the umbrella of CIS and the functionalities of each type of CIS is beyond the scope of this chapter. Still, the reader should be aware that there is technology behind it supporting health and healthcare (Fig. 11.2).

This section will describe the core systems that makeup CIS, highlight the vastness of functionality available, and address common challenges that informaticists face regarding all CIS, including issues of interoperability, integration, maintenance, and support of the end-user.

Fig. 11.2 Common clinical information systems

Electronic Medical Records/Electronic Health Records

Ms. Jones care is supported by numerous clinical information systems, including her primary care provider's EHR, the regional HIE connecting her various providers, ePrescribing that allows for more seamless prescription management, the patient portal that allows her to see upcoming appointments and receive patient education information, the LIS that supports the local lab, and the RIS that supports the mammography center.

While the terms **electronic medical record (EMR)** and **electronic health record (EHR)** are frequently used interchangeably, they are distinct entities. The United States Office of The National Coordinator for Health Information Technology (ONC) defines the EMR as a "digitized version of a patient's paper chart" [4], containing the "medical and treatment history of the patients in one practice" [5]. ONC states that EHRs "focus on the total health of the patent—going beyond standard clinical data collected in the provider's office and inclusive of a broader view on a patient's care" [5]. The key is that the EHR represents a real-time, single place for collecting health, wellness, and healthcare information on a given patient, across physical sites. An EMR contains all the capabilities that allow a given provider to capture, store, edit, and view information they have documented on their patients. An EHR allows for the incorporation of data from external sources. Ideally, everything representative of a patient's care would be contained within a single EHR, but with continued interoperability challenges, such a vision has not been achieved. Today's reality is that an individual's health is represented in many records in each place the individual has sought care with some islands of interoperability and data exchange. While recognizing the differences between an EMR and an EHR, for simplicity, we will only utilize the EHR term for the remainder of this chapter.

Core Functions of the EHR

As the healthcare landscape has evolved in the United States (US) over several decades, so too has its EHRs. Initially, medical records were developed as tools for a single department or use—repositories of patient demographics, laboratory information systems, and so forth. With time, they expanded in scope, with cross-departmental use and integration with other systems. As CIS has become more widely adopted into all clinical care and supporting systems, defining discrete categories of systems and applications within them becomes a difficult task. A review of any EHR vendor's website demonstrates dozens of capabilities within even a single given vendor system.

To simplify, we present two perspectives for categorizing EHR functionality: the first, as defined in 2013 by the Institute of Medicine (IOM) that focuses on end-user needs and functionalities; and the second as defined by the federal government's certification program requirements for EHR vendors and used to achieve incentive payments. Which vantage is of most use is dependent on one's role within a given healthcare organization: as a care provider, the IOM's perspective is of more value; as a vendor or purchaser, one's focus must be on certification criteria. These varying viewpoints elucidate the inherent conflict between providers and those with purchasing power within an institution.

Institute of Medicine

In 2013, the Institute of Medicine defined eight core functionalities of an EHR [6], representing one of the first attempts to categorize desired functionality.

These included:

1. Health information and data
2. Result management
3. Order entry/management
4. Decision support
5. Electronic communication and connectivity
6. Patient support
7. Administrative processes and reporting
8. Reporting and population health

Even today, this is a robust way to think through what functionality is needed by the end-user providing patient care. In a historical context, EHR functionality was primarily focused on replicating the patient's paper record, ensuring that these core patient care activities were accommodated. Continuing to the present day, it is possible to bucket every existing functionality under one of these eight categories. However, as broad categories, specificity around functionality is not well represented.

ONCs Certification Criteria

As with the software systems that support Ms. Jones care in the community, her entire hospital stay for her breast cancer surgery and recovery are supported by sophisticated clinical information systems. Technology allows her clinicians to document and monitor her care, track her movement through the surgical suite, support her care in the CCU, support the administrative functions of the hospital, tests, and their results, and even the food that she is provided.

With the HITECH Act and its incentives for adoption and implementation for those who used "meaningful" systems, it became necessary to define the term "meaningful". In 2010, ONC began defining certification criteria for EHRs and, to date, has released three editions providing needed definitions around functionalities. The most recent 2015 Edition Cures Update Base EHR definition includes the following base EHR Capabilities (on or after December 31, 2022) [7]:

1. Patient Demographic and Clinical Health Information
   (a) Demographics
   (b) Implantable Device List
2. Clinical Decision Support
3. Computerized Provider Order Entry
4. Capacity to capture and query information relevant to healthcare quality
   (a) Clinical Quality Measures—Record and Export
5. Capacity to exchange electronic health information with and integrate such information from other sources
   (a) Transitions of Care
   (b) Application Access
      (I) Patient Selection
      (II) Standardized Application Programming Interfaces (API) for Patient and Population Services
      (III) All Data Request
      (IV) Direct Project or Direct Project, Edge Protocol, and XDR/XDM

ONC provides significant detail around each of these capabilities, but this high-level list offers an excellent approach to defining the core functionalities of an EHR.

Beyond the EHR

To support the settings in which care takes place, the EHR as the focus of the patient record is surrounded by complex and diverse software systems including those critical to care, such as ancillary services, and software that supports the mechanics of care, such as scheduling, billing, and supply management. It would require volumes to delve into all the functionalities that support care. Instead, we will use the hospital setting as a core example of how systems and software interact in providing care and the challenges informaticists face.

Hospital Information Systems

The hospital's needs are specific enough that many apply the term **hospital information system (HIS)** to the range of software solutions available to them. Under this umbrella exist administrative, financial, clinical, and ancillary systems, in addition to the core EHR. Hospitals are certainly the most complex settings and largest consumers of CIS, with the broadest range of software tools to support them. Table 11.1 lists a sampling of HIS.

HIMSS Adoption Model

The Healthcare Information and Management Systems Society (HIMSS) Electronic Medical Record Adoption Model allows hospitals to track and categorize progress around implementing various EMR capabilities of a

Table 11.1 Examples of software solutions available to hospitals

Administrative	Financial	Clinical	Ancillary
Admission, discharge, and transfer (ADT)	Revenue Cycle	Clinical Documentation, physician, nursing, and others	Laboratory Information System
Patient registration	Inventory/Materials and Supply Chain management	Computerize Provider Order Entry	Radiology Information System
Master Patient Index (MPI)		Specialized systems for medical specialties (e.g., Anesthesia, Cardiology, Dentistry, Dermatology, Obstetrics, Ophthalmology, Oncology, Surgery, Emergency, Cardiology, ICU)	Picture Archiving and Communications System
Scheduling		Population-Level Reporting	Pharmacy Information Systems
Administrative Reporting		Infection Control Management	Specialized systems for common procedures (PFTs, EKGs, Echo, Endoscopy)
Quality Measuring and Reporting		Operating Suite	Anatomic Pathology System
Nutrition and Dietary Management			Medication Management including the electronic Medication Administration Record

health information system (also referred to as HIS) [8]. This model presents a progression of capabilities, from basic automation to a complete system capable of participating in data exchange. Of note, the HIMSS model has evolved as systems have become more widespread and sophisticated.

The model includes the following eight stages and cumulative capabilities:

- **Stage 0**: None of the three Ancillaries-Laboratory, Radiology, Pharmacy Installed
- **Stage 1**: Ancillaries-Laboratory, Pharmacy, and Radiology/Cardiology Information Systems: Picture archiving and communication system (PACS); Digital Non-DICOM (Digital Imaging and Communications in Medicine) Image Management
- **Stage 2**: Central Data Repository; Internal Interoperability; Basic Security
- **Stage 3**: Nursing and Allied Health Documentation; Electronic Medication Administration Record; Role-Based Security
- **Stage 4**: Computerized Provider Order Entry (CPOE) with Clinical Decision Support (CDS); Nursing and Allied Health Documentation; Basic Business Continuity
- **Stage 5**: Physician Documentation Using Structure Templates; Intrusion/Device Protection
- **Stage 6**: Technology-Enabled Medication, Blood Products, and Human Milk Administration; Risk Reporting; Full CDS
- **Stage 7**: Complete EMR; External health information exchange (HIE); Data Analytics, Governance, Disaster Recovery, Privacy and Security

This approach to categorizing EHR capabilities is of particular use to those creating strategies for implementation and stepwise approaches to that task.

The Traditional Ancillary Systems: "Lab/Rad/Pharm"

Long-held as core to healthcare and technology, laboratory information systems (LIS), radiology information systems (RIS), and pharmacy information systems (PIS) provide the ability to capture, store, and retrieve information related to diagnostic testing and medication orders. These ancillary systems were established early in adopting healthcare technology, forming the initial start of some of the largest EHR vendors today. These systems are generally considered "modules" that sit outside of, but interface with, the clinical record.

Laboratory Information Systems

LIS are also known as laboratory information management systems (LIMS) and laboratory management system (LMS) systems. As a natural evolution for automated systems, LIS were one of the earliest aspects of healthcare to become computerized, creating vast improvements over previously manual processes. The earliest computer terminals in the hospital wards generally performed the sole function of patient laboratory lookup using DOS roll-and-scroll functionality. These digitized systems allowed labs to increase laboratory reporting volume, efficiency, and speed and permitted exporting and storing historic patient results.

As LIS systems became more sophisticated, they evolved into today's offerings: end-to-end support for laboratory functions. These functions include receiving and processing orders, translating results into human-readable text with local reference ranges, allowing manual input of tests, stor-

Table 11.2 Laboratory information systems functionality

Pre-analytical	Analytical	Post-analytical
Orders	Results entry	Reporting
Collection	Review	Interpretation
Accession		Billing
Labels		Tracking

ing the results, pushing results out to patients and care providers, and making those results available for future viewing [9]. Today, patient portals also assist with the dissemination of results to patients.

In thinking about LIS, one useful construct is outlined by McCudden et al. [10] specifying three stages of modern LIS systems: pre-analytical, analytical, and post-analytical (Table 11.2).

Because various laboratory machines support specific laboratory tests, LIS modularity allows labs to customize their local needs, budgets, and capabilities through 'plug and play'. For instance, most labs have modules for basic chemistries and hematology and expand to microbiology, immunology, and genetics, as well as growing system functionalities within anatomical pathology. So sophisticated are these systems that large organizations have clinical informaticists dedicated to supporting them.

While LIS had the advantage of early adoption and iterations of improvement over the years, there remain challenges due to the continued variability in processing, labeling of results, and varying reference ranges between brands of laboratory devices. This lack of standardization early on continues to impede progress in areas such as interoperability. In 1994, to improve interoperability of laboratory values, Regenstrief Institute in Indiana created the logical observation identifiers names and codes (LOINC) standard that is widely used today [11]. Although codified laboratory values are critical, issues remain related to many legacy laboratory terms that exist for a single meaning.

Varying legacy terminology represents a major challenge for informaticists: a seemingly simple effort utilizing laboratory values in a CDS tool requires intensive upfront labor to map values from backend LIS systems. For example, to ensure that a hemoglobin result is incorporated into a given CDS, informaticists must include and exclude multiple values—include Hemoglobin, Hb, HGB; but exclude hemoglobin A1C and Hemoglobin S. To highlight the scope of the issue, a LOINC inquiry returns 445 hits on the term "hemoglobin".

Radiology Information Systems

RIS are the core systems for the input and storage of radiology reports, tracking images and patient flow, reporting notification to ordering providers, and billing. RIS systems typically have integrated voice recognition systems for providers to create reports quickly while attaching appropriate diagnostic and billing codes. These systems are used in concert with PACS, which stores the actual digital copy of the image. RIS/PACS were embraced early by radiologists because they created efficiencies and allowed them to be free from the constraints of reading and interpreting films within the four walls of a hospital or radiology center [12]. Radiologists began to work both at a distance from the site that used their services and asynchronously. Providers also benefited as the systems allowed for quick, ubiquitous access to previously viewable images only on physical film.

Standards have long been in use in the radiology space. Digital Imaging and Communications in Medicine (DICOM) standards allow for imaging and the resulting data communication. Although initially developed by the American College of Radiology (ACR) and the National Electrical Manufacturers Associations (NEMA) [13] for system interoperability, these standards are now used across all medical imaging. ACR has been active in pursuing standards for radiology, including the development of standardized coding schemes to represent imaging results, such as the Breast Imaging Reporting and Data System (BI-RADS) for mammography results allowing results to be codified used for reports and decision support. Recently the Radiologic Society of North America (RSNA) developed the new radiology lexicon called RadLex, containing a comprehensive set of terms to be used in reporting, CDS, registries, education, and research [14].

Over time as CIS became more robust, functionality that once was part of a RIS may now be housed elsewhere in the EHR, such as patient registration, order entry, decision support, the physician directory, and report storage [15].

Because of the large size of many images, storage and bandwidth for connecting can be more significant barriers in this space than many other areas of CIS. One solution is to have end-users tunnel into PACs for viewing or showing only thumbnails of an image within an EHR. Generally, RIS systems use inexpensive storage systems to store the vast amount of data and fast network connections to allow rapid access to images requested.

Pharmacy Information Systems

Pharmacy information systems (PIS), also known as pharmacy management systems, are central to medication management. Siska describes these systems as containing five core functionalities:

- Order management and communication;
- Order verification, confirmation, and fulfillment;
- Preparation, distribution, and inventory control, storage, and security;
- Administration; and
- Intervention and monitoring [16].

PIS interfaces with other systems integral to EHRs, including CPOE, CDS, medication reconciliation, medication dispensing,

and medication administration systems [17]. As an ancillary system, the need for tight integration leads to many challenges for PIS that are critical to patient safety. For instance, terminology must be consistent between PIS and CPOE. The ordering provider, pharmacist, those administering medications, and the patient must all see the same name when identifying the order, prescription, pill bottle, or intravenous (IV) bag. Consistency requires synching terminologies on the pharmacy system side as well as the provider facing the EHR side. Maintaining a medication catalog can be time-consuming and complex due to the vast numbers of available medications, matching generic and brand names, and the options for dose, route, frequency, duration, and indication. As medications are purchased, and formularies change, the medication catalog must be updated in the pharmacy and EHR side. What may seem to be a simple medication change results in a cascade of updates to provider-facing order sentences, medication picklists, and order sets. Failure to update across the enterprise risks providers ordering something that the pharmacy no longer stocks.

Although one would intuitively assume that information such as body mass index (BMI), age, gender, pregnancy, and lactation status would be viewable to the pharmacist when it exists in the EHR, this only occurs when these discrete data elements are explicitly mapped and coded to a pharmacy view. In the case of pregnancy status, many EHRs do not capture it as discrete data, and thus while it may be accessible on the EHR side, it may not display on the pharmacy package side.

In addition to building medication libraries and maintaining orders in the EHR, decisions around CDS also require frequent updating. It is imperative to implement CDS carefully to take advantage of its ability to reduce prescribing errors. It is worth noting that although prescribing errors are common, it is rare for an error to lead to direct patient harm [18]. Most organizations have purchased rules engines that conduct drug-duplication, interaction, dose, and allergy checking to enhance drug checking that considers patient weight, pregnancy, lactation, age, and laboratory results.

Frequently organizations make the error of activating all vendor-supplied CDS around medications in the mistaken belief this will lead to fewer errors, improve patient safety, and reduce medical liability. However, the resulting barrage of interruptive alerts of frequently clinically irrelevant information results in the opposite effect. The irrelevancy leads to clinicians reflexively overriding all alerts, commonly referred to as 'alert fatigue', and missing the rare critical alert that warranted attention and action. There is often tension between those believing that having all alerts turned on leads to legal liability protection and those attempting to constrain interruptive alerts to only those of clinical relevancy. As such, a critical role of an informaticist is to make careful, deliberate choices around which alerts to utilize and maintain. For example, alerts around known human teratogens and pregnancy have high utility. Alerts for medications with scant evidence of issues during pregnancy can create noise, are of little clinical value, result in high override rates, and cause many organizations to choose to turn off medication-pregnancy alerts altogether.

One approach that some organizations use today is to monitor override rates: a medication alert overridden most of the time is likely one that should not be used. A close look at these alerts, along with the overriding reason captured, allows the informaticist to decide how to alter the alert to add clinical relevancy or decide to retire the alert all together for lack of clinical value.

Beyond the Hospital Information System

With the core CIS representing the hub where most health data are generated, organized, and synthesized, several systems facilitate data exchange between the patient, community, and environment. To effectively communicate health information with patients, families, providers, and other stakeholders throughout and across health systems, there are multiple channels for data exchange in and out of the core CIS. Technology has enabled remote technologies such as telehealth, patient portals, and secure messaging systems to promote the flow of information between patients and providers. Registries populated with data from the CIS inform public health and healthcare systems in population health practices. As medical devices become ever more ubiquitous, essential patient and environmental data flow between devices and the CIS for diagnostic and therapeutic purposes.

Telehealth

Using telehealth, Ms. Jones has an e-consultation with a genetic specialist, who views a previously completed family history questionnaire and other history in the EHR, provide counseling, and order genetic testing. Based on test results and coordination with her surgeon, together they decide to proceed with a double mastectomy and lymph node dissection.

While telehealth is explored in greater depth in Chap. 18, we review aspects of telehealth that integrate within CIS. Telehealth uses electronic information and communications technologies to provide and support healthcare when distance separates the participants [19]. For HIS, telehealth offers a set of tools and processes that facilitate the synchronous and asynchronous exchange of information with patients and other providers. Telehealth can expand the reach of healthcare organizations and patient access to healthcare, with multiple factors affecting the integration of telehealth data into the HIS. Successful use of telehealth requires many factors, including the hardware and software for communication between patients and providers, equipment for capturing

remote patient data, and secure systems for data transmission. In addition to equipment and infrastructure, telehealth workflows are necessary to ensure support for patients and providers, documentation, and the appropriate use of data to provide clinical care. External factors that have limited telehealth adoption, including reimbursement, licensure, and geographic and practice setting restrictions, are evolving [20, 21].

Telehealth Models and Modalities

Telehealth was traditionally developed in a hub and spoke model, with large tertiary care centers as "hubs" providing specialty consultation to small rural hospitals in the periphery. Telehealth acts as a connector or "spoke" to increase access to specialty care [22]. Healthcare providers also act as hubs in providing remote care (spokes) to the patients in their preferred setting, such as their homes or primary care office. Telehealth offers a wide range of modalities that vary by synchronicity and identity of the hubs and spokes (Table 11.3). Examples of synchronous, patient-to-provider interactions, include live video interactions that use two-way audio-visual communication, such as tele-psychiatry and tele-primary care. Synchronous provider-to-provider telehealth can connect on-site providers to specialty expertise, such as tele-stroke or tele-ICU services in settings that lack specialists. Another form of provider-to-provider telehealth is tele-mentoring, where remote expert teams support primary care providers (PCPs) via videoconference. Models such as Project ECHO [23] provide tele-mentoring in various topics such as behavioral health, medication-assisted treatment, HIV care, and antimicrobial stewardship. Asynchronous or store-and-forward telehealth is defined as transmitting pre-recorded digital information, such as images, pathology slides, documents, audio files, or videos, that a patient or provider can send to another care provider or specialist. Examples include provider-to-provider e-consultation, such as tele-dermatology for remote diagnosis of skin lesions, tele-ophthalmology for screening of diabetic retinopathy, and tele-pathology for evaluation of pathology specimens. Remote patient monitoring refers to continuous assessment of patient data collected remotely, such as monitoring of vital signs, weight, or virtual exam recordings [22, 24, 25].

Telehealth Hardware and Software

Telehealth delivery requires patient and provider access to hardware and software that allows for virtual communication and secure Health Insurance Portability and Accountability Act (HIPAA)-compliant information exchange. The rise in consumer use of smartphones, tablets, and computers with high-resolution cameras has allowed personal devices for real-time audio-visual communication. Choices regarding software may be determined by practical issues, such as using previously purchased software, ease of use, familiarity for patients and staff for scheduling and technical support, integration with EHRs, and HIPAA compliance with the requirement of business associate agreements [24, 26]. Health systems with well-developed telehealth programs may have EHR-integrated tools, such as Kaiser Permanente's (KP) integrated telehealth software with their KP HealthConnect EMR, or utilize custom software applications such as the Veterans Affairs (VA) mobile VA Video Connect for video chat. In addition, these systems may have other mobile applications for patient reminders and chronic disease management [27, 28].

Outside of large healthcare systems, most telehealth programs are not integrated into the larger organizational EHR. With the need for rapid expansion of telehealth services due to the COVID-19 pandemic, the Office of Civil Rights loosened enforcement of the HIPAA rules during the nationwide public health emergency. This loosening of rules allowed health systems for the first time to leverage popular consumer virtual communication platforms for the rapid scaling up of telehealth services [29, 30].

The remote monitoring devices landscape is rapidly growing. Systems can capture various health data such as sensors to track physical activity, cardiac information through remote telemetry, heart, and lung sounds through virtual stethoscopes and vital sign information [31].

Telehealth Workflow and Integration

Telehealth implementation requires thoughtful mapping of workflow and system processes. For example, implementing remote continuous glucose monitoring (CGM) might require multiple steps: patient and device selection, scheduling and consent, delivery of equipment, training for patients and providers, processes for data review and integration, data acquisition, and appropriate documentation and billing [32, 33]. Patient selection will be affected by the level of patient engagement, insurance coverage, and the likelihood of benefit, such as patients with labile blood sugars on basal/bolus insulin or with type I diabetes. With various medical devices, customized device selection must be made to fit the patient's monitoring needs. Healthcare providers help patients obtain access to monitoring devices and provide training to patients and staff who need to download and interpret data.

With CGM devices capable of capturing glucose levels every 1–5 min, information overload can become a problem, with many data points potentially obscuring clinically meaningful or actionable information [34]. Data filtering

Table 11.3 Telehealth modalities

	Asynchronous	Synchronous	Remote patient monitoring
Patient-to-patient	Patient store & forward	Live video	Remote monitoring
Provider-to-provider(s)	E-consult	Videoconferencing Tele-mentoring	

and visualization can make interpretation easier. For example, glucose trends may inform insulin titration or reveal the risk of hypoglycemia. Data may show the duration of time that glucose values remain within the desired range or generate metrics such as the glucose management indicator or area under the curve that estimate HbA1c [35]. Integrating information obtained through telehealth and remote monitoring technologies into the CIS can vary depending on the interoperability of software, data sampling rate, and clinical workflows for data capture and documentation. Emerging technologies often have independent portals for data visualization. Integration of clinical information may depend on provider documentation or platform interoperability for data exchange. For CGM data, a remote monitoring program may download data by plugging a reader into an office computer or from the Cloud and subsequently printing a single-page ambulatory glucose profile report. These reports provide clinical care and billing documentation but may need to be scanned to integrate them into the EHR. Information may be reviewed with patients in person or through face-to-face or non-face-to-face telehealth and remote monitoring services [36]. While CGMs represent only one example, the growing use of telehealth and remote monitoring systems will vastly increase the amount of data that flows in and out of CIS.

Clinical Communication Channels and Best Practices

Ms. Jones care is greatly enhanced by the availability of electronic tools that not only allow her providers to communicate with one another—in the form of Direct messaging to providers from other organizations, messaging within the EHR, and text messaging using encrypted apps on their mobile phones—but also allow her to communicate directly with her care coordinator throughout her journey.

As healthcare delivery moves to a patient-centered, team-based approach and spreads over many locations, secure HIPAA-compliant communication channels have become critical for care coordination. This need is especially highlighted in care delivery models such as the Patient-Centered Medical Home, where care coordination is one of five essential functions. Per the Agency for Healthcare Research and Quality (AHRQ), effective care coordination can be accomplished through frequent communication and the free exchange of information with the effective use of electronic tools [37].

Accessible, timely, secure, bidirectional communication channels between the healthcare teams providing care in disparate settings are essential for patient safety during care transitions, such as discharge a patient from an acute care setting to return to the primary care team [38]. A survey showed that PCPs and hospitalists alike preferred direct communication around the Transition of Care (ToC) [39].

Communication channels between patients and members of their healthcare team are just as critical. Patient portals are currently the predominant electronic medium for such communication. However, paper, telephone, and fax still have their stronghold in healthcare, especially where access to technology is limited. Clinical informaticists should be aware of all possible channels for internal and external messaging in their institution. They will need to implement, evaluate, monitor, and optimize these channels to ensure effective and secure communication [40].

Regulatory Factors

Several regulatory factors impact clinical communication that the informaticist should be familiar with. The Meaningful Use (MU) Program incentivized the collecting and sharing clinical data in a structured format through progressive implementation stages. The program defined secure messages as "any electronic communication between a provider and patient that ensures only those parties can access the communication. This electronic message could be email or the electronic messaging function of a personal health record (PHR), an online patient portal, or any other electronic means." Meaningful Use Stage 2 (MU 2) required using a patient portal for Eligible Practitioners (EPs) and/or Critical Access Hospitals, summarized in Box 11.1 [41].

Box 11.1. Communications Using CIS Regulations

2015 Meaningful Use Core Objectives:

1. Use secure electronic messaging to communicate with patients on relevant health information.

2015 Meaningful Use Patient Access Objectives:

1. Provide patients the ability to view online, download, and transmit their health information within four business days of the information being available to the EP (for EPs only).
2. Provide patients the ability to view online, download and transmit their health information within 36 h after discharge from the hospital (for Eligible Hospitals/CAHs only).

The latest iteration, Promoting Interoperability [42], required the use of:

- Existing 2015 Edition certification criteria
- The 2015 Edition Cures Update criteria; or
- A combination of the two.

Specifically, the 21st Century Cures Act requires EP and CAHs to attest to Prevention of Information Blocking and requires that data part of the US Core Data for Interoperability (USCDI) be made available electronically upon request in all instances except for a few exceptions. It clearly states that the data be made accessible to patients via smartphones and modern software apps leveraging secure, standardized APIs.

The main mechanism for requesting and receiving health records is often a patient portal. Patient portals can be tethered or untethered. Tethered portals are those that are connected to an EHR vendor and a particular organization. These offer two-way communication. Untethered portals are EHR agnostic and have a range of capabilities, such as the ability to import and upload data from various sources. Currently, these untethered portals only allow for unidirectional data flow, that is, from the source to the portal, and cannot send health care data back to the source or update the source information.

Security

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 consists of several rules. The Privacy rule and Security rule are key components that apply to secure messaging in healthcare. The HIPAA Privacy rule defines Protected Health Information (PHI). The HIPAA Security Rule [43] protects a subset of information covered by the HIPAA Privacy Rule [44], in that all individually identifiable health information a covered entity creates, receives, maintains, or transmits in electronic form. The Security Rule calls this information "electronic protected health information" (e-PHI). Secure messages in healthcare by nature contain e-PHI and must comply with the standards outlined in the Security Rule. The rule requires covered entities to maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI. Specifically, covered entities must:

- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce.

Channels for Communication

While traditional paper-based modalities, such as mailed patient letters and faxed laboratory results or discharge summaries, persist in many areas, here we will focus on available informatics tools.

Secure communication channels are required between,

1. Members of the healthcare team in one setting;
2. Across healthcare teams in different locations; and
3. Healthcare professionals and patients and their families.

Communication in Acute Care or Hospital Settings

In the acute hospital setting, while the healthcare team is generally part of one institution and geographically close, the pace of communication is rapid and occurs simultaneously in multiple directions. Often, communication channels are the primary connections between groups working together for one patient, but with different roles and responsibilities. The challenge to a clinical informaticist in this setting is to implement a technological solution that enables secure, rapid two-way communication between the appropriate personnel and allows for triaging of the messages to avoid alert fatigue.

Commonly the flow of communication is one-sided, interrupted across a variety of channels, and lacking standardization. Pagers still play a major role in this landscape, but several studies highlight this system's inefficiencies [45, 46]. For instance, pagers may provide a false sense of security, but unless encrypted and provided with a display lock, they are not a secure means to share PHI.

Consider the situation depicted in Fig. 11.3. Here, the patient reports a complaint to the bedside nurse. The nurse then contacts the on-call clinical team using a web-based text paging application with a call-back number. Confusion about which team member is the correct contact for the patient delays communication [46]. The receiving provider calls the number provided and waits for the clerk to contact the nurse, who may have moved on to other tasks. This process is fraught with delays and leads to wasted time for busy clinical teams. Furthermore, communication by the outpatient/ambulatory care team with the acute care/inpatient team is practically non-existent, as discussed later in this section. Often the care teams resort to text messaging (SMS) on personal devices for timely communication and risk ePHI being shared and stored in a non-HIPAA compliant manner [47].

The need for efficient closed-loop communications has led to the development of numerous EHR vendor-based and independent applications. These applications provide several layers of functionality and have been shown to improve the efficiency of interdisciplinary communication when compared to traditional pagers [48].

One case study classifies these into three tiers based on the functionality as follows [49]:

- Tier 1: Basic Secure Communication
- Tier 2: Secure Communication within an Existing Clinical System

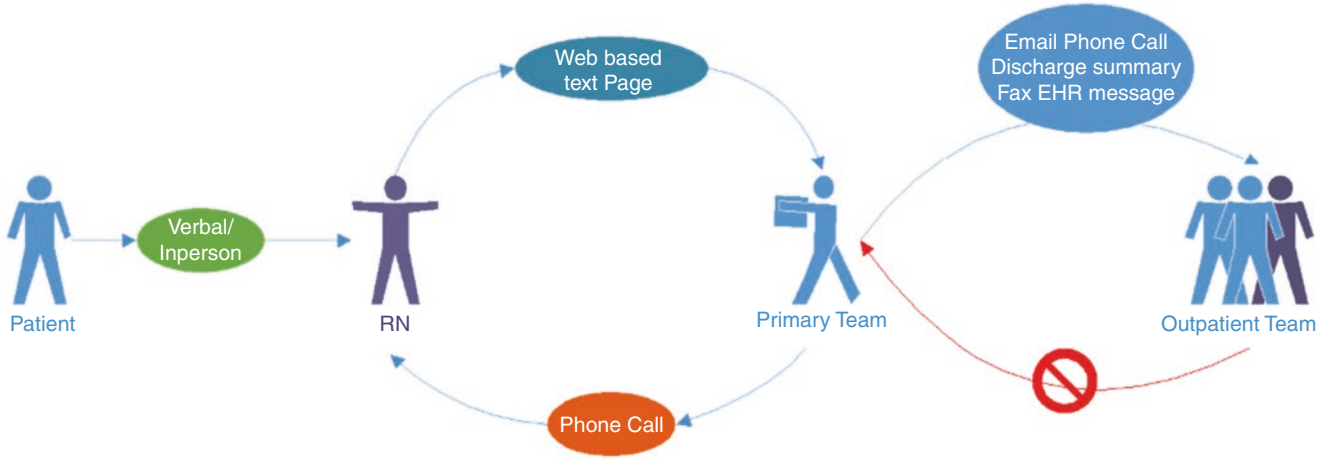

Fig. 11.3 Flow of communication between the patient and the care team

Table 11.4 Secure messaging application tiers: pros and cons

Tier and example applications	Pros	Cons
Tier 1		
HIPAACHAT Tigertext free edition	• Secure communication platform • Inexpensive/free	• No functionality to help with workflow • Minimal functionality to improve communication • Might be difficult to get full adoption due to minimal functionality
Tier 2		
CareAware Connect (Cerner secure messaging) Cores secure messaging Epic secure messaging Medisas miSecureMessages (AMTEICO) Mobile Heartbeat TeamStitch	• Secure communication platform • Potentially easier to implement if you already use native system extensively (i.e. Cerner or Epic) • Some offer functionality to help with hospital workflow and communication • Well integrated with existing native system • Vendors may have been in the health care sector for long periods of time	• Additional licensing costs for messaging functionality • Difficult to integrate across multiple different clinical applications • less advanced functionality (system-dependent) • Unclear how vendors will prioritize support and development of messaging functionality compared with native application • Ability to customize or integrate with third party systems uncertain
Tier 3		
Cureatr Doc Halo Imprivata Cortext PatientSafe Solutions PerfectServe Spok Care Connect Tigertext enterprise edition Voalte Vocera Zipit Wireless	• Secure communication platform • Intended to be integrated communication platform across entire health system • Solely dedicated to this area, offer good support • Offers extensive functionality to help with hospital workflow and communication • Offers the highest functionality, including integration with electronic health records, laboratory, scheduling, nurse call alerts, monitor alerts, etc. • Most customizable to meet specific • workflow needs or integrate with third party systems	• Most expensive option • May require additional time/expense to integrate with other clinical applications to leverage advanced functionality • Note: • Vendors in this space are relatively new. and the market is evolving (uncertain which vendors will thrive with market maturation)

Table adapted from [49]. Used with permission

- Tier 3: Dedicated Communication and Collaboration Systems

Within each of these tiers are pros and cons to the approach (Table 11.4).

For the acute care setting, the study summarizes essential requirements for system capabilities under several categories:

- Basic security and administrative functionality: Secure platform, Mobile Device Management (MDM) features, usage analytics, administrative controls, discoverable message logs, transparent message status updates with timestamps.
- Integrations and advanced functionality:
  - Active directories for secure login and recognition of users

ADT information
Staff scheduling software that can:
- Allow for role recognitions (Attending versus resident); and
- On-call personnel recognition (ex: primary nurses versus charge nurse to automatically forward unanswered messages)

- Communication and workflow functionality:
  - Inclusive and available for various roles such as doctors (primary team and specialists), nurses, physical therapists, social workers, etc.
  - Ability to have two-way messaging and group communication channels.
  - Ability to include various data formats such as pictures.
  - Quickly and automatically notify the correct personnel for hospital emergencies, Code Blue, etc.
- Technical: Wi-Fi, availability on multiple mobile Operating Systems (OS)

Some commonly available secondary features that commercial solutions advertise include integrating their content into the EHR and delivering alarms to the messaging application. These features seem useful at face value but only amplify the already noisy alarms in acute care settings with minimal enhancement to the workflows.

Clinical Informaticists must take a thoughtful approach when implementing communication platforms to optimize workflow efficiency as alert fatigue is a well-established issue in health informatics [50]. In the project planning phase, an interdisciplinary design discussion should occur to determine the alerts to be sent to the application and those that would add to the noise. Bring-Your-Own-Device (BYOD) is often a cost-effective approach to implementing secure communication platforms. Installation of Mobile Device Management software is vital in either strategy to mitigate the risks of loss of patient information if the device were to be hacked or lost. Detailed institutional policies addressing best practices for communication and escalation of care are critical.

Communication in Ambulatory Settings

Tethered—linked to the EHR—patient portals are the primary electronic communication tools between the healthcare team and the patients in the ambulatory arena. Communication is usually asynchronous and can be initiated either by the patient or the care team. The conversations can be saved to the patient's EHR for future reference. Most major EHR vendors offer a patient portal, particularly after it became a required feature for becoming a Certified EHR under the MU Use program. Non-Tethered communication solutions have also been gaining traction, especially among small independent practices. These are primarily in the form of two-way secure texting and calling solutions that can protect the personal mobile number of a practitioner. Some popular platforms offer additional features such as performing video visits and sending and receiving fax communication and are comparatively inexpensive compared to the prominent EHR vendors.

Communication Between the Clinical Teams Across Healthcare Venues

There is a significant gap in the availability of solutions focused on the area of inter-venue healthcare communications. There are two main channels available.

1. TOC using Continuity of Care Documents (CCD): Documents in this category range from dictated and transcribed discharge summaries to more structured electronic documents faxed or sent via direct messaging to primary care physicians. MU 2 leveraged HL7 standards; TOC documents were based on Clinical Document Architecture (CDA) following the implementation rules of C-CDA and sent via direct messaging or portals. While these standards aimed to improve semantic interoperability, the result did not translate to improved quality or uniformity of information available in these documents [51, 52]. Poor mapping of data elements often leads to missing information from the CCDs. As we move towards leveraging USCDI, Fast Healthcare Interoperability Resources (FHIR), and APIs, hopefully, the quality of TOC documents will improve.
2. Messaging between providers using the EHR tools or other secure communication channels tends to occur primarily within a healthcare institution where an existing communication channel can be leveraged. While there are EHR and institution agnostic independent communication applications available, these have not been adopted widely.

Clinical Registries

The cancer registrar at the institution where Ms. Jones had surgery to resect her breast tumor would collate her data including demographics, tumor staging, pathology report, and treatment record to the State cancer registry. The information is then reported to the National Program of Cancer Registries (NPCR) once a year. Her outcomes taken together with others in the registry will inform future research!

As EHRs and other means of collecting structured clinical data, such as LIS and Electronic Laboratory Reporting, have become widely adopted, the process of collecting

data for reporting to a clinical registry is also being automated. AHRQ defines a clinical registry as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes" [53]. Clinical registries and their role in Public Health Informatics will be covered in more detail in the relevant (Chap. 25), but we will give a brief outline here. A clinical informaticist needs to understand the process of reporting data to registries electronically via flat-file reports or APIs and how this information is leveraged for various purposes.

National Quality Registry Network (NQRN) conducted a landscape survey that reported various registries based on the purpose and use [54]. The top five purposes were quality improvement, benchmarking, clinical effectiveness, safety and harm, and comparative effectiveness research based on the survey. The top five uses were clinical decision support development, education development, measure development, QCDR, and guideline development.

Some specific examples include:

1. Quality Improvement, CMS's Qualified Clinical Data Registry (QCDR) leveraged in the QPP programs;
2. Disease surveillance, such as the National Program of Cancer Registries (NPCR) under the CDC and the National Cancer Institute's SEER program. There are several other programs for specific diseases, including a rare disease registry, and a comprehensive list can be found on the NIH website;
3. Procedure or Device surveillance, such as medical device registries or surgical procedure outcome registries; and
4. Population Surveillance, such as Vital Statistics and National.

Registries can be sponsored by national organizations with mandated reporting or voluntary sharing of information initiated by patients. Registries can also be created locally at an institution level for the population under its management for reporting purposes in Alternate Payment Models (APMs), for example, a QCDR.

Uses and Value

Clinical registries can be leveraged not only for research but also for quality improvement and performance measurement, participation in payment programs, benchmarking, guideline development, clinical decision support, public reporting, hazard reporting, population health, and so forth. NQRN published a registry maturation framework to evaluate the capability and use of clinical registries [55].

Mechanism of Data Entry and Interfaces with EHR and Other Sources

Data is transferred from the EHRs via push or pull certification model (eCQMs) or manual chart abstraction. Some registries are also linked to external databases such as vital statistics and other CIS such as laboratory or pathology reporting. Increasingly, there is a focus on incorporating patient-reported outcomes such as quality of life or depression scales into registries.

To support data collection for reporting to registries, institutions often need to employ trained clinical registrars and invest in Clinical Registry Management Systems. Lack of adequate standards leads to incomplete data and requires time-consuming manual chart abstraction and resubmission. Incomplete data will ultimately affect any conclusions drawn from the data [56]. Each registry has specific formatting requirements for successful reporting. There is a significant need to leverage informatics principles to design interoperable clinical registries to minimize this inefficiency burden [57, 58]. HL7 Common Clinical Registry Framework Domain Analysis Model and FHIR standards may provide this much-needed interoperability.

Regulated Medical Devices

The definition of a regulated medical device in Section 201(h) of the Food, Drug, and Cosmetic Act is [59]:
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).
In addition to the multiple interacting electronic information systems, many integrated medical devices exchange information within the health system. Medical devices are omnipresent, from diagnostic devices such as telemetry, vital sign machines, and glucometers to therapeutic devices such as infu-

sion pumps, medication dispensing systems, and implanted devices including pacemakers and insulin pumps. The Internet of Medical Things (IoMT) concept describes networks of physical objects embedded with sensors and software that connect and exchange medical data over the internet [60]. In healthcare delivery organizations, the management of medical devices is challenging. It can encompass everything from pre-procurement processes, purchasing, installation, network configuration, workflow design, ongoing maintenance and support, and device decommissioning. Many skillsets are necessary for integrating, managing, and operating medical devices that will often require a collaborative effort between manufacturers, IT experts, biomedical engineering, and end-users.

During Ms. Jones' surgery, multiple medical devices are used including IV pumps, monitors, and the ventilator. All data from the devices are incorporated into her medical record.

Medical Device Integration

Integration of medical devices into HIS is a multi-step, complex process that requires multidisciplinary collaboration. The implementation of new regular infusion pumps, for example, requires simultaneous changes to the ordering system and the pharmacy information system. Using integration of patient-controlled anesthesia (PCA) infusion pump as an example, several parallel processes must occur. After procuring the pumps, IT may work with the manufacturer on-device installation, testing, and optimization. They will need to make network configuration decisions based on whether data is stored on the device or server, the directionality of information flow, and which site-specific systems the device interacts with. The PCA pump may need to interact with the EHR for recording medication administration and CDS, with the pharmacy system for interaction alerts and medication inventory, and communicate with nursing displays to show pump performance information. Based on the device use case, workflow models must be developed that account for clinical, patient, and provider needs and quality control and billing documentation. For the PCA pump, a team representing nursing, informatics, and the acute pain service may be tasked with developing the protocols and training materials for patients and providers who will use the devices. As part of the implementation process, the project team also needs a long-term maintenance plan for the device. Factors they may consider include the degree of manufacturer versus on-site support, frequency of support needs (24/7 versus sporadic), device utilization, risks associated with device failure, designated contact for device updates and support, and device storage. The types of networked-enabled medical devices are currently limited, e.g., patient monitors, infusion pumps, imaging. Still, as the percentage of connected devices grows, health delivery organizations will need to develop EHR-medical device integration strategies. Organizations such as the American Society for Testing and Materials (ASTM) guides standards such as the Integrated Clinical Environment (ICE) standard to promote medical device interoperability [61–63].

Medical Device Management Systems

Given the vast spectrum of medical devices and the settings where they are used, the scope of work involved in medical device informatics is staggering. For healthcare delivery organizations, it is essential to have a high-level framework to inventory, organize, manage, and secure medical devices. Medical device management is often dictated by care settings, workflows, and the physical environment in which they are used. Relatively "fixed" devices in an operating room with sporadic use may have different requirements than continuous-use equipment that travels with a patient to multiple care settings. Inventory management systems can capture data about medical devices and organize the information to support maintenance and operational optimization. A critical function of these systems is to identify and locate devices due for updates or patches or medical devices that have been subject to recall. Utilization data can also inform operations. For telemetry equipment frequently utilized at capacity, managers can consider purchasing additional units or reviewing the appropriateness of use, whereas devices that are rarely used may be retired. In addition to physical and utilization tracking, medical device management systems must also monitor information traffic. Network access should be limited to the extent where devices can access the information they need to function appropriately but limited to avoid the risk of exposing patient data or affecting other systems in the event of a device malfunction, downtime, or cyberattack.

The landscape of medical devices presents a significant cybersecurity risk to organizations; managing the growing number of connected devices is a daunting task. This was highlighted by a safety communication from the US Food and Drug Administration (FDA) in 2017 regarding potential concerns of malicious interference with the programming in several St. Jude pacemaker models [64]. With the explosion in medical devices, vulnerability management involves identifying and prioritizing exploitable vulnerabilities for cyberattacks. Depending on the risk severity and impact on the organization, healthcare delivery organizations may apply increasingly effortful measures to patch, mitigate, or segment networks to reduce vulnerability from medical devices [65].

Medical Device Standards Organizations

Standards organizations guide the integration and management of medical devices in healthcare delivery organizations. The National Institute of Standards and Technology (NIST) provides an example implementation and best practice guide in its *Securing Wireless Infusion Pumps* publication [65]. This resource is targeted towards business decision-makers, IT

professionals, and project managers. It guides the approach and architecture for developing security platforms, life cycle issues, risk assessment, and functional evaluation. With a focus on medical device cybersecurity, the non-profit MITRE Corporation published a playbook with guidance on device procurement, inventory management, vulnerability analysis, and cybersecurity support [66]. Standards development organizations have also published tools to address security issues related to medical devices. The Manufacturer Disclosure Statement for Medical Device Security (MDS2), jointly developed by HIMSS and NEMA, is a voluntary standard for manufacturers' disclosure of security-related features of integrated medical devices [67, 68].

Regulation of Medical Devices

The US FDA Center for Devices and Radiological Health is the operating division of the Department of Health and Human Services responsible for assuring the safety and efficacy of medical devices. Medical devices are classified as Class I, II, and III based on the level of risk, indication for use, the population being diagnosed or treated, and manufacturer claims. The FDA ensures that devices are safe and efficacious when they enter the market and for a duration of time on the market as the uses of medical devices evolve. The FDA recognizes selected standards, parts, or standards as appropriate for addressing medical device product testing as listed on the agency's website [69–71].

Emerging Trends

Ms. Jone's daughter Courtney delivers a 30-week infant named Benjamin, who is transferred to the NICU at the tertiary care hospital. Wishing to breastfeed her infant, Courtney uses a pump at home and freezes the breastmilk. The hospital gives Courtney preprinted labels for the bottles from their new innovative breastmilk barcoding system. The system will track the age of the milk, how long it has been out of the freezer, and disallow milk to be put back if it has been out for 15 min or more. Prior to be given to Benjamin both he and the bottle will be scanned to ensure that the breast milk is from the correct mother and not beyond its expiration date.

As in all technology areas, CIS continues to evolve rapidly with many new innovative approaches to its development and use. Exciting emerging trends include expansion into pediatrics, improvements in documentation tools, machine learning (ML) and artificial intelligence (AI), expansion of patient-facing technology, and further infiltration in areas such as supply chain and blood bank systems. Even management of breast milk has been made safer with innovative technology. Below we present several of these new areas of innovation.

Pediatric Functionalities

Historically outpatient EHRs had failed to support pediatric functionalities needed to take care of children safely [72, 73]. These functionalities include weight-based or body surface-based dosing, age-appropriate development documentation and reminders, immunization tracking, and forecasting, to name a few [74, 75]. The 21st Century Cures Act addressed this issue by introducing voluntary pediatric certification currently being developed by the Drummond Group [76].

Documentation

Notes in US EHRs are substantially longer than in other countries [77]. The most likely cause includes a more litigious society with a higher risk for malpractice in the US with documentation as a prophylactic approach. However, note length may also largely be driven by requirements from the 1997 CMS's Documentation Guidelines for Evaluation and Management Services that described in great detail how many systems had to be reviewed, and physical exam systems had to be documented to be reimbursable for care. The resulting checkboxes within EHRs that generated normal physical exam findings, for example, contributed substantially to note length [78]. In addition, the use ease of "copy and paste" has substantially contributed to longer, 'bloated' notes. While convenient for providers, copy and paste has propagated errors, making important information hard to discover and notes much harder to read and digest. Fortunately, tool kits for managing the use of copy and paste have been developed [79]. Some recommendations include (1) to "provide a mechanism to make a copy and paste material easily identifiable"; (2) to "ensure that the provenance of copy and paste material is readily available"; (3) to "ensure adequate staff training and education regarding the appropriate and safe use of copy and paste"; and (4) to "ensure that copy and paste practices are regularly monitored, measured and assessed".

Use of Artificial Intelligence

AI is increasingly used in health care. Radiology imaging systems have been a prime target for ML and AI in diagnostic decision support. AI can provide a more efficient workflow, shorten the reading time, reduce radiation dose and contrast agents, and permit earlier diagnosis of disease. However, examples of bias have been noted in AI, which has generated further study [80]. These include referring black people less than white people with similar clinical complexity to patients with complex medical needs [81] and flagging

people from poorer neighborhoods with more African Americans as being less ready for hospital discharge.

Innovation in Portal Use

Another effect of EHR use has been the increased use of patient portals, especially for diseases that require frequent but not in-person contact between patients and providers [82]. Portals have reduced the need for phone calls to physicians and reduced unscheduled visits [83].

While interoperability and health information exchange from EHRs have to date failed to deliver the effect and value that had been hoped for [84], novel legislation in the 21st Century cures bill will make most content in the EHR available to patients immediately after it has been created, further engaging patients into their care. This requirement is likely to drive further innovation in this area.

Laboratory Information Systems

The recent emergence of SARs-COVID 2 and the subsequent world pandemic exposed weaknesses in our current systems and presented opportunities for innovation. Laboratories had to adjust to increased testing volume and develop new approaches for that testing. Many laboratories introduced pooled testing, where multiple samples are combined in a pool and are tested jointly. If a pool tested negative, then all samples were considered negative. If a sample tested positive, all samples would be rerun individually. Using this approach saved valuable resources which were limited during the pandemic.

Pharmacy Information Systems

Automation of pharmacy functionality is expected to grow by 11% between 2018 and 2025 [85]. Reducing labor costs and medical errors are driving this development. Automated medication dispensing systems are one example of this trend. With medication and dispensing errors being a major risk factor for hospitals, these systems aim to remove the inherent human risk factor of dispensing while providing an auditable trail. These systems are integrated with the PIS and allow institutions to dispense accurate doses at the point of care, reducing the possibility for error and reducing labor [86]. Other areas of automation in pharmacies include tabletop tablet counter systems, automated medication compounding systems, automated storage and retrieval systems, and automatic packaging and labeling systems.

Supply Chain Systems

Other newer CIS systems include inventory tracking systems, blood bank managing systems, and supply chain management systems. The recent pandemic highlighted the criticality of supply chain managing systems to ensure adequate supplies. For example, they keep track of the supply of personal protective equipment, ensure the rotation of supplies to be used before expiration, and flag items needing reordering [87]. Supply chain systems are dependent upon accurate measures to ensure adequate supply [87]. Failures in supply chains can lead to a slowdown or halting of operations. One example of a supply chain failure was caused when dispensing cabinets failed to report withdrawals in inventory to the central supply chain system, failing to reorder supplies, resulting in shortages of medical equipment.

Blood Bank Systems

Blood bank systems collect, manage, and store data related to blood donations, aliquots, testing results and use them to assure safe transfusion practices. These systems can manage inventory and predict demand for blood, and monitor transfusion practices of providers [88]. One area of development is using genotyped transfusions [89].

Summary

The rapid growth and adoption of CIS has meant that they are now found in all areas supporting and delivering the care of patients. While the EHR is the foundation of these systems within clinical practices and hospitals, portals, telehealth, and mobile technology have weaved the patient into these systems. Exciting, innovative developments mean that these systems will move far beyond where they are today. The role of the informaticist has become increasingly critical to the success of both the implementation and optimization of CIS, as these systems have become increasingly complex and integrated throughout society.

Questions for Discussion

1. List and describe two clinical information systems. How do these CIS contribute to patient care?
2. What are the three criteria for a regulated medical device according to the U.S. Food and Drug Administration (FDA)?

3. The hospital is considering replacement of pagers, yet some of your colleagues strongly wish to keep their pagers in opposition of the plans to adopt an electronic communications tool. How would you convince them to ditch the pager and use a new unified communications platform?
4. Name and describe three hospital information systems beyond the EMR.
5. Discuss the difference between patient-to-provider and provider-to-provider forms of telehealth. Name at least one modality for each type of telehealth system and describe how it supports the delivery of care to patients.

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System Development Life Cycle

12

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Learning Objectives
At the end of the chapter, the reader should be able to:

- List and describe the four stages of the systems development life cycle (SDLC).
- Discuss what happens in a clinical environment during each phase of the SDLC.
- Explain how the SDLC facilitates the adoption of information systems in clinical enterprises.

Practice Domains: Tasks, Knowledge, and Skills
- **K055**. Information system maintenance requirements
- **K056**. Information needs analysis and information systems selection
- **K057**. Information systems implementation procedures
- **K059**. Information system and integration testing techniques and methodologies
- **K064**. Clinical system functional requirements

Case Vignette
Consider a scenario where pre-defined documentation templates are implemented into an electronic health record (EHR). This informatics project aims to add functionality to the EHR so that it can be used to help a provider document their encounter with a patient. In this case, the strategic phase requires that appropriate documentation templates are developed and validated, and approved through the governance process that exists within the institution. The method of creating and uploading the templates into the EHR also needs to be defined. The new functionality needs to be socialized with individual clinical departments and providers who will be using them. The execution phase may require informaticians to manage processes that involve hardware and software. The delivery stage will require a significant interface with end-users to train providers on how to use the added functionality and troubleshoot any issues that may develop. Informatics processes often include an evaluation stage as part of product and process delivery that allows informaticians to understand how successful the preceding stages were and learn from missteps to improve iteratively. And of course, once the delivery stage is deemed successful, the organization can begin to plan for the next iteration of the project's lifecycle.

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Introduction

Typically, the structure or framework of informatics projects seen in healthcare comprises three broadly defined stages: an initial ***strategic phase*** that requires planning and conceptualization of a product or service, followed by an ***execution phase*** where the project is implemented. Once the project is executed, the project enters a ***delivery stage*** where the project pivots to deliver support to clinical activities (Fig. 12.1).

What Is SDLC?

System Development Life Cycle (SDLC) is a methodology that structures how an organization operationalizes projects at a conceptual level. It represents the process of developing, implementing, maintaining, and retiring information systems through a defined process that moves an organization from a phase of *a strategy* to a phase of *execution* using a standard methodology that is uniform and replicable. The overarching goal of using a methodology like SDLC is to allow each project to transition through a series of well-defined stages to reach a successful conclusion.

Recognizing the advantages of utilizing such a framework, healthcare organizations have uniformly begun to utilize a structured methodology to drive their information

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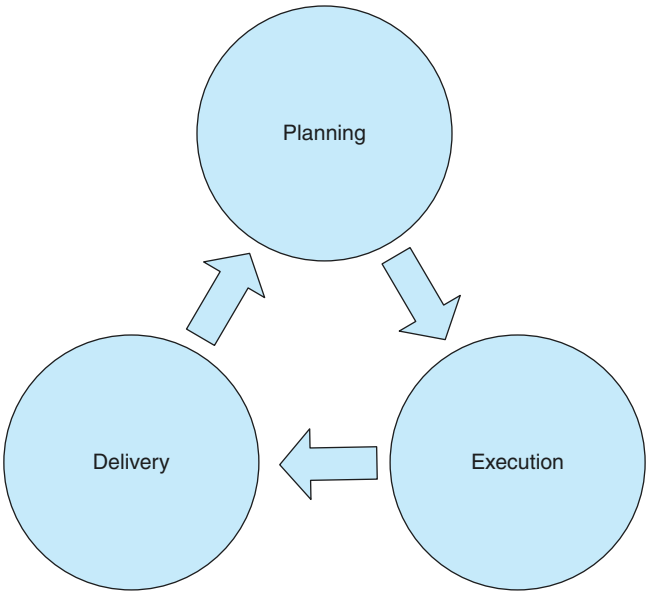

Fig. 12.1 Stages of clinical informatics projects

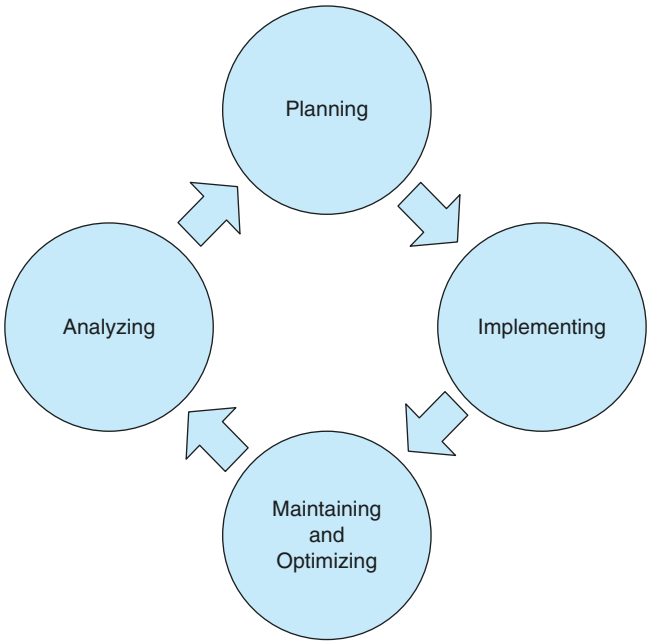

Fig. 12.2 Breakdown of system development life cycle by phases

technology (IT) projects, especially those used within the context of clinical informatics. One advantage is that if the phases of each project are clearly defined, then all personnel associated with the project know the status of the project at any given time. Second, having a structured methodology with well-defined processes allows project planning to occur in a meaningful way so that allocation concerning time, personnel, and financial resources is appropriate throughout the project's lifespan. Third, enterprise IT and informatics projects can be complex and often consist of many moving parts. SDLC helps frame the project's complexity into a manageable context and allows the organization to manage multiple aspects of any given project more effectively, thus reducing the risk of project failure.

Every SDLC map follows the same general pattern (Fig. 12.2). An initial planning phase is typically followed by a product acquisition or service initiation that involves a deployment or implementation phase. The product or service is maintained and optimized, followed by a phase where data is analyzed to improve the next iteration of the cycle.

Brief History of SDLC and Its Relevance Today

The idea of SDLC is not new. Businesses in the 1960s and 1970s processing large amounts of data quickly realized that they needed to proceed systematically and structured way. They began to use a rigid model to build their information systems and operate them. PANDATA, a company in the Netherlands, developed a structured software development model in 1970. This company was acquired by Capgemini, a French company in the 1980s, which continued to use the model. Others adopted the model as the "*Cap Gemini System Development Methodology*". In parallel, the UK's Central Computer and Telecommunications Agency came up with a methodology called *Structured Systems Analysis and Design Method* (or SSADM) in the 1980s, which again was a rigid, sequential, waterfall-like model to design deploy information systems. These models have gone through several iterations, but they are still used today, even though the organizations that designed them were using now obsolete technologies such as punch cards and COBOL.

Thus, the SDLC methodology framework remains sound and should be utilized even after many of the technologies that it was used to deliver have become obsolete. To a significant extent, the longevity of SDLC is because it doesn't matter what the actual technology is that is being implemented; the lifecycle development process stands up to scrutiny whether the technology is an EHR or a bar code medication administration system, or a data warehouse. A particular appeal of SDLC has been its ability to be applied to informatics projects involving hardware, software, and people in any proportion.

An excellent resource on SDLC is the book *Connected for Health* [1], which profiles the implementation of the enterprise EHR within Kaiser Permanente. This book details the phase of the SDLC as they played out within KP. The book represents an excellent case study in the SDLC as applied to a large CIS project, and it is used by many CIS professors who teach in business or management information systems

programs. The story of KP represents one of the earliest clinical organizations to utilize the SDLC to implement an enterprise EHR system.

Phases of SDLC

The term "life cycle" implies birth and death, which is true for software and hardware. There literally is a birthing process for technology tools like an EHR or a computer workstation. Then the product ages over time until it finally reaches obsolescence or end of life. At this point, it is routinely decommissioned, and in the case of hardware, it is typically disposed of in some way after it is no longer in use.

Typically, there are four (and sometimes five) phases in any SDLC (Fig. 12.3). They include:

- *The **initiation*** phase,
- *The **development/acquisition*** phase,
- The ***implementation*** phase,
- The ***operations/maintenance*** phase, and, in the case of some projects,
- A final, ***disposal*** phase.

Figure 12.3 also demonstrates the linear nature of the structuring of the life cycle. One phase leads to the next in a defined way, each phase is a logical succession from the previous phase, and the sequential ordering of phases is important. SDLC comprises a collection of distinct phases, each of which guides the IT systems development process through a particular stage of the product life cycle. Many software-related SDLC frameworks hinged on a "waterfall" software development model; however, while the life cycle model itself is linear, a similar level of linearity and rigidity is not required of the project execution protocol for SDLC to be utilized. Thus SDLC has been successfully adapted to other software development models, such as the fountain, build-and-fix, spiral, rapid prototyping, and incremental models, to name some of the more commonly utilized paradigms. Chapter 21 discusses various project management methodologies that can be used to plan, execute, and monitor the SDLC.

While rooted in the software industry, SDLC is also particularly amenable to informatics projects since it can be adapted to the typically sociotechnical context of most clinical informatics endeavors.

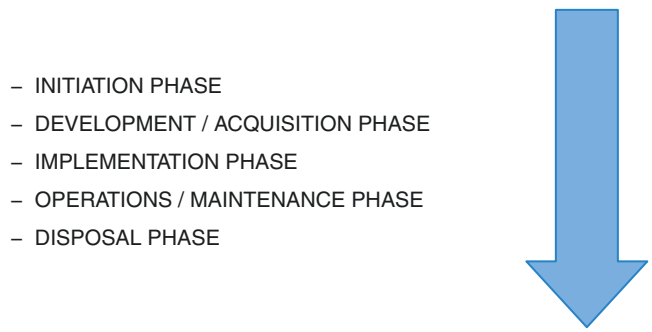

Fig. 12.3 SDLC—breakdown of tasks

The Initiation Phase

Projects might begin as ideas, but the first concrete step to bring ideas to fruition in a defined operational informatics project is the initiation phase. Here the organization determines the need for the system and then justifies the need. This typically occurs in two stages (Fig. 12.4). First is the *Planning* stage, where initial steps are taken to build the foundational understanding required to move the process. These preliminary steps may require socializing the idea through organizational leadership, shepherding it through several committees to seek approval, utilize a systematic method to identify stakeholders and include them appropriately from the early days of the lifecycle to gain their support for the project, define the engagement strategy, and to set the scope for the project. Since informatics projects are typically sociotechnical projects, completing this stage usually requires an understanding of both people and associated processes and the technical details of the system itself.

The second, *Analysis* stage of initiation is typically achieved by conducting needs assessments targeted at different groups and processes and explicitly identifying resources, including defining a budget and selling it to organizational leadership. This is also the time when those involved in the planning process typically make sure that necessary personnel are in place. If not, they can initiate the processes required to recruit them. For some organizations, this can be a lengthy and relatively complicated process.

Organizations also assess risk at this stage and determine if it is easier to move ahead with elements of the lifecycle using resources that are available in-house, whether new

Fig. 12.4 The initiation phase

– INITIATION PHASE

- Planning – *obtain approvals, identify stakeholders, initiate engagement, define scope*
- Analysis – *assess needs (clinical, stakeholders, business), delineate resources + capital, risk assessment*

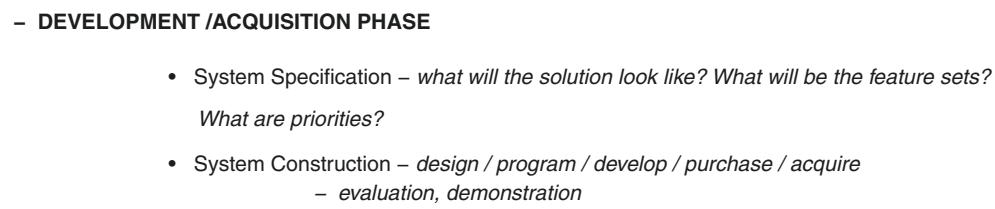

Fig. 12.5 The development and acquisition phase

assets or personnel need to be recruited to internally facilitate the project, or if some or all elements of the project need to be outsourced to a third party, such as consultants or a contractor. For example, an organization that is in the initiation phase for an EHR implementation may decide during the analysis phase that they do not want to assume the risk (or expense) of hosting the EHR database on-site. So from the early stages of the systems development life cycle, the project planners might decide to outsource hosting the EHR database to an external entity, such as the EHR vendor, with the implication that the database will be hosted remotely. This single decision will likely have a significant trickle-down effect in subsequent phases of the lifecycle, from specifying the system itself to acquiring IT human resources to implementation and subsequent maintenance of the EHR.

The Development and Acquisition Phase

Once initiation is complete, the next stage focuses on development or acquisition. If the organization is designing the system, meaning the informatics solution is to be developed *de novo*, then the solution will be engineered. Otherwise, the clinical organization will engage in system acquisition, procuring the informatics solution from an external source.

This phase also has two common components (Fig. 12.5). First is the **system specification stage**, which asks and answers questions pertinent to the nature of the solution, its functionality, and feature sets. Special attention is usually given at this stage to organizational, departmental, and individual end-user priorities that need to be addressed. The system specification stage sets the tone for the final product that is designed or acquired and is informed by the analysis stage of the initiation phase. Input for system specification may be provided by stakeholders identified in the earlier planning stage of the initiation phase. This exemplifies the linear nature of this model, and it is easy to see how it would be a natural fit for a waterfall software development mechanism as it unwinds.

The second component is the ***construction phase***, where the system is either designed in-house or purchased from a vendor. If the project is to be entirely internal to the organization, this phase may utilize one of many specific software design models that align well with clinical *analytics* projects. If the system is to be purchased, this stage should include an evaluation or demonstration of the product to determine its suitability for the organization. This is also the stage of *vendor selection*. Most organizations pay a great deal of attention to this stage in the EHR implementation process, but it is just one element of the entire SDLC and one stage of a larger phase of the life cycle.

Fig. 12.6 The implementation stage

The Implementation Phase

Next is the *implementation* phase. With the advent of the Meaningful Use federal incentive program designed to promote the adoption of EHRs as a consequence of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), which in turn was part of the American Recovery and Reinvestment Act of 2009 (ARRA), EHRs are now in widespread use in the United States. After the flurry of EHR implementations to replace paper-based medical records, many healthcare institutions are now facing the challenge of transitioning from one EHR to another. EHR implementations (paper-to-EHR and EHR-to-EHR) are associated with their own unique challenges, but the SDLC model works well for each type of transition. Implementations also pertain to new components within EHR systems, such as the introduction of a health information exchange (HIE) or clinical decision support (CDS) module. An implementation might even consist of deploying a new version of the EHR system, such as a major upgrade or patch that will involve changes in the user interface, workflow, or how end-users find information in the EHR.

During this phase, there are significant, multiple, complex activities in what is typically a compressed time period (Fig. 12.6). These activities typically revolve around getting a product or service into the hands of end-users and enabling them to utilize the new system without significant long-term impairment to their workflows and efficiency. This phase may involve writing code, setting up hardware, designing various elements of the system from user interfaces to database architecture, installing the actual hardware or software or both, testing the system, training end-users, and ironing

out any last-minute issues which may involve troubleshooting both the technical aspects as well as solving problems that arise with people.

During this process, timing is key—there may be many moving pieces that are critically interdependent on others; thus, much of the effort for this phase may be expended in making sure that the pieces that comprise the project are moving as intended and are aligned as planned. Each piece may include elements related to construction, installation, testing, and training, all of which need to be managed. The implementation phase may also burn a staggering amount of resources very quickly. So close attention to the budget and tight financial control processes are critical to ensuring that there are no cost overruns in this stage of the project. Chapters 20 and 21 are critical to the implementation of new systems or components.

It is worth taking a moment to appreciate the complexity of the implementation phase. The following interrelated activities must be planned and executed:

- **Construction**. This component focuses less on the EHR software and more on the technical environment in which the EHR will be implemented. Organizations may need to purchase hardware as well as additional software or services necessary to host the EHR system. A CDS service could be hosted in the cloud [2], but the organization might still need to purchase some equipment to access the service or integrate it into the local EHR system.
- **Installation**. Installing an EHR system or component is not as straightforward as deploying a new version of Microsoft Word on a local PC. Once acquired or built, the software must be carefully installed within the technical environment. Often this involves installation in 1–3 different environments, including a testing environment as well as a production environment (where end-users will access the system). Some organizations utilize a third, staging environment where the system will also be installed to run updates and new components for a while with real end-users prior to being deployed across the clinical enterprise.
- **Testing**. Prior to asking end-users across the clinical enterprise to use a system, it is a best practice to test the system. Testing typically involves interaction by the IT team as well as several super-users in the clinical organization who will try all of the various functions of the system prior to the larger enterprise implementation. Ideally these users will walk through several common scenarios in which real-world users would need to enter or lookup information in the system. Bugs or kinks in the system can be identified through this process and resolved prior to rollout in the production environment.
- **Training**. During this important component, end-users across the clinical enterprise are trained on how to use the system to conduct routine tasks. Trainings are usually tailored to the various jobs in healthcare. Most healthcare organizations develop a training plan to ensure end-users become familiar with the system prior to rollout. During implementation, the organization might also offer just-in-time training as the system goes live, providing end-users support as they begin to use the real system to deliver care.

The Operations/Maintenance Phase

The next phase of the SDLC is the *operational* or *maintenance* phase; now that the system is implemented, three important elements to the operations phase need to be considered (Fig. 12.7).

First, the support and maintenance stage, which is the backbone activity of any operational informatics department—to keep the system operational and healthy, to perform routine maintenance and troubleshooting, to maximize the utility of the system, to continue to train end-users who are new to the system or whose roles have changed, and to remain vigilant regarding the privacy and security features that were incorporated into the system.

Once an organization has reached this SDLC phase of maintenance, it often turns its attention to **optimization**, explicitly looking to improve the system itself and improve healthcare delivery utilizing elements that are integral to the system. These improvements may be related to various organizational goals like improving operational efficiency or enhancing patient safety. Still, the critical business focus is typically on maximizing return on investment (ROI) under system deployment and minimizing risks associated with incorporating the new system into the old paradigm. For example, once patient data is collected in the EHR database, it can be mined and analyzed to improve multiple parameters of care delivery. Only when the operational phase has reached a steady state can the benefits of implementation truly be reaped. Attention to unintended consequences of system deployment can also help optimize the system's operating characteristics at this stage of the SDLC.

And of course, a key element of this phase is evaluating the system to know what elements were executed well during previous stages and what can be improved. This is an integral aspect of the life cycle because it informs future iterations or

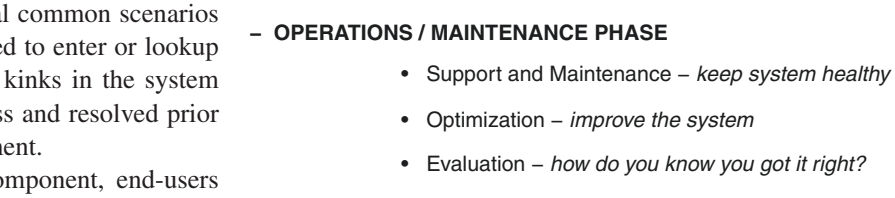

Fig. 12.7 The operations/maintenance phase

new system development life cycles and allows the lessons learned from one life cycle to be passed on to the next. It also helps an organization identify strengths and weaknesses that they can proactively replicate or mitigate.

The Disposal Phase

The final phase of the SDLC—the *disposal* phase—is often particularly important in healthcare because of privacy, security, and safety concerns. For example, protected health information (PHI) stored on EHR servers and hard drives necessitates utilizing specific processes and protocols that need to be explicitly followed for their disposal so that data cannot be inadvertently retrieved from obsolete hardware. Additionally, some hardware in healthcare like IV pumps and glucometers require specific disposal policies because of their biohazard risks. And governmental regulations that are in place may also determine how the lifecycle of healthcare IT products winds down. In some healthcare IT projects, the cost of disposal can be quite high and will need to be factored into the project budget in the planning phase.

Discussion of SDLC in Use: A Common Clinical Informatics Software-Related Project Scenario

Consider this scenario: a hospital uses EHR A, but the vendor is discontinuing the product, so the institution needs to switch to EHR B.

This may be a large and complex capital project with multiple moving parts, but the SDLC blueprint for this endeavor is surprisingly efficient and linear (Fig. 12.8). During the planning phase for this project, close attention to budgets and timelines will invariably occur, but this may also be a good time for project planners to think ahead about the future needs of the institution and plan accordingly. The institution may also extend its future state prioritization exercise to other elements of clinical operations such as clinician wellness or billing optimization or new service lines—a large capital expense like a new EHR may spur a re-imagination of the "vision" of the institution. However, managing change is frequently complex, often difficult, and can be dangerous. At times, the level of ancillary change that the institution plans to occur around the EHR implementation may be a threat to the EHR implementation itself. It so may need to be addressed in the planning stage.

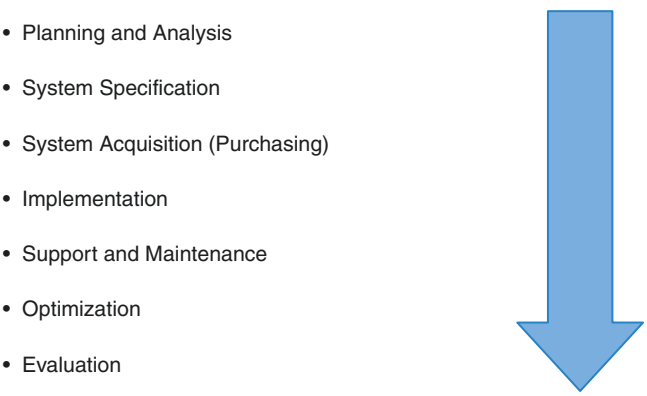

Fig. 12.8 Software-related project SDLC phases

A detailed analysis of the present state with the EHR and correlation to the future anticipated state on the new system may inform the system specification stage. At the end of this stage, the hospital hopefully will know what it wants concerning EHR functionality and features and audition a few products from different vendors to see the best fit.

During the subsequent system acquisition stage, the hospital may fleetingly consider building its own "home-grown" EHR but will probably quickly disabuse itself of the idea given the complexity and costs associated with developing and deploying an EHR from the ground-up. An SDLC storyboard of the process will probably be enough to move the hospital towards acquiring a product from a vendor rather than developing it themselves!

But the process of system acquisition can be complicated and protracted, especially the EHR vendor and customer typically engage in a delicate negotiation process. The stakes during this stage are high since the amounts involved can be enormous. And suppose the implementation is an expensive proposition. In that case, the true cost of an EHR is maintaining it, not just for large healthcare organizations with many clinical settings and end-users but also for smaller practices that might operate in a single clinical location. Indeed, one study suggested that almost half the cost of implementing the EHR in a small primary care physician's office was spent maintaining the product—for just the first year! Therefore, the hospital needs to pay close attention to the support and maintenance phase costs, and this needs to be factored into the SDLC planning process.

The optimization stage is potentially the most rewarding stage of a product life cycle, since not only is it an opportunity to maximize ROI, but it is also an opportunity to deliver truly better care by making meaningful changes in the current paradigm, whether it is data-driven or related to optimizing workflows and clinical practice. So in this stage of the SDLC planning process, the hospital may plan to use analytics fueled by EHR data to implement new quality improvement and workflow efficiency projects that will improve clinical care outcomes and their financial bottom line. While

many optimization projects are pre-planned, some are opportunistic and take advantage of intrinsic benefits associated with the system's maturity. The SDLC can be adapted to accommodate these "on-the-fly" projects.

And finally, the hospital may engage in pre-determined evaluation processes to look for success factors associated with individual SDLC stages and those associated with the entire life cycle. Engaging in a thoughtful evaluation process offers the hospital the ability to learn from the current life cycle of the newly implemented EHR and apply these lessons to the next systems life cycle; thus, each lifecycle iteratively improves the future state from the previous state. This model of iterative cyclic advancements is not just limited to SDLC—it has been the cornerstone of longitudinal healthcare quality improvements, and the plan-do-study-act-evaluate cycle has been the fulcrum around which healthcare QI has revolved in the last few decades.

Discussion of SDLC in Use: A Common Clinical Informatics Hardware-Related Project Scenario

Consider this scenario: a healthcare organization wants to incorporate the use of network-enabled glucometers into clinical inpatient workflows. These glucometers can connect to the hospital intranet and remotely transmit their readings to the EHR.

This is predominantly a hardware integration project, although there are some software elements associated with implementing any hardware product. Interestingly, apart from a few project-specific changes, the same SDLC framework that we saw in the prior Scenario for software implementation can also be applied to this project.

Pre-implementation planning specific to this project may include assessing the need to inspect the wireless network and update it if necessary to ensure the glucometers can transmit data appropriately and conducting testing to ensure transmitted data is appropriately incorporated in the EHR database.

Some elements such as how the project is supported will also be different compared to the previous Software-related project scenario—hardware tends to fail, and much of the support may end up as a roadmap to find ways to physically keep the devices operational, but it is worth noting that most hardware used today have associated software needs—almost all computerized medical devices have firmware that needs to be regularly updated. Compatibility with the clinical information system is often just as critical for hardware as it is for software.

Of course, upgrading hardware may be a different process than upgrading software. Disposal of hardware is associated with its own challenges. Still, for the most part, the stages of the systems development life cycle for this project will be very familiar to the previously described Scenario, with planning and analysis informing a system specification, which in this case informs design, testing, and acquisition, leading to a compressed high-stakes implementation stage followed by support and maintenance (Fig. 12.9).

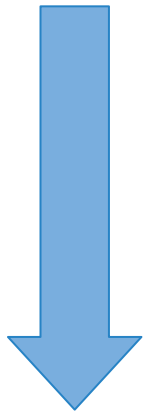

Fig. 12.9 Hardware-related project SDLC phases

Conclusion

In sum, SDLC methodology is generalized enough and adaptable enough to be useful in varying contexts without giving up either its effectiveness or value.

Questions for Discussion

1. What is the role of the SDLC in managing the implementation of EHR systems?
2. Identify and describe an example of a Health IT system gone bad in your organization.
   (a) First, discuss how best SDLC practices were followed or not followed, and how they contributed to the failure.
   (b) Second, pretend you could go back in time to lead the acquisition and implementation of this system. Describe key strategies and activities you would employ at each stage of the SDLC to ensure system success.

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Healthcare Data and Exchange Standards

13

William Hersh

Learning Objectives

- Explain the importance of standards and interoperability for health and biomedical data and information systems
- Describe the major issues related to identifier standards, including the debate on patient identifiers
- Discuss the various message exchange standards, their explicit usage, and the type of data they exchange
- Discuss the different terminology systems used in biomedicine and their origins, content, and limitations
- Describe the role of platforms for interoperability, including SMART on FHIR

Practice Domains: Tasks, Knowledge, and Skills

1. Fundamental knowledge and skills
   (a) K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])
   (b) K010. Development and use of transaction standards (e.g., American National Standards Institute X12)
   (c) K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)
   (d) K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System [LIS])
   (e) K013. Development and use of data model standards
   (f) K014. Vocabularies, terminologies, and nomenclatures (e.g., Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine—Clinical Terms [SNOMED-CT], RxNorm, International Classification of Diseases [ICD], Current Procedural Terminology [CPT])
   (g) K015. Data taxonomies and ontologies
2. Enterprise information systems
   (a) K095. Standards related to storage and retrieval from specialized and emerging data sources
   (b) K111. Methods and standards for data sharing across systems (e.g., health information exchanges, public health reporting)

Case Vignette

One evening, an elderly patient who lives in a suburb of Indianapolis, Indiana, USA develops sharp abdominal pain while visiting her sister in nearby Chicago, Illinois, USA. The patient, who has difficulty keeping track of her medicines, decided to go to the local emergency department. The patient is asked to provide information about her medical history and a current list of medications during the triage process. She is unable to provide many of the details given her limited capacity. Given that her regular doctor's office is closed, and she is at a hospital she had never visited before, what steps can the treating team use to provide the best patient-centered care for this woman? What data is needed, and where would it come from?

Introduction

Although data standards have been a core component of the discipline of clinical informatics for several decades, their real-world need became readily apparent with the widespread adoption of the electronic health record (EHR) incentivized by the HITECH Act. Their use was enshrined in federal policy through the 21st Century Cures Act. Fortunately, many standards were mature and ready for use, with an emerging framework for their use.

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Standards and Interoperability: Basic Concepts

Data standards are critically important in clinical informatics. They promote consistent naming of individuals, events, diagnoses, treatments, and everything else in healthcare. They allow better use of data for patient care [1] and re-use that data, such as for quality assurance, research, and public health [2]. Standards enhance the ability to transfer data among applications, thus leading to better system integration. Although the Health Information Technology for Clinical and Economic Health (HITECH) Act successfully achieved widespread adoption of the EHR in the United States, the national implementation fell short in adopting data standards, with a resulting difficulty of EHR systems sharing data [3]. The best resources for learning more about standards come from the book by Benson and Grieve [4] and the Web site of the HL7 International organization,[1] whose activities will be described extensively throughout this chapter.

Before we discuss the actual standards of healthcare, let us define what a standard is. According to the International Standards Organization, a standard comes from "*a standard document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the optimum degree of order in a given context*" [5]. (Underlining emphasizes critical components.)

Standards facilitate a critical process known as interoperability. The original definition of interoperability was published in 1990 by the Institute for Electronic and Electrical Engineers (IEEE), and continues to be widely cited: "*Interoperability is the ability of two or more systems or components to exchange information and use that information; that has been exchanged*" [6]. IEEE subsequently updated its definition of interoperability. Its current definition is now "*the ability of a system or product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards.*"[2]

The recognition of incomplete adherence to data standards resulting in interoperability problems in the US EHR landscape led to provisions in the federal legislation, as part of the 21st Century Cures Act, to increase interoperability among clinical data systems, including the EHR [7]. This legislation defined interoperability for healthcare as[3]:

- Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user
- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law
- Does not constitute information blocking

The value of standards has been known throughout human history and is not unique to the computer era. Roman chariots placed the wheels a specific distance apart to be used as pathways throughout ancient cities. The emergence of standards for railroad cars enabled different railroads to be built across various countries, all adhering to a standard of the wheels being a certain distance apart. When telephones started to become international, the emergence of standards allowed calls to be made from one country to another, from one type of phone to another. An early standard with computers was ASCII text. Even though there are some variations between end-of-line characters for different computer operating systems (e.g., Windows, Mac, and Unix), ASCII text is a standard, and text written on one computer from one vendor can be used on another computer. Even more recently, standards such as Wi-Fi enable computers, smartphones, tablets, and other devices to connect wirelessly to the Internet. Many global financial transactions are based on standards. The ubiquitous automated teller machine (ATM) allows access to the currency from our bank accounts almost anywhere globally.

While there are many benefits of standards, there are also some limitations. Standards can lead to dominance by one segment of the industry and may stifle innovation. They may limit computer applications to a more restricted feature set. For example, the standards for operating systems and productivity applications that emerged from Microsoft in the latter part of the twentieth century—Microsoft Windows and Office—have benefits of widespread use and limitations. Sometimes the world does not fit into standards. A well-known example is the language Esperanto, an attempt to create a standard language by which humans could communicate, especially in business, science, and other types of transactions [8]. Ultimately, however, English prevailed in that function, and Esperanto never achieved widespread use. There is also a famous quote, "*The nice thing about standards is that there are so many of them to choose from*" [9]. This tongue-in-cheek quote refers to the fact that sometimes people or groups will create new standards when existing ones are already in use, thus defeating the purpose of having a single standard.

[1] http://www.hl7.org/

[2] https://www.standardsuniversity.org/article/standards-glossary/

[3] https://www.healthit.gov/curesrule/

Standards Development

Hammond describes four common approaches to developing standards [10]:

- Ad hoc—groups agree to informal specifications
- De facto—single vendor controls industry
- Government mandate—government agency creates standards and mandates its use
- Consensus—interested parties work in an open process

The development process for standards is fundamental. Hammond lists the stages of development of a standard [10]:

- Identification
- Conceptualization
- Discussion
- Specification
- Early implementation
- Conformance
- Certification

Standards Development Organizations

If standards are going to be developed in an open and transparent process, there need to be standards bodies to convene those developing and, ultimately, using the standards. Typically, these are private nonprofit organizations. In the US, there is an organization called the American National Standards Institute (ANSI),[4] which accredits standards development organizations (SDOs), including those that work in health care. Some SDOs work in health care focused on different standards applied in other areas:

- The Accredited Standards Committee (ASC X12)[5] focuses on business transactions
- HL7 focuses on messaging standards
- The American Society for Testing and Materials (ASTM)[6] is also an SDO and has a committee that develops health IT related standards, Committee E31 on health care informatics.

Of course, standards need to interoperate not only in the United States but also globally. The most important international standards body is the International Organizations for Standardization (ISO).[7] ISO has many technical committees, one of which is Technical Committee 215, focusing on health informatics standards. There is also a European standards organization similar to ANSI in the United States. The European Committee for Standardization (CEN) has a Technical Committee 251 in CEN focused on health informatics standards. Another standards organization of note is the International Telecommunication Union (ITU),[8] an agency of the United Nations focused on telecommunication standards in general.

In the United States, health information standards have been promoted by government and private nonprofit organizations. There have been several approaches by the US government over the years that, for the most part, have attempted to identify standards that are ready for use and then to promote their use. Most health-related standards work in the US is led by the Office of the National Coordinator for Health IT (ONC).[9] A critical standards-related activity of ONC is its publication of the annual Interoperability Standards Advisory (ISA),[10] which recognizes interoperability standards and implementation specifications for industry use to fulfill specific healthcare interoperability needs.

The National Institute for Standards and Technology (NIST) has aided the health information standards process. This US federal agency leads standards development, not only in healthcare but across all industries. NIST has focused its efforts in health care on supporting ONC and the National Library of Medicine (NLM),[11] focusing on terminology standards and making sure that there is appropriate terminology being used within messaging standards, such as HL7.

Another important standards and interoperability effort is Integrating the Health Enterprise (IHE).[12] This is a non-federal effort, so a private nonprofit organization identifies and demonstrates solutions to real-world interoperability problems. IHE organizes interoperability showcases to demonstrate various solutions, both in person at various meetings and virtually over the Internet.

One topic that commonly comes up in healthcare standards is, why can't health IT be more like banking? After all, with banking, we can take our ATM card from our local bank and put it in any ATM around the world and, due to a standard—ISO 8583[13]—we can get out local currency and have

[4] https://www.ansi.org/
[5] https://x12.org/
[6] https://www.astm.org/
[7] https://www.iso.org/
[8] https://www.itu.int/en/
[9] https://www.healthit.gov/topic/standards-technology/health-it-standards
[10] https://www.healthit.gov/isa/
[11] https://www.nlm.nih.gov/
[12] https://www.ihe.net/
[13] https://www.iso.org/obp/ui/#iso:std:iso:8583:-1:ed-1:v1:en

it charged against our bank account. If banking can do standards worldwide so easily, why not healthcare?

Bernstam and Johnson have discussed why the analogy often does not hold [11]. Banking data is relatively simple, i.e., mainly consisting of numbers. The actions, the context, the users, and the banking workflow are all very simple relative to the complexity of health care. Even though we need to have strong security around banking data, the complexity and variability of health data are much more significant. And, again, while we can learn some from banking about standards, it doesn't completely describe why we are not yet there with health IT standards.

Identifier Standards

Identifier standards aim to create identifiers for all entities that participate in healthcare: patients, providers, employers, health plans. We will cover each of these in this section.

Patient Identifiers

Of these identifiers, probably the most complicated are patient identifiers. There is value in having a single, standardized patient identifier [12]. Among these benefits are the easy linkage of records, such that when different records exist for a patient, they can easily be linked together. This facilitates health information exchange when patients move from one healthcare organization to another. It also potentially reduces errors and costs from duplicate records, and they need to be merged. These same benefits, however, can be risks. The easy linkage of records potentially compromises the privacy and confidentiality of a patient.

Standard identifiers aim to reduce the problems of both *duplicate* and *overlaid* records. A duplicate record occurs when more than one record exists for a patient, whereas an overlaid record occurs when more than one patient is mapped to the same record. Identifier errors can compromise the quality of care and can be costly [12]. There is both time and cost to correct errors from duplicate and overlaid records. Duplicate records are more likely to be associated with missed abnormal test results [13]. One study of five large academic centers found large numbers of patients with matching names (17–41%, although reduced using other data) and highly variable policies for preventing, detecting, and removing duplicate records and mitigating errors [14]. A recent study noted improved patient identification better identifies adverse drug reactions [15].

What are some of the key attributes we would want in patient identifiers? Riplinger states they should include [12]:

- Unique—only one person has an identifier
- Non-disclosing—discloses no personal information
- Permanent—will never be re-used
- Ubiquitous—everyone has one
- Canonical—each person has only one
- Invariable—will not change over time

While a national health identifier is a controversial political issue in the United States, it is a non-issue in most industrialized, developed countries. For example, in New Zealand, there is a National Health Index.[14] Not only is that index used for all health purposes, but there is a Web site that describes why that index exists, why it is essential, and what the government does to protect privacy. In Singapore, all citizens have a national registration identity card (NRIC). In addition, all long-term visitors get a foreign identification number (FIN). These national numbers are used for all identification, not just healthcare. Most Western European countries also use national patient identifiers without much controversy, with some using a general unique identifying number (UIN) and others using a specific unique health identifier (UHI) [16].

Should there be government-issued patient identifiers in the United States? This was mandated by the Health Insurance Portability and Accountability Act (HIPAA) legislation in the mid-1990s. HIPAA mandated that there be patient identifiers for all citizens in the United States. But there was tremendous political pushback, and legislation was passed (recently repealed) banning government funding for any sort of national health identifier [17].

We already have a national identifier in the United States, the social security number (SSN). For many years, the Veterans' Administration used the SSN as its patient record number. It turns out, however, that the SSN is an insufficient identifier. There are several issues related to SSNs [18]. There are many duplicates in the population, estimated to be up to 3–5%. There is no check digit in the SSN that enables a checksum process to validate when the number is electronically transmitted. The SSN is also used for many other purposes, and for that reason, many advocate that it not be used for healthcare. It has been shown that the SSN can be used to de-identify individuals in public health data sources [19]. So even if the US desired a national health identifier, it should probably not be the SSN.

Are there alternatives to a national patient identifier? The most promising approach is probably using probabilistic matching algorithms, where various attributes of the patient, e.g., name, address, date of birth, phone number, and others, are matched in a probabilistic manner. These attributes are not always recorded identically and may change over time,

[14] https://www.health.govt.nz/our-work/health-identity/national-health-index

so robust algorithms are required that can provide matching with a high level of confidence. There is a long history of research in this area dating back over a decade and showing that many methods that have been developed indicate a relatively high level of accuracy in matching patients [20–22]. Some of these methods are used in health information exchange systems, where it is a requirement to match patients across different health systems [23, 24]. There are still problems such as non-standardized [25] or dirty and missing data [26] that make these algorithms challenging.

The ONC commissioned a report on the current state of patient records matching [27]. It noted that successful record matching techniques were imperative for patient safety, care coordination, data quality, and other reasons. The report reviewed the current state of the art and noted that, for the most part, it works well, but would benefit from some changes to standards in health care systems, namely, the standardizing of patient identifying attributes in patient records, such as:

- First/given, middle/second given, and last/family names
- Suffix—e.g., Jr./Sr., II/III/etc., MD/RN/Ph.D., Esq., etc.
- Date of birth—YYYYMMDD, with HHMMSS if available
- Current and historical addresses—in some international format
- Phone number—all known
- Gender—from HL7 value set; M, F, UN

The report noted there would also need to be a process for handling changes in these attributes across the healthcare system, for example, a name change or address or a phone number changed.

The 21st Century Cures Act legislation mandated a federal report on patient matching published in 2019 [28]. Other recommendations for improving the process have been published [29, 30]. The Indiana Health Information Exchange noted that the most crucial factor in probabilistic patient matching has been standardizing patient addresses [31]. More on patient matching and workarounds can be found in Chap. 14.

Other Identifiers

Other types of identifiers in healthcare are much less controversial. Few would argue that we should not have identifiers for healthcare providers. The original provider identifier was the Universal Physician Identifier Number (UPIN), which the US government maintained for physicians who treated Medicare patients. But since not all physicians treat Medicare patients, this was superseded by the National Provider Identifier (NPI), which is assigned to all physicians in the US. A national provider system issues the NPI, a 10-digit number whose last digit serves as a check digit. This allows a checksum process to verify that the identifier is transmitted correctly. The payor for Medicare in the US, the Centers for Medicare and Medicaid Services (CMS), will not process claims without using the NPI.

Employers and health plan identifiers are also unlikely to be controversial, perhaps except for the administrative overhead they may cause. Employers must have a standard Employer Identifier Number (EIN). Facility standards are important to identify where patients receive care, especially when care is received in multiple locations [32]. In addition, the Affordable Care Act requires health plans to have either a Health Plan Identifier (HPI) or an Other Entity Identifier (OEID) that is an identifier for use in transactions.

Transaction Standards

Transaction standards are essential for the business of healthcare. A set of transaction standards for healthcare called ASC X12N were developed to encourage electronic commerce for health claims, simplifying what was previously a situation of over 400 different formats between insurance companies and others. The HIPAA legislation mandated using the ASC X12N standards for healthcare business electronic data exchange under the guise of "administrative simplification." The original version of ASC X12 was called 4010. This was superseded by a new version that was released in 2012 called 5010. The use of the 5010 transaction standards is a requirement for payment for any government healthcare-related transactions and is used by many private insurance companies.

The major transactions in 5010 and their identifier numbers include:

- Health claims and equivalent encounter information (837)
- Enrollment and disenrollment in a health plan (834)
- Eligibility for a health plan (request 270/response 271)
- Health care payment and remittance advice (835)
- Health plan premium payments (820)
- Health claim status (request 276/response 277)
- Referral certification and authorization (278)
- Coordination of benefits (837)

One of these transaction standards made the front-page news around October 2013 when the healthcare.gov website was launched for the Affordable Care Act (ACA). Initially, there were many problems with the website, a significant one of which was the improper implementation of the 834 standard for enrollment and disenrollment in health plans. A reporter from *The Washington Post* said that ACA's most important number was 834, referring to many insurers' problems with

the inadequate implementation of the standard [33]. (A more technical description of the problem was also described [34].) There were also many other informatics lessons to be learned from the rollout of healthcare.gov, not just the political issues, but the federal IT procurement issues and the management of large-scale, complex projects [35].

Message Exchange Standards

There are many message exchange standards that focus on different types of messages and various types of data. On one level, healthcare data standards are almost synonymous with "HL7." However, the name HL7 refers to several entities. There is HL7, the organization that develops and supports standards, which is properly called HL7 International. There are also the standards of HL7 themselves, mainly the two different versions of the main HL7 messaging standards. These two standards are substantially different and incompatible with each other. The name HL7 comes from the OSI 7-layer model of network communications.

HL7

Version 2 of HL7 is widely used throughout health care. It is a so-called syntactic standard, whereas Version 3 aims for true semantic interoperability. HL7 Version 2 has several versions that have added subsequent refinements, but they are all part of HL7 Version 2. HL7 Version 2 is supported by most vendors of health care information systems for the interchange of data. HL7 Version 2 messages use the ASCII format to delimit the different fields with the vertical bar character (|).

HL7 Version 2 is primarily a syntax. This means that the sender and the receiver must understand the meaning of the messages. Some of the later versions of HL7 Version 2 add more semantics (or meaning) so that the messages are consistent. Within HL7 Version 2, each message has segments, and each of the segments has a three-character identifier and then values that follow it. Some of these segments and their identifiers include:

- MSH—message header
- EVN—event type
- PID—patient identifier
- OBR—results header
- OBX—result details

Here is an example of HL7 Version 2 message [4]:

```
MSH|^~\&||^123457^Labs|||200808141530||ORU^R01|123456789|P|2.4
PID|||123456^^^SMH^PI||MOUSE^MICKEY||19620114|M|||14 Disney Rd^Disneyland^^^MM1 9DL
PV1|||5N|||||G123456^DR SMITH
OBR|||54321|666777^CULTURE^LN|||20080802|||||||SW^^^FOOT^RT|C987654
OBX||CE|0^ORG|01|STAU||||||F
OBX||CE|500152^AMP|01||||R|||F
OBX||CE|500155^SXT|01||||S|||F
OBX||CE|500162^CIP|01||||S|||F
```

We see the message has different segments and each of the segments has a header. The first is the message header, which tells us that this is a report from an entity called Lab 123457. It lists the date and the reference number of the lab test. It also provides patient identifying information. The patient is named Mickey Mouse, with a date of birth, gender, address, and city. There is another segment on the provider, which is Doctor Smith with identifier G123456, who is located on Ward 5N of a hospital. The observation is a swab from the right foot that is being assessed for bacterial culture. The result of the test is an organism, which, in this case, is *Staphylococcus aureus*. All microbiological specimens are tested for susceptibility to different antibiotics, including ampicillin, trimethoprim-sulfa, and ciprofloxacin. We see that the organism is resistant to ampicillin but sensitive to trimethoprim-sulfa and ciprofloxacin.

There have been different releases of HL7 Version 2, starting with the first and basic version implemented in 1990. Each of the new releases is backward compatible with previous releases of HL7 Version 2. HL7 Version 2 has been a highly successful standard, and it continues to be widely used. Its major limitation is that it is a syntactic standard. There are only a few semantic definitions, so the sender and the receiver need to know the language of the message.

HL7 Version 3 is an attempt to introduce semantics into messaging [36]. Its goal is semantic interoperability so that each HL7 Version 3 message has a specific meaning no matter which system is using it. If one adheres to the standard, any system can understand the meaning, at least in principle, of an HL7 Version 3 message. For this to happen, HL7 Version 3 is based on Reference Information Model (RIM). This is an object model of the entities that pass messages. HL7 Version 3 is also implemented in a more modern format, namely Extensible Markup Language (XML). However, HL7 Version 3 is complex, and some would say complicated. Others have gone as far as to call it incoherent. HL7 Version 3 works by building messages around the RIM. The RIM is object-oriented, and there are five abstract classes, with the elements of the message defined in the context of these abstract classes:

- Entity—things in the world, e.g., people, organizations, other living subjects, drugs, devices
- Role—capability or capacity, e.g., patient, practitioner
- Participation—role in the context of an act, e.g., performer, target

- Act—clinical or administrative definitions, e.g., observation, diagnosis, procedure
- Act relationship—links between acts, e.g., diagnosis act

All clinical, administrative, financial, etc., healthcare activities can be expressed in "constraints" to the RIM. The uptake of HL7 Version 3 message has been very modest. In addition, it has been criticized for its complexity [37]. As such, the need for a new standard that was more "modern" than V2 and less complex than V3 gave way to the Fast Health Interoperability Resources (FHIR) standard. FHIR steps backward somewhat in terms of the complexity of HL7 Version 3 but moves forward to allow interoperability to proceed. When FHIR emerged as the leading candidate for interoperability, HL7 International took over its development. Because of its current prominence in the standards and interoperability realm, FHIR will be described later in this chapter.

The HL7 International organization has many other activities. These include the Clinical Context Object Workgroup,[15] which aims to develop standards such as single sign-on and passing of the clinical or patient context across applications being used. The Clinical Decision Support Workgroup aims to develop standards around clinical decision support applications.

Another important activity of HL7 is the Clinical Document Architecture (CDA) [38]. CDA is vital because most health care information is in the form of documents, and these are used to allow humans to read them. But as documents become electronic, it may be desirable for them to also have computable structures. CDA defines a standard format and the metadata for that structure. A key aspect of CDA is templates. These are reusable parts of documents that occur across different documents. The unstructured part of documents can then be wrapped in the CDA framework.

The current version of CDA, Version 2, has three levels of interoperability:

- Level 1—general document specification
- Level 2—adds document types with allowable structures
- Level 3—adds mark-up expressible in a structured form, such as RIM

In recent years, there has been an effort towards Consolidated CDA (C-CDA).[16] C-CDA consists of a series of reusable templates for documents and sections. Document templates represent the specific types of documents commonly used in medical records, such as clinical notes, discharge summaries, operative reports, and history and physical exam. Within each document, templates are different sections, each of which contains actual data. For example, allergies may appear in many kinds of documents, so wherever allergies occur in any type of document, they adhere to the allergy section template.

In essence, C-CDA allows the building of documents from standardized components, which, in turn, contain standardized information. One of these documents is the Continuity of Care Document (CCD), which summarizes the patient is moving from one care setting to another, from hospital to home, or when referred from one facility to another. Other documents are typically used in patient care, such as the consultation note, diagnostic imaging, discharge summary, history and physical, operative note, procedure note, progress note, and another general unstructured document. Each of these documents has reusable section templates.

Imaging Standards

Of course, documents are not the only type of data in healthcare for which interoperability is desired. Another necessary type of data in health care is image data, for which we may want to move from the devices that capture them into records so that they can be viewed, and then we may want to archive them in various ways. The Digital Imaging and Communications (DICOM) standard is intended for the transport of images. It was developed by the American College of Radiology and the National Electrical Manufacturers Association, and there is a Web site devoted to its details.[17]

DICOM defines how images and the metadata associated with those images are moved between various electronic devices, including information systems. The systems that store images and make them available for multiple healthcare uses are called picture archiving and communication systems (PACSs). There are two overall parts to a DICOM message, the header and the actual image data. The header data contains information about the patient, the type of image, and how it was captured. It also includes information on the structure and compression of an image, e.g., how much compression has been used on that image if it is a JPEG image. One of the challenges for DICOM is that the ease of moving images around in the modern Internet, being able to display them in Web browsers, has led to a good deal of image transfer that does not use DICOM or take advantage of all the standardization inherent within it. This leads to clinical problems in that the information associated with an image may not be complete.

Prescribing Standards

Another necessary type of message to exchange is the prescription. A family of standards around electronic prescrib-

[15] https://www.hl7.org/Special/committees/visual/index.cfm

[16] https://www.healthit.gov/topic/standards-technology/consolidated-cda-overview

[17] https://www.dicomstandard.org/

ing developed by the National Council for Prescription Drug Programs (NCPDP),[18] whose SCRIPT is the communications standard between the prescriber and the pharmacy. SCRIPT is required for use in the Meaningful Use criteria and has led to widespread electronic prescribing.

Patient Summaries

Another type of information that we may wish to exchange is a patient summary. This was recognized over a decade ago and led to the Continuity of Care Record (CCR). The goal for the CCR was to be "a *set of basic patient information consisting of the most relevant and timely facts about a patient's condition*." The goal for its use was to be available when the patient was referred or transferred or discharged, either among health care providers or facilities, and it would convey essential information for providing continuity of care. However, the original CCR standard was not compatible with any existing standards. This led HL7 and several vendors to create the Continuity of Care Document (CCD), which would be based on HL7 Version 3, the Clinical Document Architecture (CDA). There were battles and lawsuits, but eventually, the CCD prevailed because it was compatible with other standards.

The CCD has resulted in a more common use of the document [39]. However, many implementations of the standard make errors [40, 41]. There is also some allowable variation within the standard, such that its semantic interoperability has not been fully achieved. Nonetheless, the CCD is an important document that is a patient summary easily moved between most EHR and other patient information systems.

Another use of the patient summary is to allow the patient to download his or her summary. This began with the Veteran's Administration (VA) Blue Button Initiative,[19] allowing VA patients to go to the VA portal and download an electronic summary of their medical data. ONC and several vendors then took up this idea in their personal health record (PHR) systems.[20] More recently, CMS has developed Blue Button 2.0, which adds functionality specific to Medicare beneficiaries.[21]

Terminology Standards

The final category of standards we will discuss is terminology standards. The benefits of computerizing clinical data depend upon its "normalization" to a consistent and reliable form to carry out tasks such as aggregation of patient data, clinical decision support, and clinical research. However, clinical language is also inherently vague, sometimes by design, which can be at odds with the precision of computers. A comprehensive reference on all of the different terminology standards is the book by Giannangelo [42].

With terminology, some terms may mean the same thing, like *cancer* and *carcinoma*. But inside a computer, the ASCII codes for the letters of those words are no more similar than the codes for *apple* and *zebra*. Medicine is sometimes criticized for having such vague language. Some have argued that we need "*fewer words and more meaning in medicine*," such as in air traffic control, where the communications that are allowed between pilots and air traffic controllers are much more limited [43]. Another example is the military, where communications on the battlefield use language that is constrained.

Just as we saw at the beginning of this chapter, there is a standard to define a standard; likewise, there is a terminology of terminologies. The term *terminology* itself generally refers to a collection of terms. But the notion of a term is not so simple. Most terminology is based on concepts, things, or ideas expressed in one or more terms. Concepts have *synonyms* where different terms describe the same concept. There are also *polysems*, which are terms that mean more than one concept.

We sometimes talk about *dictionaries*, which have concepts plus their meaning. Dictionaries often list some of the different terms that describe a concept, i.e., the synonyms. A *thesaurus* is a resource that groups synonyms by the concept to which they refer. We also talk about a *vocabulary* collection of concepts and terms in a domain, such as healthcare, information technology, or some subset. And then, there is an *ontology* consisting of structured concepts and the relationships between them that give a more formal representation of knowledge.

Dealing with language and terminology is usually a lot harder for computers than humans. As humans, we understand synonymy and polysemy of terms. For example, there are many ways we can say *common cold*. There are many different synonyms that humans, especially those who have some training in medicine, can understand. We use terms like *cold*, *upper respiratory infection*, *URI*, *laryngitis*, *bronchitis*, *rhinitis*, *viral syndrome*, and more. They are not all quite precisely synonyms, but we understand the similarity between the terms.

On the other hand, computers just view these as bits in memory and do not understand that they mean similar things unless we program the computer. Likewise, for polysemy, we can take a word like *lead*. It can be used in many ways in medicine. It can be used as a verb, as *hypertension leads to heart disease*. We can also talk about an *EKG lead*, *lead poisoning*, and others.

Cimino has elucidated some of the "*desiderata*" for constructing medical or clinical vocabularies [44]. Most vocabu-

[18] https://ncpdp.org/

[19] https://www.va.gov/bluebutton/

[20] https://www.healthit.gov/topic/health-it-initiatives/blue-button

[21] https://bluebutton.cms.gov/

laries have a hierarchical structure and some coding scheme where a code is assigned to every concept. We ultimately want to represent the terms and the concepts as codes, and we want to use these codes in information systems. Various approaches can be used for codes. They can be numerical, where they are assigned sequentially or randomly. They might be a mnemonic, such as an abbreviation. There could be a hierarchical code that indicates the level in the hierarchy that the concept exists. There may be a juxtaposition of codes where composite codes indicate a concept consisting of more primitive concepts. And then there is a combination codes where those composites use ordering. In general, as argued by Cimino, we should avoid semantic codes that put meaning into the codes themselves [44]. Concept codes are best represented by an identifier that does not say anything about the meaning.

There are many terminology standards in biomedicine. Some of them have evolved to carry out specific purposes. There are terminology standards for diagnoses, drugs, laboratory findings, procedures, and other aspects of healthcare. There are several terminologies for nursing. There are terminologies for literature indexing and medical devices. A couple of comprehensive terminologies attempt to cover all these areas and link the terms from these different terminology standards into a comprehensive whole.

International Classification of Diseases (ICD), Version 9

One of the earliest terminology systems, and still highly important, is the **International Classification of Diseases (ICD)**. ICD was first developed in 1893 when it was called the International List of Causes of Death. And the initial primary purpose for ICD was to compile mortality statistics. It was developed in London and eventually passed to the World Health Organization. Along the way, ICD changed in name to International Classification of Diseases, as it has evolved to code diseases more than just the cause of death. In modern times, the primary use of ICD is in coding diagnoses for health insurance claims, which is why we sometimes hear data collections with ICD codes called *claims data*. In addition to diagnosis codes, they may include procedure codes and other data types used for health insurance claims.

Until recently, the version of ICD used in the US was ICD-9.[22] ICD-9 was approved by the World Health Organization in 1975. Even though ICD-10 was released in 1990, ICD-9 continued to be used in the US until 2015. ICD-9, the original version from the World Health Organization, was organized hierarchically, with one digit in the code for each hierarchy level and having codes up to four digits.

[22] https://www.cdc.gov/nchs/icd/icd9.htm

ICD is often extended by different countries in the US to ICD-9-CM, with CM standing for clinical modifications. This process added more detail and a fifth digit, so there could be up to five-digit codes. ICD-9-CM also had an additional set of codes, V codes, for encounters related to prevention and screening. If a patient is screened for something, they would not get the diagnosis code, but rather the V code that they were being screened for that diagnosis. ICD-9-CM also has G codes that document the provision of specific services, such as those embodied in quality measures.

The US finally discontinued ICD-9 in October 2015 with the transition to ICD-10-CM, although there is still plenty of data encoded in ICD-9-CM. Here is an example of ICD-9-CM for some types of heart disease:

Diseases of the circulatory system (390–459)
Ischemic heart disease (410–414)
(410) Acute myocardial infarction
(410.0) MI, acute, anterolateral
(410.1) MI, acute, anterior, NOS
(410.2) MI, acute, inferolateral
(410.3) MI, acute, inferoposterior
(410.4) MI, acute, other inferior wall, NOS
(410.5) MI, acute, other lateral wall
(410.6) MI, acute, true posterior
(410.7) MI, acute, subendocardial
(410.9) MI, acute, unspecified
…
(414) Other forms of chronic ischemic heart disease
…

- + (414.01) Coronary atherosclerosis, native coronary artery
- + (414.02) Coronary atherosclerosis, autologous vein bypass graft
- + (414.04) Coronary atherosclerosis, artery bypass graft

One type of heart disease is acute myocardial infarction, which is listed under diseases of the circulatory system under the subcategory of ischemic heart disease. Acute myocardial infarction has an ICD-9-CM code of 410. The fourth digit indicates the location in the heart of the acute myocardial infarction, e.g., anterior, inferoposterior, or subendocardial. If the clinician has not specified where the myocardial infarction occurs, the last category 410.9, myocardial acute unspecified, is used. There are other types of ischemic heart disease. Under 414, we see different types of ischemic heart disease, one of which is coronary atherosclerosis, which itself may occur in the native coronary artery of an individual, or it might happen in a bypass graft, which has come either from a vein or an artery. There are specific codes that go out to the fifth digit.

There are several limitations of ICD-9 that limit its usefulness beyond just providing billing codes so that reimbursement can take place [45]. One of the limitations of ICD-9 is the use of Not Otherwise Specified (NOS) codes. These indicate another category that often can be ambiguous, especially when diseases change over time. For example, decades ago, clinicians spoke of *non-A, non-B hepatitis* when medicine did not know about any of the other types of hepatitis. Now there are hepatitis C, hepatitis D, and others. For a patient who might have been coded from the past as non-A, non-B hepatitis, it would be challenging to perform queries in databases that use the newer, more specific names. Another limitation of ICD-9 is Not Elsewhere Classified (NEC). This indicates that there is no separate specific code other than what is given. For example, even though there are several codes for so-called major depression, there is only one code for non-major depression, 311, Depressive Disorder Not Elsewhere Classified.

There are many other limitations of ICD-9 [45]. For example, using digits in the codes can be problematic when there are more than ten items at a given hierarchy level. Another problem with ICD-9 is that the granularity, the level of detail, is often inadequate. For example, there is only one code for most cancers in each location, e.g., 162.4, malignant neoplasm of middle lobe, bronchus, or lung. Of course, many different types of neoplasms can occur in that area, and ICD-9 does not provide the ability to specify them. In addition, for the most part, ICD-9 is not extensible, so modifiers cannot be added for more detailed location, severity, and it cannot indicate any kind of causal relationships.

International Classification of Diseases (ICD), Version 10

The World Health Organization adopted ICD-10 in 1990. There were significant changes made in the structure from ICD-9, allowing more granularity of codes. After numerous delays over several years, it was finally implemented in the US in October 2015 as ICD-10-CM [46]. Also, inpatient procedure codes were added in the US and called ICD-10-PCS, although CPT-4 is still used for outpatient procedures.

There are major differences between ICD-9-CM and ICD-10-CM. The total number of codes in ICD-10-CM is tripled from ICD-9-CM. In addition, the codes themselves can extend out to seven characters compared to five for ICD-9-CM. In ICD-9-CM, that first character is a number, or the specific V or G, or E codes. In ICD-10-CM, the first character is a letter, so any letter. The second character is a number, and then the remaining characters can be letters or numbers.

For both systems, the first three characters in the code give the category. In ICD-9-CM, the following two characters in the code provide more detail about the etiology, anatomical site, or other clinical detail. That is extended to three characters in ICD-10-CM. There is also a seventh character in ICD-10-CM called an extension, and it allows the code to be extended in various ways. The most common way to extend the code is to talk about the visit to the health care system, whether it is the initial encounter, a subsequent encounter, or sequelae from one of them. But there are other extensions as well.

The major difference between ICD-9-CM and ICD-10-CM is the increased granularity on a massive scale. In contrast, many ICD-9-CM codes represent perhaps a single disease or a single condition; ICD-10 adds many modifiers and, as such, has much higher granularity. An example of this is seen with the difference between the single ICD-9 code, 995.29 Unspecified adverse effect of other drug, medicinal and biological substance and the following sample of codes related to adverse drug events:

- T360X5A Adverse effect of penicillins, initial encounter
- T361X5A Adverse effect of cephalosporins and other beta-lactam antibiotics, initial encounter
- T362X5A Adverse effect of chloramphenicol group, initial encounter
- T363X5A Adverse effect of macrolides, initial encounter
- T364X5A Adverse effect of tetracyclines, initial encounter
- T365X5A Adverse effect of aminoglycosides, initial encounter
- T366X5A Adverse effect of rifampicins, initial encounter
- T367X5A Adverse effect of antifungal antibiotics, systemically used, initial encounter
- T368X5A Adverse effect of other systemic antibiotics, initial encounter
- Plus 170 additional codes

ICD-10-PCS increases the number of procedure codes massively. ICD-9 had relatively moderate numbers of procedure codes, but now ICD-10-PCS increases that substantially and has a seven-character structure representing the aspects of procedures listed here, the specialty of the body system, the root operation, body part, and body part approach, device, and qualifier.

Granularity is an issue for ICD-10-PCS as well. A single ICD-9 code for pericardiectomy, removing the pericardium, the membrane surrounding the heart, has many codes in ICD-10-PCS, with different operative approaches and different operative techniques reflected in various codes. Many commentators have had fun poking at the excess granularity of ICD-10-CM, whether it reaches a point of absurdity, particularly those critical of healthcare bureaucracy [47]. An example is how a falling object might strike one on board a watercraft. ICD-10-CM goes to the level of detail of what type of watercraft, e.g.,

- V93.40—Merchant ship
- V93.41—Passenger ship
- V93.42—Fishing boat
- V93.43—Powered watercraft
- V93.44—Sailboat
- V93.48—Unpowered watercraft
- V93.49—Unspecified

About half of ICD-10-CM codes are related to the musculoskeletal system, particularly injuries. This is not surprising, given the combinatorial explosion that occurs from all the different possible injuries in all the other anatomical sites involving all the various anatomical parts of the human body. A quarter of all codes are related to fractures due to that combinatorial explosion. About a third of codes distinguish laterality, left versus right. Therefore, most impacted by ICD-10 are the medical specialties, or areas, of orthopedics, obstetrics and gynecology, and behavioral health. Primary care has a medium level of impact, with the other medical specialties having a low level of impact.

There have been several informatics concerns about ICD-10-CM. One of these is the excess granularity described above. Many advocated that ICD-10 never be adopted, that it just be skipped, and the US move from ICD-9-CM directly to ICD-11 [48]. Part of the reason for that is that ICD-11 will be built on a compositional terminology, SNOMED, described below [49].

Diagnosis Related Groups (DRGs)

Another terminology standard for diseases is the **Diagnosis Related Groups (DRGs)**. DRGs were initially developed to aggregate ICD-9 codes into groups that could be used for health services research to look at hospital costs. The DRG system consists of several hundred codes that lump hospital illnesses roughly comparable in the resources they should be using. However, not true to its original intention, DRGs were adopted by the predecessor of CMS, the Health Care Financing Authority (HCFA), to be used for the Prospective Payment System for hospitalization under Medicare starting in the 1980s. Since then, all hospitalizations have been classified by their DRG, which influences the reimbursement hospitals to receive for the hospitalization.

Here are some examples of DRGs for respiratory diseases:

- Respiratory disease w/ major chest operating room procedure, no major complication or comorbidity 75
- Respiratory disease w/ major chest operating room procedure, minor complication or comorbidity 76
- Respiratory disease w/ other respiratory system operating procedure, no complication or comorbidity 77
- Respiratory infection w/ minor complication, age greater than 17 79
- Respiratory infection w/ no minor complication, age greater than 17 80
- Simple Pneumonia w/ minor complication, age greater than 17 89
- Simple Pneumonia w/ no minor complication, age greater than 17 90
- Respiratory disease w/ ventilator support 475
- Respiratory disease w/ major chest operating room procedure and major complication or comorbidity 538
- Respiratory disease, other respiratory system operating procedure and major complication 539

These DRG codes tend to categorize multiple diseases in the same general body area and require the same resources. The definitions of these DRGs are laid out in quite explicit detail, and they define how much reimbursement the hospital gets for the patient hospitalized with this condition. The DRG system has been a transition to ICD-10-CM [50].

Drug Terminology

Several different code sets around drug terminology are interrelated, but it is sometimes confusing as to their roles. The US government mostly leads these different code sets. There is a collaboration among various federal agencies called FedMed, where there has been an agreed set of standards, comprehensive, and freely accessible federal medication terminologies. Included in FedMed are the **National Drug Codes (NDC)**, the Unique Ingredient Identifier (UNII), the VA National Drug File Reference Terminology (NDF-RT), the NCI Thesaurus Structured Product Labeling (NCIt SPL), and RxNorm and RxTerms from the National Library of Medicine.

The NDC is a packaging standard. There is an 11-digit code maintained by the US Food and Drug Administration for every pharmaceutical preparation.[23] The first five digits representing the manufacturer, the following four digits represent the product name, strength, and dose forms; and the final two digits are the code for packaging, such as the number of tablets in the bottle. One of the significant challenges of NDC is that those middle four digits about product name, strength, and dose vary from different manufacturers. Thus, the same drug from a different manufacturer will have a different middle four digits. This problem is overcome because the NDC codes map into the other terminology systems. Still, many data aggregations contain NDC codes, making it challenging to perform queries and analyze that data.

[23] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Other drug terminology standards are part of FedMed. The UNII specifies the ingredients in drugs and other compounds, both active and inert substances. The NDF-RT maintains much detail about drugs' mechanism of action, physiologic effect, and structural class.[24] The NCIt SPL maintains pharmaceutical dosage form, route of administration, and potency.

RxNorm brings all of these drug terminologies together and is meant to be the semantic structure for all formulations and their components of drugs.[25] Within RxNorm is RxTerms, which provides an interface terminology to RxNorm so that the name of drugs can be linked to the more specific details about them {Fung, 2008 #5619}. In FedMed, RxNorm and RxTerms are the standards into which other drug terminologies must map. There are tools related to RxNorm. One is RxNav, which provides an API for term lookup.[26] Finally, RxMix allows applications to be built from different APIs around RxNorm, RxTerms, and RxImageAccess.[27]

Logical Observation Identifiers Names and Codes (LOINC)

The **Logical Observation Identifiers Names and Codes (LOINC)** standard started for laboratory tests and names but extended into other measures and languages beyond English [51, 52]. LOINC consists of observations, and each observation has several attributes, the main one being the component, or analyte, which is the substance or entity being measured or observed. These components may have properties such as mass concentration, numeric fraction. They have a time that they were observed. A specimen usually comes from a system in the body, such as blood or cerebral spinal fluid. There is a scale by which the observation is measured. It may be qualitative, quantitative, ordinal, or nominal. There may be a method associated with the observation, which is used to make that observation. Also in the distribution of LOINC is the Regenstrief LOINC Mapping Assistant (RELMA),[28] a Windows program that allows searching the LOINC database and helps one map their local codes to LOINC codes. LOINC codes themselves do not contain the reason for the test, details about specimen or testing machine, test interpretation, who or where the test was performed, or anything else not part of naming the test.

Below are several examples of LOINC codes:

- Blood glucose GLUCOSE:MCNC:PT:BLD:QN:
- Serum glucose GLUCOSE:MCNC:PT:SER:QN:
- Urine glucose concentration GLUCOSE:MCNC:PT:UR:QN:
- Urine glucose by dip stick GLUCOSE:MCNC:PT:UR:SQ:TEST STRIP
- Ionized whole blood calcium CALCIUM.FREE:SCNC:PT:BLD:QN:
- 24 hour calcium excretion CALCIUM.TOTAL:MRAT:24H:UR:QN:
- Automated hematocrit HEMATOCRIT:NFR:PT:BLD:QN:AUTOMATED COUNT
- Manual spun hematocrit HEMATOCRIT:NFR:PT:BLD:QN:SPUN
- Erythrocyte MCV ERYTHROCYTE MEAN CORPUSCULAR VOLUME:ENTVOL:PT:RBC:QN:AUTOMATED COUNT
- ESR by Westergren method ERYTHROCYTE SEDIMENTATION RATE:VEL:PT:BLD:QN:WESTERGREN

LOINC has codes for individual observations as well as collections. Examples of individual observations include:

- 6690-2 Leukocytes [#/volume] in Blood by Automated
- 2339-0 Glucose [Mass/volume] in Blood
- 29463-7 Body weight
- 55423-8 Number of steps in unspecified time Pedometer
- 57021-8 CBC W Auto Differential panel – Blood

Collections can include panels and documents, such as:

- 34565-2 Vital signs, weight and height panel
- 44249-1 PHQ-9 quick depression assessment panel
- 36813-4 CT Abdomen and Pelvis W contrast IV
- 18842-5 Discharge summary

LOINC is also compatible with other standards, such as:

- HL7 V2 – OBX||NM|26453-1^RBC # Bld^LN||4.82|10*6/uL|
- Embedded SNOMED code – OBX||CE|625-4^Bacteria Stl Cult^LN||5933001^Clostridium difficile (organism)^SCT|
- Retrieval via FHIR API[29]

[24] https://www.oit.va.gov/Services/TRM/StandardPage.aspx?tid=5221

[25] https://www.nlm.nih.gov/research/umls/rxnorm/

[26] https://rxnav.nlm.nih.gov/

[27] https://mor.nlm.nih.gov/RxMix/

[28] https://loinc.org/relma/

[29] https://fhir.loinc.org/CodeSystem/$lookup?system=http://loinc.org&code=4544-3

Current Procedural Terminology (CPT-4)

Another important terminology to physicians is **Current Procedural Terminology (CPT-4)**, copyrighted and maintained by the American Medical Association. This is a classification of the procedures that physicians perform. Usually, in addition to an ICD-9 code, there must be a CPT-4 code reported so that the government or private insurance company can reimburse the physician. There are also certain CPT codes called evaluation and management (E&M) codes, which document the intensity of clinical encounters such as office visits.

CPT-4 is part of a more extensive procedure coding system, the HCFA Common Procedure Coding System (HCPCS). HCPCS provides different levels of procedure coding. The first level contains CPT-4 codes. Then the second level includes other codes for items and supplies and non-physician services. There used to be a third level, allowing organizations to create their local codes, which were abolished under the HIPAA standards rules in 2003.

Systematized Nomenclature of Medicine (SNOMED)

The **Systematized Nomenclature of Medicine (SNOMED)**[30] is a controlled terminology that covers medicine and health care. It is more formally known as SNOMED Clinical Terms (SNOMED CT). SNOMED was initially developed by the College of American Pathologists (CAP), who created the Systematized Nomenclature of Pathology (SNOP). In the 1980s, SNOP was extended to cover all of medicine and was renamed SNOMED. The SNOMED CT moniker comes because the original SNOMED merged with another terminology system developed in England called the Clinical Terms Project. These two joined into a single system in 2000 to become SNOMED CT [53].

In 2007, the ownership of SNOMED was transferred to an international standards body, the International Health Terminology Standards Development Organization (IHTSDO). This standards body now maintains SNOMED CT and continues developing and expanding it and translating it into other languages. SNOMED CT is currently available in US English, UK English, Spanish, Danish, and Swedish, and it is being translated into additional languages.

One of the original limitations of SNOMED CT was a license that restricted its usage. In 2003, the former owner of SNOMED, the CAP, negotiated with the NLM to create a 5-year license for all United States. The license has now been transferred to IHTSDO and continues to be available. The license allows SNOMED to be used in the US by all public and private entities for health care, public health, research, educational, or statistical use. Many other countries have licensed SNOMED CT for countrywide usage. This allows SNOMED CT to encode patient-level data sets and redistribute them to others if large vocabulary portions are not extracted and transferred.

One of the critical features of SNOMED is the use of what is called a *multiaxial* or *compositional* approach. This means that compound terms can be combined from smaller terms, such as lung inflammation, without requiring a term for inflammation in everybody's location. In addition, there can be modifiers added to terms, such as *severe* or *worsening*. SNOMED CT contains more than 300,000 concepts, more than one million descriptions or terms that express those concepts, and more than one million relationships between those concepts. SNOMED also recognizes that, when using terminology, especially interface terminology, we do not necessarily want to construct complex terms from simpler ones, so there are many *pre-coordinated* concepts with a clinically meaningful term that is a combination of more basic terms.

Nursing Terminologies

Nursing vocabularies are also designed to capture nursing observations, diagnoses, interventions, and patient outcomes. There are several different vocabularies, and they suffer from the same problems seen in vocabularies in general. The vocabularies are based on irreconcilable information models that are not easily combined. In addition, the terms in the vocabulary are not always expressed in how clinicians express them, so there can be challenges in mapping observations made by clinicians into the terms of the vocabulary. The vocabularies can also be very tedious to use in patient documentation. And these lead to a question of whether the data that has been captured then can be transferred across settings. A recent report from ONC highlighted the nursing terminologies landscape [54]. There have been recent efforts in the nursing informatics community to reconcile these various terminologies [55, 56].

Unified Medical Language System (UMLS)

As far back as the 1980s, it was recognized that there were many different vocabulary systems, and to achieve the full value of computerized data, there was a need to reconcile these. This led to the development of the **Unified Medical Language System (UMLS) Project**,[31] which was launched

[30] https://www.snomed.org/

[31] https://www.nlm.nih.gov/research/umls/

by the NLM in the late 1980s and attempted to reconcile these vocabularies [57, 58]. There are three components of the UMLS:

- Metathesaurus—the thesaurus based on all the component vocabularies of the UMLS, described in more detail below
- Semantic Network—maps generic relationships between the semantic types of the concepts that are in the Metathesaurus, such as diseases and treatments
- Specialist Lexicon—a collection of words and terms mainly designed to assist in natural language processing applications

According to its documentation on the UMLS Web site, the Metathesaurus is a "*database of information on concepts that appear in one or more of the number of different controlled vocabularies and classifications used in biomedicine*." It is designated a "Metathesaurus" to identify equivalent terms across terminologies or vocabularies and link them.

In the Metathesaurus, all terms that are conceptually the same are linked together as a concept. Each concept may have one or more terms, representing an expression of the concept from a source terminology that is not just a simple lexical variant (i.e., differs only in word ending or order). Each term may consist of one or more strings representing all the lexical variants represented for that term in the source terminologies. One of each term's strings is designated as the preferred form, and the preferred string of the preferred term is known as the canonical form of the concept.

Each Metathesaurus concept has a single concept unique identifier (CUI). Each term has one term unique identifier (LUI), all of which are linked to the one (or more) CUIs with which they are associated. Likewise, each string has one string unique identifier (SUI), which similarly are linked to the LUIs in which they occur. In addition, each string has an atomic unique identifier (AUI) that represents information from each instance of the string in each vocabulary. Figure 13.1 depicts the English-language concepts, terms, and strings for the Metathesaurus concept *of atrial fibrillation*. Each string may occur in more than one vocabulary, in which case each would be an atom.) The canonical form of the concept and one of its terms is atrial fibrillation. Within both terms are several strings, which vary in word order and case.

There are several limitations to the Metathesaurus, which is one reason why its use has been modest. The Metathesaurus only maps one-to-one relationships. There may be a term in one vocabulary that might map to multiple terms in another vocabulary. Still, the Metathesaurus does not map those many to one or one to many relationships. It only maps one into one relationship. Another limitation of the Metathesaurus is that the only terms in it come from the source vocabularies. There may be other ways to express a term, but if that expression of the term is not in one of the source vocabularies, it will not be in the Metathesaurus. Another limitation of the Metathesaurus is that there is no unifying hierarchy. It contains descriptions of all the hierarchies of the source vocabularies, but there is no unified hierarchy for the entire Metathesaurus. And finally, it is not extensible like SNOMED, in that terms are individual and atomic, and they cannot be combined or modified. For all these reasons, the Metathesaurus has relatively modest use. Its value has been more as a repository for vocabularies where system developers who use different vocabularies can go and find information about terms in those terms' vocabularies and perhaps expand their systems by taking advantage of the linkages to other vocabularies.

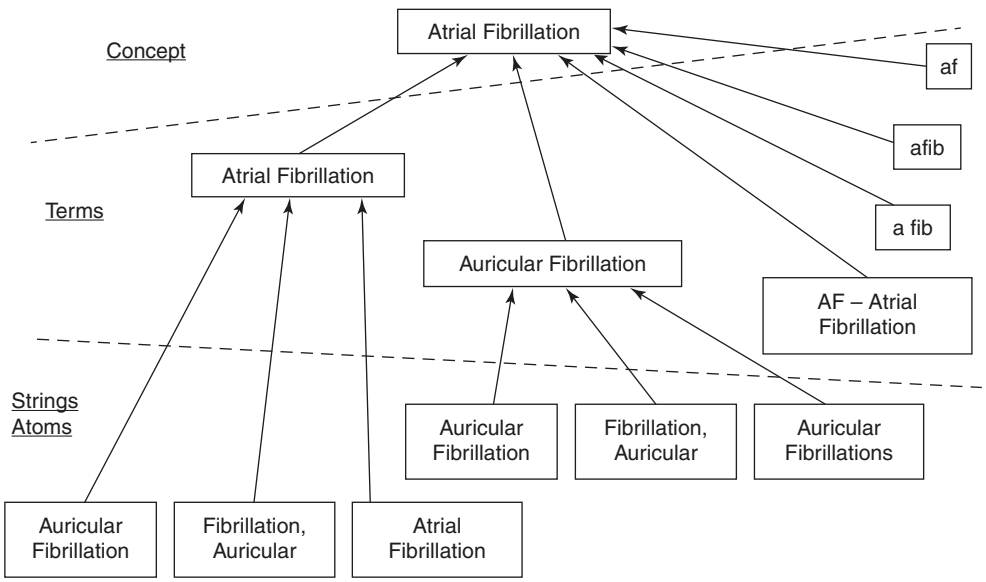

Fig. 13.1 UMLS Metathesaurus structure for atrial fibrillation

Other Terminologies and Activities

There are several other healthcare vocabularies with specific uses:

- Common Dental Terminology (CDT)—the equivalent of CPT for dental procedures
- Medical Subject Headings (MeSH)—used to index biomedical literature for retrieval
- Universal Medical Device Nomenclature (UMD)—describes medical devices
- Diagnostic and Statistical Manual of Mental Disorders (DSM)—catalogs psychiatric and psychological conditions
- International Classification of Functioning, Disability, and Health (ICF)
- International Classification of Primary Care (ICPC)
- Unified Codes for Units of Measure (UCUM)

Another terminology activity is the designation of common data elements (CDEs)[32] for research studies. These have been developed by the US National Institutes of Health and aim to standardize reporting in different research studies. Examples include:

- Patient Reported Outcome Measurement System (PROMIS)[33]
- National Institute of Neurological Disorders and Stroke Common Data Elements Project[34]
- Rare Diseases Registry Program (RaDaR)[35]
- Consensus Measures for Phenotypes and Exposures (PhenX)[36]

There are also many commercial efforts in aspects of terminology. One comes from the company Intelligent Medical Objects (IMO),[37] which provides various terminology services such as mapping free text to control terms of keeping terminologies systems like ICD-10 and SNOMED up to date and providing means to access that terminology. Another commercial effort is Medcin (Medicomp),[38] a terminology system focused on documentation at the point of care using an EHR. Finally, 3M has developed HDD Access,[39] which has been moved to an open-source model.

The overall goal for standardized clinical terminology is semantic interoperability, i.e., a "computer utterance" in one information system has the same effect as in any other [59].

Semantic interoperability must function for the two broad types of healthcare data, discrete data elements, and narrative documents. The emerging three major clinical terminology systems in healthcare are LOINC, SNOMED, and RxNorm [60]. Some have noted that LOINC contains the question, and SNOMED CT provides the answer.

SMART on FHIR

As noted above, the rapid adoption of EHRs in the United States resulted in incomplete interoperability. The 21st Century Cures Act mandated better interoperability among EHR systems. At the same time, the HL7 Version 2 standard was showing its age, while HL7 Version 3 was providing too complex for widespread adoption. This led to the emergence of the **Fast Healthcare Interoperability Resources (FHIR)**[40] messaging standard. When paired with the **Substitutable Medical Apps, reusable technologies (SMART)**[41] application programming interface (API), the emerging SMART on FHIR standard[42] provided a modern framework for interoperability. The so-called Cures Rule has also led to the US Core Data for Interoperability (USCDI)[43] that mandates what EHR data must be standardized and available through SMART on FHIR interfaces.

FHIR is a messaging standard that aims to facilitate interoperability among health IT systems. HL7 is the Standards Development Organization for FHIR. FHIR is different from the existing HL7 messaging standards. It adds more semantics, so more semantic interoperability than HL7 Version 2. It does not have the complexity of a HL7 Version 3. The most recent release of FHIR is Release 4, the first version to provide normative content, meaning that some of the APIs are standardized and will not change.

It is essential to recognize what FHIR is not. FHIR is not a terminology standard, though it can use standardized terminologies such as SNOMED and LOINC. FHIR is not a security standard, although it can be used with modern security standards such as OAuth2. In addition, FHIR is not a user interface standard. It is just a standard to message data between health IT systems.

[32] https://cde.nlm.nih.gov/home

[33] https://www.healthmeasures.net/explore-measurement-systems/promis

[34] https://www.commondataelements.ninds.nih.gov/

[35] https://rarediseases.info.nih.gov/radar

[36] https://www.phenx.org/

[37] https://www.imohealth.com/

[38] https://medicomp.com/medcin/

[39] https://www.hddaccess.com/

[40] https://www.hl7.org/fhir/

[41] https://smarthealthit.org/

[42] https://docs.smarthealthit.org/

[43] https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

A key component of FHIR is its Resources, which comprise the content of its messages. There are six types of resources[44]:

- Clinical—content of the clinical record
- Identification—supporting entities involved in the care process
- Workflow—managing the healthcare process
- Financial—supporting billing and payment parts of FHIR
- Conformance—manage specification, development, and testing of FHIR profiles
- Infrastructure—general functionality and internal FHIR requirements

FHIR came about amidst criticism that today's EHRs are large, monolithic systems and not platforms on top of other applications and innovations. Mandl and Kohane called these monolithic systems "traps" and argued the need to move beyond them [61]. This led them to develop the SMART platform, based on the idea that there should be an underlying platform upon which "apps" can build that access a common store of data and functions [62, 63]. This builds on an analogy of smartphones with many underlying functions, such as a global positioning system (GPS) that different apps can access. SMART apps may be mobile apps or Web-based. The platform also uses a security standard called OAuth2.

SMART had been around since 2010 but achieved much more prominence when paired with FHIR [64]. It has been implemented for EHRs and extended to areas like genomics [65] and precision medicine [66, 67]. Major vendors, such as Epic, have started to support it [68]. The monograph by Hay demonstrates a real-world clinical case that maps into FHIR [69].

FHIR has additional features that add to its clinical utility [4, 70]. *Bundles* are groups of interacting Resources that can represent a more complex clinical situation. Semantic interoperability can be achieved via standardized terminologies, as there is an explicit mechanism for using standard code systems, such as SNOMED CT or LOINC. Value sets provide for specific uses of codes in a given clinical context.

FHIR Resources are somewhat generic, and FHIR has *Profiles* used to constrain Resources for specific contexts. For example, different countries have different specifications for the designation of gender. Profiles can also be used to add extensions to the base FHIR Resources. *Conformance* is the set of rules that specify adherence for Profiles.

[44] http://www.hl7.org/fhir/resourcelist.html

Emerging Trends

Now that the use of EHRs is widespread, the need for data standards and interoperability is clear. The 21st Century Cures Rule should ensure steady movement toward that goal. Significant developments include the designation of US Core Data for Interoperability (USCDI), APIs to access USCDI, and the SMART Application Launch Framework using OAuth2 and OpenID. Of course, there will also be a need for standardizing other types of data coming forward in the future, such as data concerning social determinants of health (SDOH) [71]. All of these data sources will enhance the ability of consumers and patients to manage their health and allow healthcare organizations to improve the delivery of care and enhance research. Clinical informatics professionals will likely be working with these standards as they implement interoperability across the EHR and other information systems under their purview.

Summary

This chapter looked at different standards for identifiers, transactions, message exchange, and terminology. The ultimate goal of all these standards is to move towards semantic interoperability, described as a computer utterance in one information system having the same effect as any other [59]. Whether a diagnosis or a clinical finding leads to data aggregation or clinical decision support, the computer utterance should have the same effect in any computer system.

Questions for Discussion

1. What are the benefits and drawbacks of a national health identifier? Should the United States have one?
2. Where will SMART on FHIR likely achieve the most success as a platform (if it will at all)?
3. Some advocate that healthcare move from vendor-centric EHRs where patient data is stored in the institution's system where care is obtained to an approach of each patient having a cloud-based, personally-controlled data store of their entire medical record. Do you agree that this vision should be pursued? If so, what concerns must be addressed?

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Health Information Exchange and Interoperability

14

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Learning Objectives

- Define the informatics concepts of interoperability and health information exchange.
- Review policies and activities that promote the adoption and use of health information exchange.
- List and describe at least two common scenarios in which interoperability and health information exchange could facilitate improvements to patients and population health.
- List and describe at least three challenges to interoperability and health information exchange.
- Describe methods for linking patient records across various health information systems.
- Discuss emerging technologies likely to impact the adoption and use of health information exchange during the next decade.

Practice Domains: Tasks, Knowledge, and Skills

- **K018**. Technical and non-technical approaches and barriers to interoperability
- **K061**. Methods of communication between various software components
- **K062**. Network communications infrastructure and protocols between information systems (e.g. Transmission Control Protocol/Internet Protocol, switches, routers)
- **K079**. Health information exchanges
- **K080**. Patient matching strategies
- **K081**. Master patient index
- **K082**. Data reconciliation
- **K111**. Methods and standards for data sharing across systems (e.g. health information exchanges, public health reporting)

Case Vignette

A 32-year old male sustains a traumatic brain injury (TBI) along with several lacerations and minor abrasions during a scooter accident. He is treated at an emergency department and admitted overnight for observation. His TBI is determined to be mild to moderate in severity. The next day he is discharged from the acute care hospital to an inpatient rehabilitation hospital. After a few days, he is discharged from the rehab hospital to home. Upon discharge, he is directed to follow up with his primary care provider. His spouse calls the primary care doctor and makes an appointment for 2 weeks later.

At check-in to the primary care clinic, the office staff asked the patient for documentation from his accident. He can provide a folder that contains the discharge instructions and patient education materials given to him at discharge from the rehab hospital. The medical assistant scans the materials into the clinic's electronic medical record system. When the provider logs into the EMR, she can access the scanned PDF document. However, the information in the document is not sufficient to provide her with all the infor-

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mation she needs on his care in the emergency department and the two hospitals.

The doctor talks with the patient and tries to get as much detail as possible about his course of treatment in the emergency department and hospital. Unfortunately, the patient is only able to recall a few details from his experience in the hospital. His spouse can provide some additional information, but the doctor desires more details about his previous encounters. She, therefore, asks her nurse to gather discharge summaries and other details from the hospitals where the patient was treated. She then tells the patient to come back in a couple of weeks after she's had time to access the records.

On the following day, the primary care nurse calls the other hospitals to request the information. The acute care hospital is familiar with the doctor for whom the nurse works. Therefore, the hospital faxes over the records from the emergency department and the overnight stay within a few hours. However, the rehab hospital has never heard of the primary care doctor. That facility faxes a form to the nurse to be completed by the clinic to officially request a release of records for the patient. The faxes were received at the end of the day, which happens to be Friday. So, the nurse completes the form the following week when she is back in the office. She faxes the form to the rehab hospital and waits. After a few days, she calls the rehab hospital to follow up on the request form. After locating the form, the rehab hospital staff tells her that they will send over the records within a few days. Luckily, the rehab hospital faxes the documentation on the patient's stay the day before his follow-up appointment. The nurse scans all of the records from both hospitals into the EHR as a PDF. The doctor can review all of the documentation by scrolling through the PDF.

This is the state of care coordination within the US healthcare system in 2021. Even though most hospitals and clinics have adopted EHR systems, most records are exchanged for fax machines. This fun fact about the US healthcare system was highlighted as one of the many problems that hampered efforts to control the COVID-19 pandemic [1]. Why could the doctor not access the discharge summaries through her EHR system? And how come records need to be printed from a fax machine only to be scanned into the EHR? What would be a better way to organize electronic health data and information to be electronically shared between the emergency department, acute care hospital, rehab hospital, and primary care clinic? These are the questions that we will address in this chapter.

Introduction

As the case vignette highlights, sharing clinical information is challenging and messy. Electronic health records have dramatically changed how healthcare is delivered. Providers can enter data and information into EHR systems, and they can access the information they enter later. They can even access information entered by their colleagues, but usually, only colleagues in their clinic, hospital, or network. It remains challenging for most providers to access data and information electronically for out-of-network facilities, such as competing hospitals or ancillary services provided in the community. Just because one hospital can access data electronically from another hospital does not mean that all hospitals in that area can share data electronically. Moreover, just because hospitals in one part of the country can access information electronically from other hospitals and clinics does not mean that this functionality exists across the nation.

The goal of interoperability and health information exchange (HIE) is to enable the electronic sharing of health data and information among all organizations that have a relationship with the patient. Primary users of these data will be doctors who care for the patient. Others who need access might include health insurance companies who pay for the care, pharmacists who fill prescriptions ordered by the physicians, and public health agencies that monitor the health of the communities in which the patient lives, works, and plays.

In this chapter, we will explore the concepts of interoperability and HIE. Many methods, standards, and systems enable interoperability and HIE, some of which are more than 20 years old. However, interoperability and HIE are not yet ubiquitous across the US health system. One of the perennial challenges in clinical informatics is to enable interoperability and HIE among the landscape of clinical information systems managed by healthcare systems. The chapter will explore the facilitators and barriers to interoperability and HIE. The chapter will further discuss emerging trends in these areas.

Interoperability and Health Information Exchange

Interoperability refers to "the ability of two or more [EHR] systems or [health information technology] components to exchange information and to use the information that has been exchanged" [2]. *Health information exchange (HIE)* refers to the electronic sharing of health data or information between two or more organizations (e.g., hospitals, physician practices, laboratories, pharmacies, nursing homes) using nationally recognized standards (see Chap. 13).

While extremely related and often used interchangeably, interoperability and HIE denote different aspects of electronic data sharing between health organizations. Table 14.1 outlines the differences between these terms. The term HIE has a broader meaning than interoperability, a more technical term used to describe the ability of two computing systems to exchange data or information. For example, electronically

Table 14.1 Important, yet sometimes subtle, differences between the terms interoperability and HIE (health information exchange)

	Explanation	Examples
Health information exchange	The act of sharing data or information about a patient (or population) electronically between two health organizations. Can also refer to an organization or technical system that facilitates data sharing (e.g., HIE network)	Hospital A electronically delivered a discharge summary to Dr. Smith using the community HIE network following an emergency department visit Hospital A used HIE to retrieve a patient's prior radiology images from Hospital B
Interoperability	A technical capability of two or more health information systems that allows information to be exchanged electronically and the information used by the receiving system	The EHR system at Hospital A is interoperable with the EHR system at Hospital B if laboratory results from both hospitals are usable (e.g., displayed, trended) by physicians at each hospital no matter which EHR system is used to access the results

sending medical records as a PDF from a specialist to a primary care provider using the Direct network would be considered HIE. Yet, it would never be considered a form of interoperability because the primary care EHR system could not do anything meaningful with the received PDF document.

Interoperability and HIE in Medicine

Whereas informaticians concern themselves with the technical details for how data are exchanged and the standards that enable interoperability, most physicians and other end users in medicine only concern themselves with how HIE networks are used. There exist a variety of scenarios in medicine where HIE is used. The most common scenario involves the emergency department (ED). When a patient arrives at the ED for an acute illness or injury, a physician working in an ED connected to an HIE network can access the patient's past medical history. This may be useful when the patient is unconscious or simply cannot recall the details of a prior hospitalization or recount all of the medications he or she is currently taking. These details may be important to the diagnosis or treatment of the individual.

There are, generally speaking, three uses of HIE by most physicians and other health care providers:

1. **Query/Find Information**. In this scenario, an end-user accesses the HIE network to look up or query information about a patient. This is the scenario often described in the ED. Various providers might use a query function to look up different information—medications, recent imaging procedures, etc. However, the general use case involves human querying for information the same way a medical student searches PubMed.
2. **Send Information**. In this scenario, an end-user actively transmits (aka pushes) information to another user or information system. For example, once the patient is discharged from the ED, a discharge summary document created by the attending physician might be electronically sent to the patient's primary care provider. Alternatively, the discharge summary might be sent to the patient's personal health record application on his or her smartphone.
3. **Receive Information**. In this scenario, an end-user or information system receives a document or data from another user or information system. This scenario is the reverse of the "Send" scenario. For example, following a visit to a specialist (e.g., cardiologist), the patient's primary care provider might receive a detailed summary of the notes from the specialist. In this scenario, the cardiologist might not have actively pushed a button to send the information. Instead, the primary care provider simply received the summary document sent by the cardiology EHR system. Similarly, a hospitalist might receive an electronic document from a smaller hospital that transfers patients for advanced, or more complex, care.

Providers might engage in one or more of these general HIE use cases. For example, a hospital might regularly send documents to their affiliated primary care providers and receive information from affiliated skilled nursing facilities (SNFs) for patients who receive emergency care. Hospitals can participate in all three general HIE use cases depending on the HIE networks they utilize. Some providers might only participate in one kind of HIE use case. All of this will depend on the available HIE services. Think of this like subscribing to an Internet streaming service or cable company to access shows or movies. Some consumers will subscribe to two different content streaming services A and B, others will subscribe to the local cable company plus content streaming service A, and other customers will only subscribe to the cable company. Specifics on which shows or content are available on which platform will vary and evolve. A consumer will likely need to subscribe to multiple services to access everything they want to watch (or make everyone in the household happy).

Interoperability and HIE for Population Health

Beyond care delivery and processes for patients, interoperability and HIE are critical to population health. Increasingly health systems desire to track populations—either identify populations at risk or in need of services or measure out-

comes for a population impacted by a service or program. Moreover, public health organizations seek to leverage HIE and interoperability to gather data from a variety of sources on populations to better identify disease outbreaks or measure disease burden over time [3].

A registry is an organized system that uses observational study methods to collect uniform data to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, serving one or more predetermined scientific, clinical, or policy purposes [4]. It is common for medical societies and patient advocacy groups to develop clinical disease registries, such as the preeclampsia registry (https://www.preeclampsiaregistry.org/) and the American College of Surgeons Trauma Quality Improvement Program (https://www.facs.org/quality-programs/trauma/tqp/center-programs/tqip). Public health agencies also maintain registries, including immunization registries [5, 6], which became critical informatics resources during the COVID-19 pandemic, and cancer registries [7–9].

Based on criteria outlined in the Meaningful Use and Promoting Interoperability regulations, providers are encouraged to use health information systems to support the development of specialized disease registries. For example, many health systems have developed diabetes registries to monitor patients with diabetes and ensure they receive guideline-based care such as annual foot and eye exams. Both HIE and interoperability are tools that can support exchanging data with clinical and public health registries.

Health Information Exchange Networks

At this point, it should be clear that HIE and interoperability refer to the electronic movement of health information. At the highest level, such movement can only occur when both governance and technology are in place. Governance specifies the "rules of the road"—who is sharing data, what is being shared, what technical protocols are used for varied aspects of data sharing, etc. The technology is the infrastructure that enacts the governance and allows data to be shared electronically across disparate information systems. We typically refer to the entity leading the governance and implementing the associated technology as an HIE network (usually referred to as just an HIE). There are many types of HIE networks (HIEs) in practice, and the varieties have expanded over time.

A Brief History of HIE Networks

HIEs have been around for more than 25 years. In the 1990s, the John A. Hartford Foundation began a Community Health Management Information System (CHMIS) initiative to improve access to data in support of cost and quality improvement [10]. The idea was to support integrated delivery networks' access to information by engaging health care stakeholders (the network members) to electronically exchange transactions that would feed central data repositories. Large investments were made in several states to form what became known as CHINs (Community Health Information Networks) and, slightly later, Local Health Information Infrastructure (LHII). Whereas the CHINs focused on supporting the exchange of data to meet the needs of IDNs facilitating managed care, LHIIs focused on clinician-driven, community-wide initiatives focused in scope. For example, providers in the Indianapolis area desired to share information among emergency departments to support transitions of care [11]. In addition, LHIIs focused on first developing stakeholder engagement rather than jumping directly into discussions around the technical architecture design. Emphasis was placed on building trust and establishing a strong, shared vision for what services the LHII would provide and for whom they would be provided. Although arguably more successful than the CHINs, many LHIIs also failed to become fully operational or sustain operations [12].

Yet LHII failures and successes proved to be excellent lessons for the next generation of HIEs—the Regional Health Information Organizations (RHIOs). Whereas the LHIIs emphasized "local" by engaging stakeholders in a city or county, RHIOs aimed to become regional HIE authorities. The idea was that HIE might not be sustainable on a small scale but would be sustainable with economies of scale across an entire state or group of states. Several RHIOs were funded through grants by the Agency for Healthcare Research and Quality [13–15]. Using the funding, the RHIOs aimed to become operational and develop the business case for HIE [16]. Surveys from the late 2000s by the eHealth Initiative found that over 100 communities reported they were in various stages of developing a RHIO [17, 18]. Yet, like many LHIIs, many RHIOs failed for similar reasons as their antecedents [19, 20]. As many as 25% of efforts identified in the previous year's survey no longer existed when community efforts were surveyed the following year.

The passage of the HITECH Act ushered in the current era of HIEs. Funding to create statewide HIE efforts, particularly under the State HIE Cooperative Agreement Program, pushed the industry to drop the "R" from RHIO. HIOs—both new and expanded versions of existing RHIOs—began to diversify concerning form (e.g., centralized data repository), technology platform (e.g., push, pull), and governance. While some focused on supporting IDNs, others focused on creating *networks of networks* in which HIE could be performed by a wider array of local, regional and national level stakeholders. National level HIE efforts emerged, including the eHealth Exchange [21] that seeks to connect state and regional HIE initiatives with federal government agencies as well as national data networks that focus on specific types of

exchange, such as the SureScripts, LLC ePrescribing network.

HIE Networks Today

Despite diversification, there is a common understanding of five types of HIE networks today: Private HIE, State government-facilitated HIE, Community-based HIE, Vendor-facilitated HIE, and National Networks/Frameworks.

Private HIE

While there still exist many "independent" hospitals and physician practices (e.g., management of the hospital or practice is solely performed by the physicians or CEO), many hospitals, physician practices, nursing homes and even public health clinics operate as part of a larger corporation, referred to often as a health system. These systems can also be referred to by other names, including integrated delivery networks (IDNs) or accountable care organizations (ACOs). Because these health systems are composed of 2 or more hospitals, physician practices, or other care facilities, they need to exchange data and information among the network or group of affiliate organizations.

When a health system interconnects its affiliates, we refer to this as *Private HIE* because the exchange is only within the membership group. For example, the U.S. Department of Veterans Affairs (VA) operates 153 medical centers as well as 909 ambulatory care and community-based outpatient clinics across the U.S. and its territories. In the early 2000s, the VA interconnected its facilities using a software program referred to as VistaWeb. The software is an Internet-based viewer. Clinicians at the VA medical center in Indianapolis, Indiana, can access documents such as the discharge summary from the VA medical center in Palo Alto, California, for a veteran who had surgery in Palo Alto last year while visiting his grandchildren. This is a private HIE, because VistaWeb cannot look up information on facilities outside the VA health system, only those facilities managed by the VA. Those who recently practiced within the VA may be familiar with newer tools, such as the Joint Legacy Viewer (JLV, which provides access to Department of Defense military health records) or VHIE (Veterans HIE, which provides access to private medical records) [22]. The JLV could be considered a private HIE since it is accessible only through VA and DoD systems. However, VHIE signals that VA is moving away from its private HIE approach towards other models described below.

State Government-Facilitated HIE

The HITECH Act provided eligible U.S. hospitals and providers with incentives for adopting EHR systems and funding for the Office of the National Coordinator for Health Information Technology (ONC) to stimulate HIE. ONC invested over $500 million in state-based HIE programs [23]. To apply for funding from ONC, each state needed to identify a state-designated entity (SDE) to receive and manage HIE efforts within the state. While some states designated entities such as quality improvement organizations or a single HIO within the state, most states elected to designate a state government agency (e.g., Governor's office, Medicaid office) to receive and manage the funding given the close ties between HIE and the state's efforts to encourage EHR adoption among Medicaid providers. Although some state government agencies redistributed the funds to HIOs within the state to support local HIE efforts, many states created a state-level HIE effort. For example, in Michigan the state created the Michigan Health Information Network (MiHIN) Shared Services, a collection of shared software and professional services at the state level. Qualified organizations, state agencies, as well as private HIEs that demonstrate technical capability and execute the appropriate legal agreements can connect to MiHIN for several statewide HIE services, such as public health reporting [24].

Thus, when state governments or other publicly funded organizations act as either a statewide HIO or primary facilitator of HIE within state boundaries, we refer to this as government-facilitated HIE. This designation distinguishes these activities which are driven by very public and policy priorities (e.g., alignment with Medicaid programs) from the efforts of private HIE which are usually driven by the priorities of a private health system. Government-facilitated HIE efforts are also unique. They typically operate at a technical level that supports a "network of networks" in which data and information are "pushed" from provider A to provider B at a single point in time. However, the information pushed is not stored in a central data repository or retained by the state HIO. Such a model allows each state to have multiple HIOs that operate independently of the statewide network and focus on community-level HIE activities.

The former Nationwide Health Information Network (now referred to as the eHealth Exchange) is an example of a Government-facilitated HIE. The network was facilitated by the U.S. Federal government, which established a set of HIE services that could be leveraged to exchange information among networks including Private HIE networks (e.g., the Veterans Health Administration) and Community-based HIE networks [25]. Often one of the organizations involved in the HIE was a federal agency, such as the U.S. Social Security Administration [26]. However, the network was also used to exchange data that did not involve the federal government. In 2012, the network became a public-private partnership as the number of non-government networks expanded. Therefore, today the eHealth Exchange would likely be characterized as a Community-based HIE even though it shares many similarities with the Government-facilitated type.

Community-Based HIE

Community-based HIE involves the exchange of data and information among providers and health care organizations that may be marketplace competitors or otherwise unaffiliated, meaning they have no financial relationship with each other. For example, an academic medical center, large hospital system, and group of federally qualified health centers might agree to exchange data for better serving low-incoming populations in an urban area. While they compete in the marketplace, these organizations recognize they are better served through HIE because they routinely observe patient crossover, which leading to repeating tests and procedures for patients who receive uncompensated care. If each organization became more aware of these patients' history, they might save money while sparing patients from unnecessary care.

Typically, community-based HIE efforts are facilitated by a HIO that operates within a specific geographic area (e.g., city, county, state, region). A well-known example of a community-based HIE is the Indiana Health Information Exchange in Indianapolis, Indiana [27]. Yet, there exist national-level networks in which members span multiple, non-contiguous states. A key distinguishing feature of community-based HIE is that the HIO is driven by priorities set by its Board or governance group, which is often composed of Chief Information Officers (CIOs), ICT Directors, or Chief Medical Informatics Officers (CMIOs) at the various organizations that participate in the HIO. Sometimes HIOs can also have Board members from the larger community, including community foundation directors, elected officials, or large employers.

Vendor-Facilitated HIE

Over the past 5 years, vendor-facilitated HIE has grown rapidly. As the name implies, this form of HIE is facilitated by an EHR system vendor such as the Cerner Corporation (Kansas City, MO). Like the Government-facilitated form, the EHR vendor layers a set of HIE services on top of its EHR infrastructure, enabling its customers to send or receive information to other customers of that vendor's EHR system. And like the Community-based form, the vendor services enable the exchange of information with hospitals and facilities outside a given integrated delivery network. An example of this form of HIE is Care Everywhere™ from Epic Systems (Verona, WI). End-users can click an "outside records" button while viewing a patient's chart. The clinician then searches for another institution part of the network (e.g., another Epic customer). Once an institution is selected, the provider then searches for the patient within the EHR system of that institution. The provider then enters a reason for the query and completes an authorization form attesting to the need to release medical information. Finally, the information from the other EHR is available for viewing.

National Networks/Frameworks

National networks have gained momentum recently due largely to the proliferation of the other four types of networks and the need to pursue more network-of-network approaches that allow participants to join a single network but have connectivity to others. This category includes multi-EHR vendor networks (e.g., Commonwell or Carequality), which can be used to exchange health information either directly through an EHR or health information exchange (HIE) vendor using a record query (pull) approach. DirectTrust is a different type of national network that is widely used and focuses on supporting secure messaging (a push approach) by implementing key governance components and technology such as a provider directory (in which to look up the address to which to direct a secure message). National networks are generally distinguished by their geographic reach and focus on aligning governance and technology via a lowest common denominator that allows different networks to connect.

The 21st Century Cures Act included a provision for the development of a national Trusted Exchange Framework and Common Agreement (TEFCA) for the United States. As of the writing of this book, the TEFCA was in its initial stage of development. A recognized coordinating entity (RCE) was selected by ONC to develop the common set of principles, terms, and conditions to enables nationwide HIE [28]. The coordinating center will provide guidance to Qualified Health Information Networks (QHINs), which will be certified by the RCE and recognized as entities that are authorized to serve as regional or sub-national networks for HIE. Each QHIN will be required to send and receive data with other QHINs, and together they will form a national HIE network for the United States. The precise number of QHINs to be selected, and the final structure of each one is yet to be determined. As of late 2021, only a draft technical framework [29] is known with a final version due to be released around the same time as this book. It is likely that existing national networks, such as the eHealth Exchange, will become some of the first QHINs.

Which Type of HIE Network Is Best for My Hospital?

Taken together, the different types of networks create an uneven patchwork of connectivity. In some ways they compete with each other—often trying to sign up the same participants to meet the same HIE needs. In other ways they are complementary, connecting different groups of providers and/or providing different HIE services. Yet the fragmented patchwork of HIE frustrates many health care financial officers who question why a hospital or health system needs to

belong to more than one HIE network. So, what is the ideal HIE approach?

Since there is no top-down approach to dictate which types of health care delivery organizations should be connected to which HIE networks or how HIE networks should connect, it is challenging for Chief Medical Informatics Officers (CMIOs) and others to answer this question using a blueprint. Moreover, it is unclear how each HIE network will evolve, which will thrive, and which type may disappear. These factors further complicate the situation for CMIOs. We recommend asking the following questions to help decide for a given hospital or health system:

- Does a given HIE network provide sufficient coverage for our patient population? Most healthcare is local, although not all [30]. Therefore, the HIE network should provide access to data from providers in the local community and surrounding region. If all the providers in your healthcare referral region use the same commercial EHR, then it might be sufficient to only participate in a Vendor-based HIE solution. However, suppose the vendor-based HIE only provides coverage for less than half of the system's patient population. In that case, a second solution is likely necessary to ensure providers access the data they need to provide high-quality care.
- Does a given HIE network provide access to a high-value population? Some HIE networks provide access to specific populations that, although they comprise a small portion of the health system's overall patient population, may require extra care coordination or wraparound services, and/or access to their information may yield financial benefits to the health system. For example, some Government-facilitated HIE networks include access to Medicaid populations who might not be available through vendor-based HIE solutions. Access to Veterans' data is available through community-based HIE networks that participate in the eHealth Exchange, which might benefit hospitals increasingly serving VA populations with expanded access to private providers via the MISSION Act [31].

Many hospitals, and likely most health systems, will likely need to be connected to at least two different HIE networks, given both uncertainty in the HIE marketplace and the need to access data for their patient population. Over time HIE networks are likely to consolidate and merge, and there is the potential for development of a national framework that will stitch together the patchwork of HIEs that now exist. Yet current evidence and experience suggest that a combination of networks will be required to meet the needs of large health systems and hospitals that serve regional populations.

Adoption of Health Information Exchange in the United States

Measuring the adoption of health information exchange and interoperable data sharing presents various challenges, especially on a national level. Patients may see multiple health care providers over the course of a care episode and even more throughout their lifetimes. Some of these care transitions may benefit from simple HIE, such as admission-discharge-transfer notifications. In contrast, others may require more detailed data exchange, including images or test results to avoid unnecessary or duplicative services. How many of those patient transitions was HIE available for, how often was it clinically necessary or useful, how often was it used, and how often did it provide value in delivering care? Each case is unique, and it's nearly impossible to accurately describe the state of health information exchange adoption in this way, measuring whether electronic health data flows with patients across providers, using the data researchers have available. Instead, HIE is often measured in other ways, such as whether care delivery organizations such as ambulatory care clinics and hospitals have certain technological capabilities to send and receive data, the proliferation of community-based HIE organizations, and the coverage of vendor-mediated HIE products. While these may not capture the entirety of HIE activity, combined they serve as a useful measure of the adoption of health information exchange. However, even using these broad measures, the United States is woefully behind the goals laid out in the HITECH Act for a nationally interoperable health care delivery system.

Health Information Exchange Adoption Through the Years

Some of the earliest tracking of health information exchange comes from surveys of community-based HIE organizations. While not a direct measure of HIE activity across providers, ongoing surveys of these organizations predate the HITECH Act. The number of operational health information exchange organizations (HIOs) is a useful proxy to measure the state of data exchange in the US. The number of HIOs increased rapidly from 32 active organizations in 2007 to 119 in 2012. The number of operational HIOs then declined to 89 by 2019 [32].

The Office of the National Coordinator for Health IT (ONC) began tracking health information exchange and data interoperability using a new functionality-based, technology-agnostic definition in 2014. ONC defined four essential domains of interoperable health information exchange: sending patient summary of care records to outside organizations electronically, receiving electronic patient summary of care records electronically from outside organizations, finding

(querying for) patient data electronically, and integrating patient summary of care records from outside organizations into the electronic health record without manual intervention. These flexible domains allow a care delivery organization to use whatever technology or HIE they choose, such as community-based HIE organizations or vendor-mediated HIE tools [33].

ONC started measuring interoperability across non-federal acute care hospitals using this framework in 2014, with the most recent data available for 2018 [34]. Data from 2014 to 2018 are summarized in Fig. 14.1 using data from the American Hospital Association Annual Survey—IT Supplement [35]. As of 2014, 78% of hospitals reported they could electronically send data. Still, only 58% could electronically receive data, 48% could find or query for data electronically, and 40% could integrate data from outside sources into their EHR without manual intervention. Only 23% of hospitals reported the capability to engage in all four domains of interoperable health information exchange. These numbers had increased by 2018, up to 88% of hospitals able to send data, 77% receive, 65% find, and 62% integrate data, while 45% of hospitals reported all four capabilities.

Health information exchange adoption among office-based physician practices is considerably lower than in acute care hospitals. Using the same four domains measure, only 38% of physician practices reported sending data electronically in 2015, and only 36% did so in 2017. 38% of physician practices reported receiving patient data electronically in both 2015 and 2017, while the ability to find patient data via query increased from 34% in 2015 to 53% in 2017. Integrating patient data fell from 31% in 2015 to 28% in 2017. Overall, only 9% of office-based physicians reported the capability to engage in all four domains of interoperable health information exchange in 2015—and that number only rose to 10% by 2017 [36].

Drivers of Adoption

The decision by a health care delivery organization to participate in a health information exchange or not can be complex, with factors including clinical utility, technical difficulty, resource availability, financial incentives, and policy requirements all playing an important role. Some providers participate in HIE because it is required by federal programs such as the CMS Promoting Interoperability program. Others may choose to participate in vendor-mediated HIE because they use Epic Systems as their EHR vendor and the Care Everywhere program lowers the technical barriers to data sharing. Many providers participate in multiple forms of HIE [37], while others may pick and choose how they share data in response to several factors, including the pres-

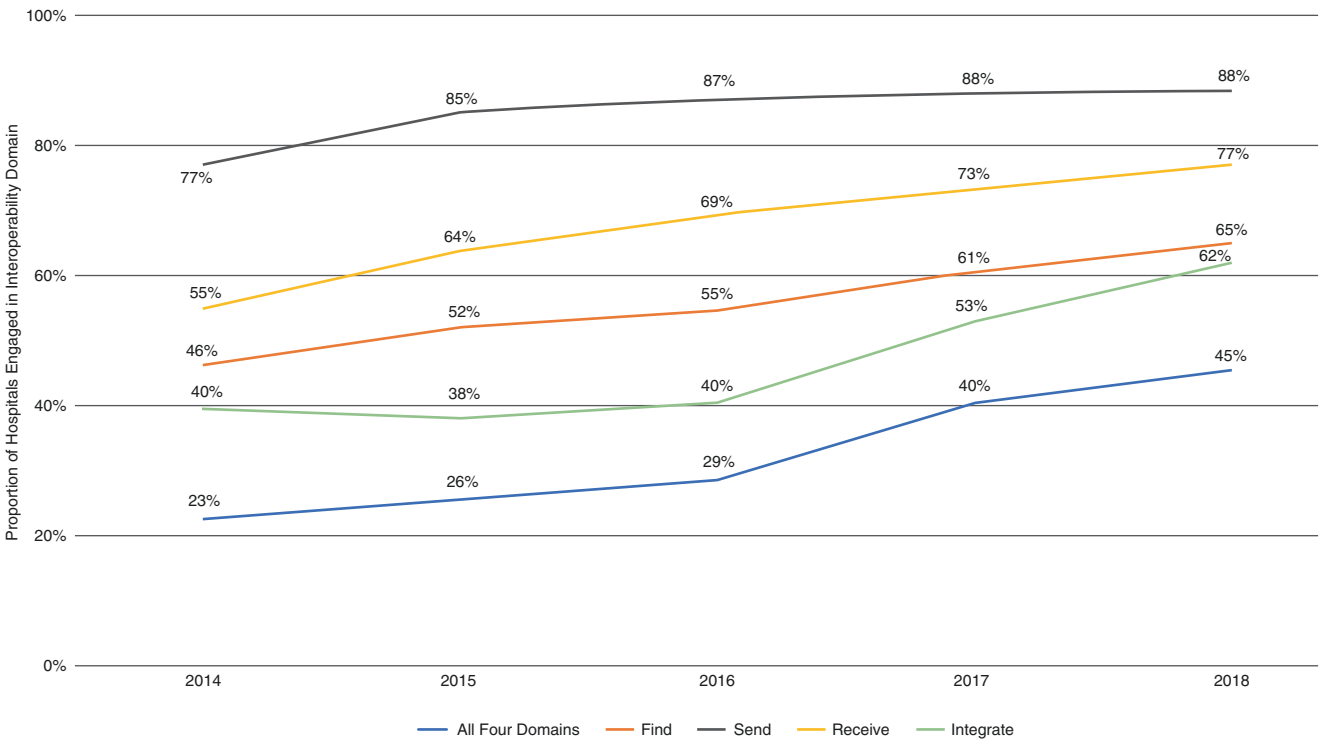

Fig. 14.1 Percent of US non-federal acute care hospitals that electronically find patient health information, and send, receive, and integrate patient summary of care records from outside health care organizations, 2014–2018. Source: Data from the American Hospital Association Annual Survey—IT Supplement

Table 14.2 Potential pros and cons of participating in different HIE types

	Vendor-mediated health information exchange	Community-based health information exchange
Pros	Easy to integrate into existing systems and workflows—no external program necessary	Geographic-based membership likely includes many health care organizations that they share patients with
	Supported by the EHR vendor, they have an existing relationship and contract with	Easier data sharing with providers using different EHR vendors
Cons	May not be able to share patient data easily with providers using different EHR software	Participation may come with costs or fees for use
	May have additional costs from the EHR vendor	May provide varying levels of technical and governance support

ence of a robust community-based HIO in their region and whether other providers they share patients with participate in that HIO. Organizational resources are also important—large, academic medical centers in urban areas are far more likely to have access to greater funding and more human capital (in the form of talented information technology professionals) compared to smaller, more rural, or safety-net hospitals. In contrast, small office-based physician practices may not even have a full-time IT staff. Research has found all of these factors are important [38]. Table 14.2 illustrates some of the potential pros and cons of participation in different types of HIE for a hypothetical health care provider organization.

While not directly incentivized to the same level as EHR adoption, several policy initiatives have actively encouraged health information exchange adoption by health care delivery organizations in various ways. Most directly, the later stages of the Meaningful Use EHR Incentive Program required attestation of sending patient summary of care records electronically. These have continued with the transition to the CMS Promoting Interoperability program [39]. Less directly, the proliferation of value-based payment models such as bundled payments and Accountable Care Organizations (ACOs) were expected to better align the financial incentives of provider organizations to encourage interoperability. These programs have care delivery organizations take on some financial risk for the overall cost of care delivery, regardless of where that care was delivered—theoretically reducing costs partially through the reduction in unnecessary hospitalizations or emergency care visits.

The success of these policy incentives has been mixed. The state of interoperability in hospitals and office-based physicians is far from universal, as described above. Among hospitals, the ability to send patient summary of care records electronically is becoming ubiquitous, with nearly 90% of hospitals reporting this capability—very likely a reflection of the direct requirement to attest to the capability to send this data in Stage 2 Meaningful Use EHR Incentive Program requirements for hospitals. In comparison, features not directly laid out in the federal policy, such as integrating data, show much lower adoption. The evidence on the effectiveness of payment policies on health information exchange is less obvious, suggesting that hospitals participating in these value-based payment models shared data with more partners and shared more types of data, but that the volume of data exchange was lower [40]. In comparison, research has found a strong correlation between information and communication technology infrastructure investment and health information exchange adoption—hospitals that have more advanced EHR functionality in other domains are more likely to report all four of the ONC domains of interoperable health information exchange (finding, sending, receiving, and integrating data), as are those who contract with a third-party HIE vendor or participate in a community-based health information exchange [41].

More recent federal policymaking has come in the 21st Century Cures Act, passed by Congress in 2016, with rule-making finalized in 2020. The Cures Act included a significant focus on interoperable health information exchange, including provisions to outlaw "information blocking", the practice of intentionally and knowingly blocking data sharing or data access by patients by health It developers or health care provider organizations, as well as updates to the ONC EHR certification criteria to mandate adoption of standardized application programming interfaces (APIs) to facilitate patient access to their own health data as well as health information exchange [42]. These new rules address critical barriers to health information exchange adoption today.

Barriers to Health Information Exchange Adoption

The barriers to widespread health information exchange adoption are multiple and complex. While each organization faces unique struggles, and the barriers to HIE vary greatly across different provider types, several prominent obstacles are commonly cited as significant barriers to electronic data exchange [43]. These can broadly be defined across two categories: (1) *technical and implementation* barriers and (2) *financial and incentive* barriers.

Technical and Implementation Barriers

The most obvious barrier to broad health information exchange adoption is a simple fact that it is technically difficult. Electronic health records are massive software

implementations, and a significant amount of customization occurs at the institution level. The end result is that each installation is both massive and unique, and facilitating data exchange between them is a technical challenge—EHRs have thousands of structured data fields and volumes of unstructured free-text documentation. Data elements may be present in multiple places, with variation in where to find a certain value not only across EHR systems or institutions, but also across individual clinicians within a single care delivery organization [44]. Developing institution to institution crosswalks for this would be impossible at any sort of scale, so standards have been implemented to streamline the process. HL7 standards have been widely used across the industry. Recent legislation has mandated the newest HL7 standard, Fast Healthcare Interoperability Resource (FHIR), but ensuring each EHR system is compliant with these standards requires development and maintenance from a team of talented IT professionals from either the provider organization, the EHR vendor, and often both.

Another barrier that encompasses technical challenges, as well as legal and governance issues, is the complex issue of matching patients across unaffiliated health systems to ensure that the correct patient information is shared. The next section of this chapter will address this issue in greater detail; suffice to say that the United States does not employ a national patient identifier, and care delivery organizations therefore rely on a variety of methods to link records across institutions including name, address, age, and other demographic characteristics. Since these variables are often inconsistent (including a middle initial or not in the name, for example), a significant amount of noise requires decision-making in the patient matching process. This further complicates the technical process of health information exchange.

Workflow

One of the most difficult implementation challenges to adopting health information exchange is integrating outside data into clinician workflow. HIE systems often force clinicians to use their IT systems in ways that interrupt their normal workflow. For community-based HIE systems, this is often in the form of a separate program that may require its own username and password to log in and query for any relevant patient data. Clinicians may also have limited training or understanding of how to access outside records in an external HIE system. Even vendor-based HIE modules are often on separate parts of the EHR user interface. While the actual amount of time necessary to navigate to another section of the EHR may be low, given the volume of patients and the uncertainty of finding clinically relevant information from an outside source, clinicians may be reticent to regularly take the time to do so. Recent studies have confirmed this is a real barrier—a simple intervention that moved outside records from a separate tab into the standard patient history tab along with local records saw a large, durable increase in clinicians viewing those records [45]. Given that physicians already face a significant burden of EHR work [46], HIE implementations that demand time and attention are likely to find limited use.

Usability/Usefulness of Data

A related barrier is that not only is patient data from outside sources often not well-implemented into existing clinician workflows, but it is also frequently unclear whether the available data will be either clinically relevant or usable for care delivery. First, even when outside records are readily available, they may not be immediately relevant to the clinician at that moment—records from previous unrelated acute care episodes may not be useful during a primary care visit. HIE can be a "fire-hose" of information overflow, pulling thousands of data elements from a lengthy patient history that may not have any relevance to the treating clinician. The second and more troubling issue is that data elements from outside providers may not be usable. For example, many care delivery organizations are wary of relying on an outside clinicians' interpretation of diagnostic imaging—if the raw image is not available, or not high enough quality; the treating clinician may need to order a duplicative test despite the presence of HIE. These data issues significantly hamper the ability of HIE to meaningfully reduce duplicative testing or imaging.

Financial and Incentive Barriers

Direct Costs

The most obvious barrier to regular electronic data exchange is the cost itself. Provider organizations must spend time and resources developing the systems necessary for sharing data and adjusting their existing IT infrastructure. The aforementioned technical complexity often makes this an expensive endeavor. Even providers using a vendor-mediated HIE solution may have to pay extra fees to their EHR vendor to use the HIE module, and participation in community-based health information exchange may come with costs to the organization. There are further financial costs to the implementation of regular HIE use—both in the technical costs of incorporating outside data into the existing IT system, as well as the cost to clinician time as they interrupt existing workflows to find outside patient data and examine it. These small workflow interruptions can add up over time and across the entire physician population, leading to reduced productivity and few billable patient encounters for health care organizations.

A second and related financial barrier is the need for sustainable funding models for community-based health information exchange organizations and other third-party

facilitators of HIE. Many of these organizations were established or funded heavily out of one-time grants from the HITECH Act. Establishing a sustainable funding model has proven challenging for many such organizations. They may charge monthly or annual membership fees to the participating organization, asking providers to shoulder the costs. They may reduce participation on the external margin, or they may charge for each individual data exchange, which may reduce use on the internal margin if physicians know there is a monetary cost for each data transaction—with an uncertain value on the part of the clinician on the receiving end of the data.

Incentives

Compounding the technical difficulties and direct costs of health information exchange, the fee-for-service payment model that dominates health care reimbursement in the United States provides no incentive for HIE adoption. Instead it provides a diffuse set of disincentives for robust data sharing. Health care organizations may consider patient health data a strategic asset that allows them to deliver higher quality care to existing patients, making them reticent to share data with other providers they perceive as direct competitors [47]. HIE also lowers barriers for new providers to siphon patients from established organizations by making the transition process of medical records more seamless. They may go as far as engaging in intentionally refusing to share data or creating artificial barriers such as charging high fees for data access—known as "information blocking", defined as any practice that interferes with, prevents, or materially discourages access, exchange, or use of electronic health information. While new rulemaking from the 21st Century Cures Act has outlawed information blocking, empirical studies have suggested that the practice is relatively common.

Even in the absence of information blocking, the incentives for health information exchange are simply not strong. A primarily fee-for-service reimbursement system means that as long as provider organizations have positive margins for performing the type of duplicative diagnostic testing and imaging that electronic data exchange is meant to reduce, investments in health information exchange may prove counterproductive to an institution's financial goals. While value-based payment programs work to better align the financial incentives of reimbursement policy to encourage HIE and reduce unnecessary, duplicative, or low-value care, so far, these programs are non-mandatory and have limited reach, with a small impact on HIE adoption [40].

Present Problems and Future Solutions

These barriers result in HIE and interoperable data sharing that is technically difficult, costly, and time-consuming. Providers and care delivery organizations have very poor incentives to invest in overcoming those difficulties. The result is a relatively low adoption rate, even well over a decade after the passage of the HITECH Act in 2009.

Future progress in HIE adoption must address both sets of barriers. Mandating a single standard, such as API-based exchange through FHIR, may help address some technical difficulties of HIE. At the same time, EHR vendors should incorporate outside data access seamlessly into clinicians existing workflows. In parallel, policymakers need to incentivize interoperability either directly through penalties for information blocking or indirectly, such as stronger incentives to reduce duplicative or low-value care. Achieving widespread interoperable HIE in the United States will require coordination across a wide set of stakeholders, leadership from policymakers and regulators, and a multipronged approach that addresses the technical challenges and misaligned incentives of patient data sharing.

Patient Matching

Uniquely identifying patients is an essential task for HIE and doing so accurately is deceptively difficult, yet crucial to delivering the right care to the right patient. Currently, in the United States, there does not exist a universal, unique patient identifier. And although some middle and low-income countries have developed unique patient identifiers, none of them conform to all 30 of the criteria established by the American Society for Testing and Materials (ASTM), which is a standards development organization accredited by the American National Standards Institute (ANSI) [48].

Because a unique identifier does not exist, health systems and HIEs employ an **enterprise master patient index (eMPI)**. The eMPI is software that assigns a unique identifier to each patient and ensures that the patient is represented only once within the enterprise EHR system or private HIE.

Each healthcare delivery organization's eMPI associates its own unique identifier with patient data; thus, a single patient may have several "unique" eMPI identifiers, one within each organization where care occurred. This lack of a shared identifier across organizations makes integration of patient data difficult in HIE. So, if John Smith visits an ED outside his usual integrated healthcare system, data about the visit would not be integrated into the EHR system record utilized by his primary care physician.

The multiple eMPI problem has an intuitive solution: create a unique identifier to span all healthcare organizations. This is typically referred to as a **client registry** [49], which adjudicates demographic attributes and other personal identifiers from each data supplier (e.g., hospitals, clinics, etc.) to create a single record for each patient within the HIE. This is illustrated in Fig. 14.2.

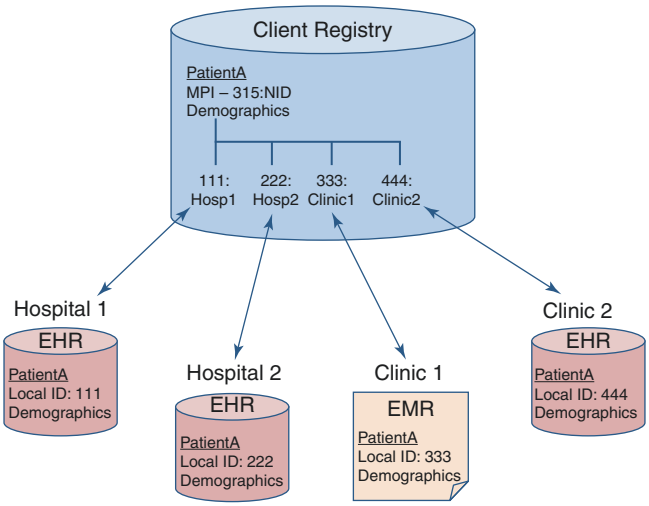

Fig. 14.2 Illustration of a client registry, implemented within an HIE to reconcile patient identifiers across multiple participating healthcare organizations sharing data with one another

Reconciling Patient Identifiers

At the heart of the client registry is its use of matching algorithms to determine whether the patient already exists in the registry, subsequently linking records regardless of the source, when applicable. Generally, algorithms can be described as deterministic, probabilistic, or combination. Many algorithms are available for matching but no single method has emerged as universally appropriate for every situation [50].

Matching can be accomplished using one or more patient traits (e.g., name, date of birth). Unlike algorithms that rely on universal patient identifiers, which are fundamentally simple by comparison, matching methods that use demographic attributes are more complex and rely upon sufficient data quality (e.g., accuracy, completeness) of multiple attributes and, intuitively, the accuracy of the matching algorithm increases with the number of (high quality) identifiers used [51]. Using an improperly tuned algorithm may result in a higher rate of duplicate records; therefore, it is recommended that the HIE develop a process to determine the appropriate matching scheme. Furthermore, because patient attributes as well as populations change over time, matching schemes should be re-examined, and possibly recalibrated, at regular intervals.

Deterministic Matching

Also known as a heuristic, rule-based, exact, and all-or-none algorithms, deterministic matching techniques typically use a set of rules based on either exact matching of two records or the use of field comparators and phonetic transformations for near matching. Deterministic models are best when both records contain a highly discriminatory field. A universal identifier, an organization-specific medical record number (MRN), and to a lesser degree, social security number (SSN), represent examples of fields often used in deterministic matching. Most information systems implement a basic deterministic matching algorithm using exact (MRN or SSN) or partial matching (name and DOB) [52]. However, basic deterministic models are severely limited by the quality and completeness of data and by the discriminatory power of the identifier. Accuracy can be improved by first matching on a ubiquitous and highly discriminatory identifier (e.g., SSN) and then confirming with additional traits such as sex, name, and date of birth [53]. Because of the need for precision and accuracy, and the heterogeneous nature of data across entities, purely deterministic algorithms are not typically well-suited for HIE. Even in instances where universal identifiers have been distributed nationwide, such as in the UK, it is advisable to supplement with additional patient traits [54].

Probabilistic Matching

The reality that information moving across entities often does not contain complete, error-free data fields or universal identifiers necessitates using probabilistic record linkage techniques. Contrasting with deterministic methods, probabilistic models do not require an exact match, and the allowance of partial matches (or non-matches) is quantified in a more statistically rigorous manner. The most widely adopted method was developed by Fellegi and Sunter [55], based on the ideas introduced by Newcombe [56], which draws from maximum likelihood theory to produce probabilities that two records represent the same person [55, 56]. At a basic level, a weight, or probability, is calculated for each matching variable. These weights are summed to create a score representing the degree to which a pair of records is believed to be a correct match. If these scores are greater than an appointed upper threshold, they are deemed a true match. If they fall below a lower threshold, they are deemed a true non-match. If they are in between the thresholds, the pair represents a possible match. Although in practice possible matches often require human review, more sophisticated decision rules have been shown to perform at a high level when human intervention is not feasible [57, 58].

A false negative occurs when a pair of records match in reality but the decision rule declared them as a non-match. On the other hand, a false positive occurs when two truly non-matching records are erroneously linked together. In healthcare, it is usually desirable to control the rate of false positives because erroneously linking together data from two different patients may result in significant morbidity and mortality from inappropriate treatments. False negatives may also lead to incomplete information regarding medical conditions, medications, or allergies. Still, these errors are analogous to the fragmented nature of healthcare without HIE, and therefore perceived by many as less severe [59].

Emerging Trends

Beyond addressing fundamental challenges to HIE like workflow and sustainability, HIE networks are innovating in several areas relevant to clinical practice. Moreover, technologies like APIs continue to evolve and support a wider array of use cases in medicine. In this section, we briefly review some of the emerging trends in HIE and interoperability. It is impossible to do these topics justice in simply this section. Therefore, if one is interested in these areas we encourage the reader to explore the references and engage with their local HIE network which is likely working on some or all of these exciting areas.

Incorporating Behavioral Health Data into HIE Networks

Although HIE adoption and use has grown significantly in primary, emergency, and inpatient care over the past two decades, HIE is not as present in other areas of health care delivery. Behavioral health services is an area where greater interoperability and HIE would impact patient and population health outcomes, yet integration of behavioral health data and providers into HIE networks is challenging.

Although many behavioral health providers recognize the utility of HIE and interoperability [60], there are legal and structural challenges that face integration of behavioral data into HIE networks. A major roadblock to behavioral health data exchange is federal regulations around the sharing of substance use disorders. In Part 2 of Title 42 of the Code of Federal Regulations, U.S. regulations govern the sharing of information about substance use disorder treatment. However, many behavioral health providers, including psychiatric hospitals and mental health clinics, consider their entire organization to be governed by CFR 42 Part 2. These perceived restrictions on behavioral health data across the organization make it challenging for health systems to share substance use and mental health data as widely available as HbA1c laboratory results and ICD-10-CM codes for hypertension [61, 60].

An exciting trend in HIE is increased efforts around the nation to bring behavioral health specialists on board with HIE and integrate behavioral EHR data into HIE networks. Efforts at the Colorado Regional Health Information Organization (CORHIO) and Quality Health Network (QHN) in Colorado provide guidance on how to appropriately navigate regulated data yet create interoperable pathways that allow behavioral health providers access to HIE networks and enable other clinicians to see important behavioral health data on their patients entered by the specialists who care for them [62]. With funding from ONC, CORHIO and QHN implemented different models in which patients provided consent for their behavioral health data to be shared with their other providers, required by CFR 42 Part 2. In QHN, mental health clinics captured patient consent during a clinical encounter. With consent on file, data from the mental health clinic could be pushed directly into another provider's EHR system via the HIE network. CORHIO, on the other hand, implemented a patient-facing portal where patients could provide consent directly, outside of a clinical visit. Patients were educated during their visit about the portal by a peer-support specialist and provided materials on how to access the portal. When primary care clinics then queried CORHIO for behavioral health data, the HIE network would query the consent portal database to ensure the patient had a consent on file. If consent was available, behavioral health data would be shared with the requesting provider. The two different approaches have pros and cons, but they both offer valid pathways for patients to provide the consent necessary to appropriately navigate the regulations established in CFR 42 Part 2. Moving forward, there is an opportunity for other HIE networks to implement one of these approaches to enable integration of behavioral health data and support behavioral health care specialists with the other data available in the HIE network.

The next 3–5 years will bring more HIE networks achieving success with integration of behavioral health data and using it to drive better care and population outcomes. Combined with greater integration of services like Aunt Bertha, which allows primary care providers to refer patients out to behavioral specialists, into HIE networks will likely drive efforts to standardize, exchange, and use behavioral data. These efforts will be particularly important post-COVID as behavioral health is increasingly recognized as the next epidemic caused by isolation, job loss, and other disruptions to normal life due to the devastating impact of COVID-19 on communities [63, 64].

Leveraging HIE Networks to Address the Social Determinants of Health

Another exciting trend in HIE is the integration and use of data relevant to addressing the social determinants of health (SDOH). Increasingly health systems recognize the importance of SDOH on outcomes such as readmission, access to care, and compliance with medication regimens [65]. The National Academy of Medicine along with the Robert Wood Johnson Foundation and Department of Health and Human Services recommend that clinical and public health systems should work together to capture data on patients' SDOH and use these data to drive health promotion and management activities across the health system [66, 67].

Currently SDOH data are available at two levels:

- *Individual-level data* are preferred as they pertain directly to the patient in front of the provider and can be used to flag patients who may need referral to community-based social services. These data are typically captured by clinic staff, including providers and medical assistants, although much of these data are captured today in notes as free text rather than structured data. EHR vendors are, however, increasingly supporting structured data capture for SDOH data elements at the patient level.
- *Population-level data* pertain to the area in which a given patient lives. For example, a neighborhood or ZIP Code might have 50% of its residents whose annual income is lower than the federal poverty rate. Patients living in that neighborhood may therefore be characterized as low income, yet this population characteristic does not generalize to every patient. Population-level data are readily available from a number of sources, including the Census Bureau. However, they are more difficult to apply to an individual patient, perhaps only indicating risk for social service needs.

The Indiana HIE, along with other HIE networks, are currently working to integrate both individual and population-level SDOH data. Researchers at the Regenstrief Institute demonstrated that population-level data integrated in an HIE network can be used to calculate a social risk score that identifies individuals with unmet social needs who may benefit from referral to social services [68, 69]. In Idaho, the state HIE network partnered with Aunt Bertha [70], a social care network, to enable providers access to information on programs dedicated to affordable housing, childcare expenses, food distribution, transit assistance and education, etc. Connecting their patients to these programs will enable clinicians in Idaho to address their patients' SDOH though available community resources. The Idaho HIE network provides an efficient platform for clinicians to access this information.

Like with behavioral health data, we anticipate that SDOH data will play a larger role in health care analytics and decision-making in the coming decade. HIE networks will increasingly seek to capture these data on individuals and populations to support referrals as well as help communities measure progress towards addressing SDOH needs. Moreover, HIE networks will drive better standardization of SDOH data captured by health systems and non-clinical organizations. Public health agencies will be particularly interested in leveraging HIE networks to measure SDOH risk and develop (and evaluate) programs that seek to mitigate risks and improve health outcomes for target populations, such as those with social isolation needs and underserved minority populations that struggle with access to care.

Expanding the Use of API-Based Information Exchange

Currently the adoption and use of APIs, particularly FHIR, is limited to a small group of early adopters, which tend to be large health care delivery systems. Admittedly there are few data published on the true extent to which API-based applications are being used across the health system. Our estimates based on early adopters suggest that there is limited use of APIs in most health facilities, if any. The ecosystem of applications available for integration is limited. Furthermore, a recent study of patient-facing APIs suggests great heterogeneity among early adopters with respect to their strategies for adopting and deploying APIs [71]. Moreover, the proposed national HIE network for the United States, dubbed TEFCA, only requires the use of consolidated clinical document architecture (C-CDA) standards, not FHIR [29].

Given the high level of interest in using APIs to overcome information blocking and interoperability technical challenges, we anticipate that the adoption and use of APIs will grow over the next decade. Early adopters are pushing the development of an app ecosystem that integrates data across various EHR platforms. Vendors have API-based components in various stages of development, suggesting that a variety of apps will be available for customer use within the next few years. Demand for APIs is high among policymakers and clinical informatics leaders, which is likely to spur greater adoption and use. As discussed above, however, there may be additional policy drivers needed to see APIs used across the health system beyond the early adopters.

Summary

Interoperability and HIE are critical to modern clinical practice. Clinicians cannot adequately treat their patients without access to comprehensive information on past medical history and current health management plans, including medication regimens. Patient health data is fragmented across multiple clinical and non-clinical organizations, making interoperability and HIE services an important sub-discipline within clinical informatics and a service to which health systems must subscribe. Federal and state policies are driving EHR vendors, HIE networks, and clinical organizations to increasingly adopt and use technologies that enable data sharing across regional and national boundaries. Navigating the details of standards, interoperable interfaces, and the governance of shared health data is an important job for clinical informaticists, yet this work is not easy.

Questions for Discussion

1. Compare and contrast the terms interoperability and HIE. In the context of care coordination, how might these terms differ? How would you explain them to your clinical team?
2. Which HIE approaches make sense for a large, integrated delivery network that consists of multiple hospitals, outpatient specialty practices, and primary care clinics?
3. Which barrier to HIE and interoperability do you think will be solved in the next 5 years?
4. Why don't Americans have a universal healthcare identifier like other countries? This solution would surely solve many challenges in HIE and interoperability, right?

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Data Information and Governance

15

Carl McKinley

Learning Objectives
At the end of this chapter, the reader will be able to:

- Understand the importance of accountability in data stewardship.
- Describe a data governance committee's purpose.
- List best practices for monitoring a data-sharing agreement.
- List common data governance policies and their uses.
- Create a data-sharing agreement.

Practice Domains
- K054. Institutional governance of clinical information systems.
- K070. User types and roles, institutional policy, and access control.
- K086. Stewardship of data.
- K087. Regulations, organizations, and best practices related to data access and sharing agreements, data use, privacy, security, and portability.

Case Vignette
HiTek pharmaceutical company approached Susan, the Chief Medical Officer of a major healthcare system, about sharing patient information from electronic medical records for an upcoming phase I cancer trial. Susan knows her health system's rural patients are not participating in clinical trials at the same rate as patients in urban settings, so including their information in the trial would enhance the generalizability of the findings. However, Susan also believes that rural hospitals often decline to participate in research because they lack a process for reviewing and approving data requests and fear the risk of unauthorized disclosure of Protected Health Information (PHI).

Introduction

The basic purpose of **data governance** is to create trust among the various constituencies providing and overseeing health information [1]. While constituency membership varies, it almost always includes individuals, governmental agencies, and health care providers and can include private corporations and quasi-governmental entities such as institutional review boards. A sophisticated data governance framework instills confidence that your organization will keep health information secure and only be used for permissible purposes. Data governance crosses clinical care with business requirements and is foundational for any enterprise that organizes and manages data assets [2]. Data governance is distinct from data quality, master data management, and data administration topics that are described elsewhere in this book.

Data governance ensures that an organization complies with many federal, state, and international laws regarding the storage, retention, and release of individuals' health information. Determining which laws and jurisdictions apply to data privacy is complex and may require consulting with legal counsel to determine which laws apply to a specific circumstance. Additionally, privacy rights are among the most legislated subjects and require constant monitoring to ensure the organization is compliant with data governance [3].

Creating a sophisticated data governance framework involves organizational structure, policy, and process [4]. Data governance also ensures that an organization is accountable for using health data. For example, in the event of a data breach, an organization must prove to governmental agencies that the organization was following the law and best practices before and after the breach occurred.

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Laws, Organizations, and Best Practices for Accessing and Disclosing Data

Laws and Regulations

It cannot be stressed enough that the reader should consult an expert in data privacy or legal counsel when creating a data governance framework. Most data governance-related laws and regulations are covered in **Chaps. 3 (Clinical Informatics Policy and Regulations), 10 (Data, Information & Architecture), and 17 (Cybersecurity)**, so they will not be revisited in this chapter. Clinical informaticists must be familiar with HIPAA, HITECH, twenty-first Century Cures Act, and TEFCA. Also, all 50 US states have, to some degree, laws regarding privacy breaches. If the data governance framework allows data for research purposes, then the Common Rule may apply for accessing or disclosing identifiable information, which is discussed in Chap. 10 [5].

State Laws

All 50 US states have, to some degree, laws regarding privacy breaches. For example, a few states, California's Consumer Privacy Act (CCPA), have laws that exceed HIPAA and include provisions like a private right of action [6]. The CCPA gives Californian consumers more control over the personal information that businesses collect about them and provides new rights to consumers, including:

- The right to know about the personal information a business collects about them and how it is used and shared;
- The right to remove personal information a business has collected from them;
- The right to opt-out of the sale of their personal information; and
- The right to non-discrimination when exercising their rights under CCPA [6].

Fortunately, non-profit organizations and governmental agencies do not meet a "business" definition in the CCPA, and this law does not apply to them [6].

The International Association of Privacy Professionals (IAPP) has an excellent resource for checking state privacy legislation at https://iapp.org/resources/article/us-state-privacy-legislation-tracker/ [7]. As of this writing, 33 states have privacy legislation pending. While most privacy bills are in committee, California, Colorado, and Virginia passed privacy legislation that exceeds the requirements under HIPAA [7].

Organizations

Many data governance organizations, such as the Data Management Association International (DAMA), the National Association of State Chief Information Officers (NASCIO), and IAPP. This chapter will focus on the Data Governance Institute's Data Governance Framework (Fig. 15.1) [8].

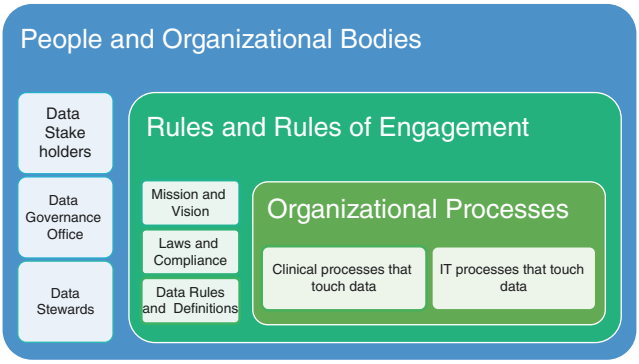

Fig. 15.1 A framework for organizational data governance, adapted from the Data Governance Institute [8]

The framework provides a visual method for clinical informaticists to organize the various components of operational governance for data and information. In essence, the framework asks clinical informaticists to answer the following questions:

1. Why is data governance important to the clinical organization? [MISSION]
2. What external drivers motivate data governance? [POLICIES]
3. Who is involved in data governance throughout the organization? [PEOPLE]
4. What is the organization doing to govern its data assets? [PROCESSES]
5. How are these individuals providing value to the organization? [PERFORMANCE]

The remainder of the chapter discusses these various aspects of the framework to some degree. The concepts involved in a clinical organization's data governance overlap with the concepts used to execute informatics projects and the IT division of a health system found elsewhere in the book. Clinical informaticists will likely interact with individuals within their enterprise responsible for IT and data governance. These individuals will rarely be the same person (except in perhaps smaller organizations). Successful informaticists span clinical operations, IT, and data governance, helping the organization align missions and processes across boundaries.

Data Access and Data Sharing Agreements

A data-sharing agreement is a formal contract the clearly states what data is being shared and how the data will be used. It protects the data provider from the data recipient's misuse of the data. Data sharing agreement requirements

vary depending on the type and identifiability of the data in question. A clear data-sharing agreement reduces the chances of a misunderstanding between the provider and recipient. It is a tool to come to a collaborative understanding that is documented by the agreement [9].

The data-sharing agreement should define the scope and purpose of the use, describe the type of data being provided, and include contract provisions relating to privacy, IP, and data ownership. Using standardized agreement language streamlines negotiations by providing familiar terms to both parties [10].

Content

Data sharing agreements can take many forms, depending on the type and confidentiality of the data sharing. Memoranda of Understanding (MOUs), service agreements, and data use agreements could all be data-sharing agreements. The agreement should be drafted in clear, concise language that is easily understood.

- Context. This section sets out reasons for sharing data and the parties involved. Consider including:
  - A description of the entities signing the agreement.
  - A statement summarizing the agreement's purpose (e.g., what are the objectives of the data sharing).
  - The main contacts in each organization for questions about the data.
  - Any financial agreements that may cover how the costs and benefits are shared.
- The Data. This section focuses on describing the data itself, so it is clear what will be shared specifically. Consider:
  - What data will be shared?
    - Specify any unique way to identify the data.
    - What is the structure of the data shared?
    - What time period does the data cover?
    - What format is the data in?
    - What quality does the data need to be?
    - What is the source of the data?
  - Is this a one-off transfer, or will updates be made?
  - When will the data be provided?
  - Roles and responsibilities. Where possible, include:
    - Name and contact detail of organizational representatives
    - A technical contact and a legal contact.
- Sharing. How the data will get from one party to another.
  - How is the data going to be shared between the parties?
  - Where can the data be accessed or transferred?
  - Where is the data going to be stored?
  - Is the transfer method secure?
  - How long is the data going to be shared?
  - Does the recipient need to destroy their copy of the data at the end of the agreement?
- Use. Specify what the data can be used for.
  - What permissions have been granted to each party that describes how they can use the data?
  - What requirements does the recipient need to follow to retain those permissions?
  - What restrictions might limit the use of the data?
  - Does the recipient need the provider's permission to further share the data?
  - Is the data licensed?
- Derived data. Derivative data incorporates data that has been shared.
  - Who will have rights products derived from the shared data?
  - Can derived data be published or reused by others? [11]

After the Agreement Is Executed

Agreeing to share the data is the first step. Once you've agreed to what, when, and how to share data, it is important to implement a plan to manage the data. Important things to consider and plan for are:

- Keep a record of the data you share and who you share it with (i.e., in an inventory).
- Scheduling and resourced data updates.
- Seek feedback from the data recipient on the data's quality, completeness, format, timeliness, etc.
- Ensure the data recipient is complying with the terms of the data-sharing agreement.
- Resource any changes to how the data is managed based on recipient feedback.
- Inform the recipient about any planned changes to the scope, provision, or availability of the data in the future [11].

Best Practices Related to Data Use, Privacy, Security, and Portability (Data Stewardship)

Data stewardship is a collection of practices that ensure an organization's data is accessible, usable, safe, and trusted [12]. A data steward ensures that data governance policies and standards are followed within the data steward's domain [13]. Data stewardship is synonymous with accountability. The data steward is responsible for the appropriate use of data and with liability for inappropriate use. Data stewardship supports society by improving healthcare through access to health data while protecting individuals' privacy [14].

Data Stewardship Concepts

Data stewardship can be summarized in a clinical setting by four principles: individual rights; data steward responsibili-

ties; security and controls; and accountability, enforcement, and remedies.

An individual has the right:

- to know what is in their health records;
- To correct one's own health data;
- To have transparency about the use of their health data;
- To participate and consent for the use of their data; and
- To be educated about the principles and practices governing the appropriate use of the health data.

A health data steward must:

- Adhere to an appropriately determined set of privacy principles and practices;
- Appropriately use good statistical practices;
- Limit the use, disclosure, and retention of health data;
- Identify the specific purpose of data;
- Apply the minimum necessary use of data;
- Appropriately de-identify data; and
- Ensure data quality, integrity, accuracy, timeliness, and completeness.

Data Stewardship also requires implementing administrative, technical, and physical safeguards to protect individuals' health data and minimize the risk of unauthorized disclosure of data. Proper data stewardship requires policies that specify appropriate use and identify clear accountability. When unauthorized disclosures occur, consequences to the accountable party must be enforced and remediation for those individuals harmed [14].

Institutional Governance

Putting together a sustainable data governance and stewardship program is complex and difficult. Every governance model has strengths, weaknesses, and levels of complexity. There is no one-size-fits-all framework. For this chapter, we will combine the best aspects of frameworks by the Data Governance Institute, NIST, and the IAPP. This design will allow an adaptable and flexible approach to data governance.

The Business Case

The data governance program begins by assessing the needs of the organization by creating a mission statement [15]. A mission statement describes the purpose and ideas in just a few sentences. It should define the scope of the governance program and lay the groundwork for the rest of the program elements. By defining the scope, the organization also identifies any legal hurdles that will need to be overcome. For example, suppose the organization's mission is to share protected health information with public health officials as widely as possible. In that case, the governance framework should be designed around those sections of HIPAA which allow for that type of sharing.

The organization must also conduct a detailed inventory of all data collected and stored to conduct a privacy risk assessment. This assessment will help determine if the data assets exist and legally support the mission statement.

After the mission statement, the organization must identify stakeholders and build a consensus for the data governance program. Examples of stakeholders include IT, HR, legal, cybersecurity, risk management, and departmental leadership. It is crucial to identify a senior leadership "champion" at the executive level that acts as the data governance advocate and sponsor [15].

Organization

An individual or committee may lead governance, and there are advantages to both. Data governance led by an individual more easily meets the accountability requirements for data stewardship, but a committee is a more common model for receiving input from all stakeholders. The role of the data governance committee is to review, approve, and promote effective data policies and best practices. The committee establishes general guidelines and policies for data usage and access. The committee also develops and oversees a process for handling requests for exceptions to these policies.

Other common roles within data governance are Data Owners and Data Stewards. Data Owner is a business-oriented role held by a member of senior leadership who can make decisions for the entire organization. Data Owners are accountable for the data as a business asset. Data Stewards are often the subject-matter experts for the data and ensure the data is protected and used appropriately. An organization must define its data governance roles with clear job descriptions, responsibilities, and duties [16].

Policies and Procedures

The Data Governance Committee is the approval authority for all data governance policies. Listed below are some common data governance policies.

Policy	Description
Collection limitation	Identifiable data should only be collected for lawful purposes with the individual's knowledge or consent.
Data quality	Identifiable data should be relevant to the stated purpose and should be accurate, complete, and current.
Use limitation	Identifiable data should not be disclosed without the individual's consent or as authorized by law.
Security	Identifiable data should be protected from unauthorized access according to applicable law and best practices.
Openness	A general policy of transparency about developments, practices, and policies concerning identifiable data

It is the responsibility of the Data Governance Committee, or its delegates, to monitor regulations to ensure policies are up to date with all applicable laws and create or update policies as needed [15].

Data Access and Data Usage Policies

The organization's data access policies must balance the data's utility with data protection because unused data is useless data [17]. Data assets value is magnified by increased data usage, which is diminished through misuse and unnecessary restrictions [18]. Data usage policies ensure data access and use only as required for a specific purpose, not for personal gain or other inappropriate use. Inappropriate usage of Protected Health Information (PHI) can result in large monetary penalties for a covered entity or business associate.

Emerging Trends

Federal Privacy Law

Multiple state privacy laws indicate that a federal privacy law may be on the horizon. California lawmakers passed the CCPA in 2018, and since then, two other states, Colorado and Virginia, have passed privacy legislation. CCPA is a long-arm statute, meaning that even if a "business" has no assets or operations in California, it can still be subject to CCPA [19]. In 2019, the Privacy Bill of Rights Act and the United States Consumer Data Privacy Act were introduced in Congress. In 2020, Senator Roger Wicker R-Mississippi introduced the Setting an American Framework to Ensure Data Access, Transparency, and Accountability Act. These initial attempts at a federal privacy law have many similarities to GDPR and CCPA.

Increasing Use of Secure Data Enclaves

Data enclaves are secure, centralized services for accessing sensitive or confidential data such as PHI. Data enclaves protect sensitive data by complying with best-in-class storage standards and transfers the security obligations for secure data storage from the data recipient to the data provider. The data provider maintains administrative control of the enclave, which improves auditing for HIPAA purposes. Secure data enclaves were previously expensive and difficult to create at the enterprise level, but many off-the-shelf applications are now available [20].

Summary

Information governance and data stewardship are about balancing access to health data for improving care while protecting an individual's right to privacy. Hospitals without sophisticated data governance frameworks break their patients' trust and risk reputational harm and regulatory scrutiny.

Questions for Discussion

1. A data-sharing agreement is an important tool when disclosing health information to a recipient. What are some of the ways to monitor the disclosure of information after the agreement is executed?
2. List and describe three common data governance policies.
3. Describe the role of a data governance committee.
4. Why is "accountability" an important aspect of data stewardship? What would be the likely result of a data governance program without accountability?

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Analytics

16

Suranga N. Kasthurirathne and Shaun J. Grannis

Learning Objectives
At the end of the chapter, the reader should be able to:

- Identify and define key terms and concepts associated with data analytics and big data.
- Identify and characterize primary and secondary data sources of relevance to clinical informatics.
- Understand and contrast the functionality, advantages, disadvantages, and uses of natural language processing, supervised and unsupervised learning approaches, and neural networks.
- Investigate the role and value of various visualization techniques in clinical informatics.
- Evaluate machine learning approaches using performance metrics such as precision, recall, accuracy, and Area under the ROC curve (AUC ROC).
- Identify practical considerations and implications that influence the adoption of analytical tools and methods.

Practice Domains
Domain 1: Fundamental Knowledge and Skills

- K004. Descriptive and inferential statistics.
- K025. The flow of data, information, and knowledge within the health system.

Domain 2: Improving Care Delivery and Outcomes

- K049. Prediction models.
- K050. Risk stratification and adjustment.

Domain 4: Data Governance and Data Analytics

- K101. Definitions and appropriate use of descriptive, diagnostic, predictive, and prescriptive analytics.
- K102. Analytic tools and techniques (e.g., Boolean, Bayesian, statistical/mathematical modeling).
- K103. Advanced modeling and algorithms.
- K104. Artificial intelligence.
- K105. Machine learning (e.g., neural networks, support vector machines, Bayesian networks).
- K106. Data visualization (e.g., graphical, geospatial, 3D modeling, dashboards, heat maps).
- K107. Natural language processing.

Case Vignette
You have just been appointed as the Chief Medical Information Officer (CMIO) of a large hospital system with an established medical record platform that has been used to capture patient data for several years. Your CEO has heard of the benefits of data analytics in informing healthcare delivery. She has tasked you with putting together a long-term plan for adopting analytics into your health system. How would you approach this challenge?

This chapter was adapted from a prior publication [1].

Introduction

Data plays a significant role in modern society and the economy. As envisioned by mathematician Clive Humby, credited with the phrase 'data is the new oil' [2], it continues to be of unparalleled value in driving the information age. Increased uptake of health information systems has led to increased accessibility and availability of health-related datasets. However, learning how to leverage various complex heterogeneous datasets to infer value in clinical settings is an uphill task. For the last several decades, researchers have demon-

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strated the ability to apply various analytical methods in response to multiple challenges impacting various clinical care domains [3–6]. Adoption of such analytical tools at scale is hampered by concerns of algorithmic bias and unfairness [7], limited generalizability and transportability of models across new patient populations and settings, and challenges in implementation and quality control [8–10].

However, these barriers are subsiding. Widespread acceptance of analytical methods and increasing demands on the clinical workforce have paved the way for ramping up efforts to develop and deploy innovative analytical solutions to address a range of use cases, including data analysis, machine learning, risk assessment and stratification, and visualization.

However, keeping up with the rapidly evolving Artificial Intelligence domain and apply these concepts to clinical informatics. Further, understanding the plethora of primary and secondary data sources captured at the patient- and population-level and leveraging these datasets to extract and model clinical, behavioral, and social determinants influencing patient health and wellbeing can be challenging. Thus, researchers and practitioners of clinical informatics need to obtain a firm grounding in the fundamentals of analytics and potential limitations and challenges that must be overcome to build robust analytical solutions. This chapter provides a detailed overview of theoretical and practical aspects of data analytics and its application in clinical informatics.

Data to Wisdom

This section provides a brief overview of data, information, knowledge, and wisdom and their relationships. It further offers an introduction to other analytical terms and the categorization of various analytical methods.

To learn about data analytics and the use of big data, readers must first understand several key terms - data, information, knowledge, and wisdom - and the hierarchical relationships between them. These relationships are described as the *DIKW* (Data, Information, Knowledge, Wisdom) pyramid (Fig. 16.1a).

- *Data* (base of the pyramid) collects discrete, objective facts or observations that are represented in raw and unorganized form without context. As such, they are of little value. As an example, the string '101' is discrete and objective but lacks any context.
- *Information* is organized or structured data that has been prepared so that it is relevant for a specific need and is therefore valid, relevant, and valuable. For example, knowing that the string '101' mentioned earlier represents an adult's body temperature in Fahrenheit adds more context and is more meaningful.
- *Knowledge* is a flux of framed experiences, contextual information, values, expert insight, and grounded intuition that offer an environment and framework for evaluating and incorporating new information [12]. For example, additional context around adult human body temperature helps a clinician understand that this patient suffers from a fever.
- *Wisdom* (the topmost point of the pyramid) is the ability to increase effectiveness. It adds value, which requires the use of judgment. Given that judgment may be influenced by an individual's aesthetic values or ethics, wisdom is often personal and inherent. For example, by evaluating the knowledge presented previously, a clinician understands that they must address the patient's fever.

The relationships between these factors are represented in Fig. 16.1(a) as layers of a pyramid, with the largest source (data) at the very bottom and the smallest source (wisdom) at the very top. Analytics (defined below) help researchers advance from data (widely available but low value) to information, knowledge, and wisdom (increasingly harder to obtain and more valued).

Key Terms in Analytics

Definitions for several key terms used in the analytics domain are as follows:

- *Data science*: The multi-disciplinary field leverages various methods, processes, and algorithms to extract knowledge and insights from structured and unstructured data.
- *Artificial intelligence (AI):* A subdomain of computer science that focuses on the simulation of human intelligence (or brain function) by a machine. AI is a broad domain encompassing machine learning and other topics, such as logic, problem-solving, and reasoning, which are out of scope for this chapter.
- *Machine learning:* The ability of a computer system to learn from the external environment or a data source to improve its ability to perform a task. These approaches enable various algorithms to learn from data without any explicit programming. Machine learning is a subset of AI.
- *Analytics*: The discovery, interpretation, and communication of meaningful patterns found in data, as well as the application of data patterns for effective decision-making.

Descriptive and Inferential Statistics

Descriptive Statistics Descriptive statistics refer to a group of analytical methods used to summarize datasets in a manner that 'describes' or summarizes a population, making them easily interpretable to researchers. Descriptive statistics are calculated using basic mathematics and statistics measures such as percentages, mean, median, and mode val-

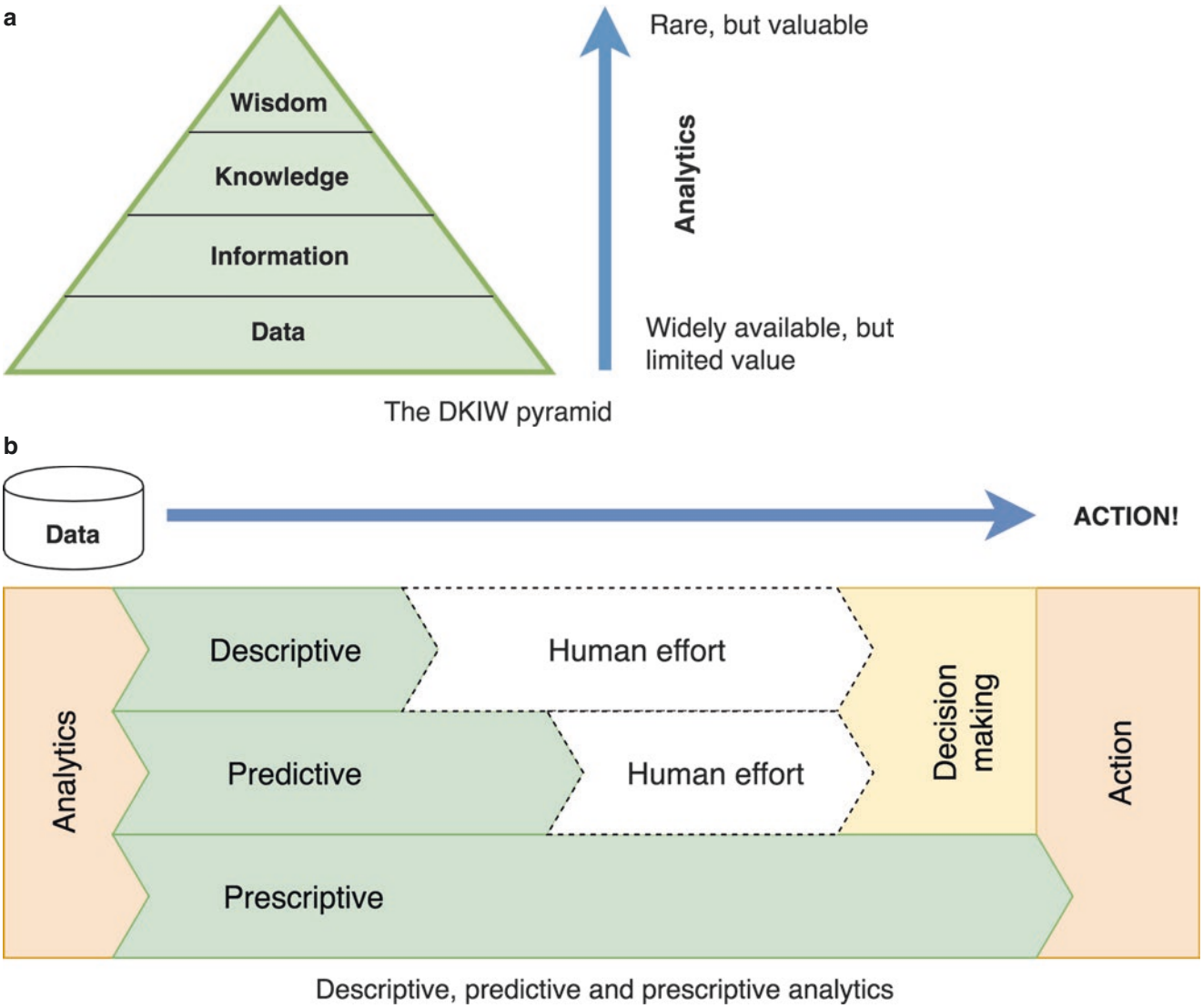

Fig. 16.1 Introduction to fundamental concepts: (**a**) the DKIW pyramid and (**b**) descriptive, predictive, and prescriptive analytics. (**b**) is derived from Gartner Inc's analytical capabilities visualization [1, 11]

ues [13]. These metrics do not allow us to make conclusions beyond the datasets under test or reach conclusions regarding any hypothesis.

Inferential Statistics In contrast to descriptive statistics, Inferential statistics reach conclusions beyond the dataset under test [14]. Inferential statistics uses a random sample of data extracted from a broader population to describe and infer a larger population of interest. As such, inferential statistical methods are essential where assessing all individuals in a patient population is infeasible. In such an event, inferential methods can make generalizations across the broader population of interest. Standard inferential statistical methods include hypothesis tests, confidence intervals, and regression analysis.

Data Sources

Data sources for clinical informatics research can be categorized into *primary* and *secondary* sources. Primary data sources are datasets collected by healthcare providers for the specific purpose of providing healthcare. Most primary data collection activities are performed using Electronic Health Record systems, lab information systems, or other medical testing equipment. Secondary data sources include existing data that were collected for other purposes. There are three main types of secondary data sources for clinical informatics research:

1. **Surveys**. A valid, commonly used method to collect demographic information, personal behaviors, and attitudes. In some cases, data from physical examinations and laboratory tests are collected in addition to these self-

reported data. Surveys are typically utilized to collect data for questions that cannot be answered from other data sources. They can be primary or secondary data sources depending on who collected the data. Generally, surveys are conducted at national (population-based), state, and local levels. These data are collected at a personal or population level, depending on the sampling methodology. Widely used secondary survey data sources include the National Health and Nutrition Examination Survey (NHANES) [15] and the Behavioral Risk Factor Surveillance System (BRFSS) [16].

2. **Registries**. A method to collect data and information on individuals suffering from specific diseases or conditions. The Agency for Healthcare Research and Quality (AHRQ) defines four types of registries [17]: (1) product (i.e., pharmaceutical, medical devices, or diagnostic/therapeutic equipment), (2) health services (i.e., exposure to medical procedures, clinical encounters, or hospitalizations), (3) disease or condition (i.e., all patients have same disease or condition), and (4) a combination of any or all of the above. Data stored in these registries are collected in a standardized, predefined method specific for each registry.
3. **Health services data**. These data are collected as part of the routine healthcare processes. They contain large samples of individualized patient data, including diagnoses, medications, procedures, imaging, and medical notes. The two main types of health services data are administrative claims data and data extracted from medical records. Administrative claims data are data which encode for diagnoses, medications, and procedures for billing purposes. They are coded using standard coding systems such as the International Classification of Diseases (ICD) [18], Systematized Nomenclature of Medicine (SNOMED®) [19], Current Procedural Terminology (CPT) [20], and Logical Observation Identifiers Names and Codes (LOINC®) [21]. However, most data collected during the healthcare process are *unstructured* (i.e., not coded) and exist as free-text, images, or video. Thus, manual medical chart reviews through Electronic Health Records (EHRs) are needed to extract and codify the data before analyses. In the past several years, developments in Natural Language Processing (NLP) and machine learning have shown promise in extracting value from unstructured clinical data. Despite the potential of NLP and machine learning, widespread adoption is limited due to concerns about their overall accuracy, lack of trust by clinicians, and generalizability. There are significant limitations to consider before utilizing health services data.
4. **Big data**. Big data refers to the field of research, methodology, and expertise on the extraction, analysis, and persistence of datasets that are too large and/or complex to be analyzed by traditional methods. Thus, what constitutes big data may be specific to an individual, implementation, or location. Three concepts drive the definitions and assessment of big data, often referred to as the three V's:
   - *Volume* (quantity of data),
   - *Variety* (types of datasets), and
   - *Velocity* (how often the data are being captured/reported) [22].

Big data for clinical care delivery became feasible due to

(a) increasing adoption of Health Information System (HIS) infrastructure, which enabled widespread collection and management of patient-level data,
(b) increased interest in the collection and dissemination of population-level datasets and Geographical Information Systems (GIS) that describe a wide variety of socioeconomic measures, and
(c) reduced technical barriers and costs associated with data persistence and management.

The advent of big data brings new challenges in translating datasets of various quality, quantity, and velocity into actionable information, and ultimately, to knowledge. Big data analytics seeks to leverage improvements in computer science to address these needs. Big data are of significant interest to the clinical informatics domain due to their ability to provide broad insight into various patient health and well-being perspectives.

Data Pre-Processing: What Pre-Processing Steps Are Necessary to Convert a Data Set into a Format Suitable for Analytics?

Any analytical process is only as good as the quality of datasets used. As such, it is essential to ensure that datasets used for analysis are cleaned and parsed to present a concise, valid, and clear picture of the clinical scenarios or patient populations under test. Often, raw data must be transformed into **data vectors**, which can be defined as collections or arrays of numbers structured in a manner that helps an analytical approach identify relationships and patterns within the data.

Introduction to NLP

Natural language processing (NLP) is a domain of AI which focuses on how computers interpret written and spoken human language. NLP is particularly relevant to clinical care initiatives, given that clinical reports consist of up to 80%

Table 16.1 Basic NLP Techniques

Technique	Description	Example
Lemmatization	Grouping together inflected forms of a word so they may be analyzed as a single item.	'Good' is the lemmatized form of 'better.'
Stemming	The task of reducing inflected or derived words into their root form to better identify various uses of a single word.	'Walk' is the stem of 'walking.'
Summarization	Produces a readable summary of a larger block of text.	Condensation of a paragraph or a larger text document into a smaller set of sentences or shorter paragraphs.
Sentence boundary detection	The task of identifying the boundaries (start and end) of sentences from within a larger text document.	Identify that the use of a dot in the term 'Dr. Walker' is intended to abbreviate the term 'doctor' and not intended as a sentence break.
Sentiment analysis or opinion mining	Identify affective states and subjective information used to infer polarity on specific topics.	Identify that the phrase 'negative for cancer' indicates that the patient does not have cancer.
Part-of-speech (POS) tagging	For each word within a sentence, determine the part of speech, such as verbs, nouns, or adjectives.	Identify all nouns and pronouns in a sentence.
Named entity recognition (NER), aka entity identification	The task of locating and classifying named entities into various predefined categories	Identify that 'car' is a type of 'vehicle' and that 'syphilis' is a type of 'illness'.

unstructured data [23]. NLP methods may also be used to augment the quantity and quality of structured datasets. Early attempts at NLP centered on regular expression (regex) based matching, hard-coded rule systems, and decision trees, rigidly tied to specific use cases. As illustrated in Table 16.1, NLP methodology has expanded to support a broader range of techniques.

These NLP techniques should be applied with due consideration to the context they are applied to. For example, noting that a social worker's note refers to a historical (not current) case of homelessness or that evidence of alcohol abuse is linked to the family member of a patient rather than the actual patient plays a significant role in efficient data extraction. While tools and techniques to evaluate the context are available [24], assessing these constraints adds additional complexity to NLP in the clinical domain.

Machine Learning Approaches

The rapid advancement of Artificial intelligence, computer science, and decreasing cost of computational and storage resources has brought about significant awareness of the role of AI-driven methods for decision-making. Increasing quantities of data and the complex nature of decision-making impedes a human expert's ability to make rational decisions based on the datasets at hand. Machine learning approaches enable users to learn from these datasets more efficiently and effectively and apply this knowledge for decision-making. Machine learning efforts can be broadly categorized into *supervised* and *unsupervised* learning approaches.

Supervised Learning Approaches

Supervised learning is an approach where, given input features and an outcome variable of interest, an algorithm can learn the mapping function to convert the input features into the outcome of interest. This is referred to as supervised learning because the outcome variable serves as a gold standard used to guide the algorithm on a learning process. However, using these methods can be costly and resource-intensive as they may require human expert input for defining and preparing a gold standard. Supervised approaches can be grouped into two major categories as described below.

(a) **Classification models** Algorithms that predict a discrete or categorical output variable. Listed below are some widely known classification algorithms:
- **Simple Logistic (SL)** Given a set of training samples with a labeled outcome, SL models develop a logistic function to predict the outcome variable. SL does not rely on assumptions of normality for predictor variables. These models are very simplistic, mainly when few or no interaction terms are used [25].
- **Support Vector Machines (SVM)** Given a set of training examples with labeled outcomes, SVM identifies an optimal hyperplane (a subspace whose dimension is −1 of its ambient space) capable of separating data into each outcome. SVM models work well on small, clean datasets given the ease of drawing clear hyperplanes across these datasets. However, they are less effective on larger, noisier datasets with multiple overlapping classes.
- **Bayesian classifiers** are probabilistic classifiers based on Bayes' theorem, which describes the probability of an event based on prior knowledge of conditions related to the event. This approach assumes that all features in a model are independent and that the presence of one feature does not impact the presence

of another. Given this assumption, their use may be somewhat restricted in the healthcare domain.

- **Decision trees** A supervised learning approach seeks to predict an outcome's value by learning decision rules inferred from the training dataset. Decision trees are simple to interpret and require little data preparation and cleaning. They can also be used for both classification and regression. However, decision tree models may result in overly complex trees that are too tightly linked to training data and do not yield satisfactory performance across other datasets.

(b) **Regression models** Algorithms that predict a numerical continuous output variable. Examples include Simple Logistic Regression and Random Forest Regression. These algorithms mimic their peers in the classification section but are designed to output a continuous variable rather than a categorical value.

In addition, several supervised learning algorithms may be integrated to develop *ensemble models.* As discussed earlier, each supervised learning algorithm poses unique strengths and weaknesses. An ensemble model combines multiple machine learning algorithms into a single predictive model, thereby combining the advantages of each unique model towards the final outcome prediction. Decision trees are traditionally implemented as ensembles consisting of 'forests' of multiple trees. Two of the most widely known ensemble-based implementations are Random Forest [26] and eXtreme Gradient Boosting (XGBoost) [27]. Random Forest builds all trees and then averages the predictions made by each tree, while gradient boosting methods build new trees focused on addressing errors in prior trees.

Unsupervised Learning Approaches

Unsupervised (or clustering) learning approaches are methods where an algorithm learns to model the underlying distribution of data elements given input features but no outcome variable. Such approaches are data-driven and rely purely on the quantity and quality of data used in the training process. Unsupervised methods are relatively easier to train because they do not require the manual cost and effort needed to develop a gold standard. However, this usually leads to weaker performance. Listed below are two widely used clustering algorithms.

- **k-means clustering** An approach that seeks to group each observation into a subset of clusters where each observation belongs to the cluster with the nearest mean value. k-means are one of the oldest and widely used clustering algorithms. They are efficient and straightforward and therefore suitable for large-scale datasets. However, the algorithm cannot pre-determine an optimal number for k, meaning that the best value must be selected via incremental evaluation using multiple k values.
- **Hierarchical clustering** An approach that seeks to build out a hierarchy of clusters. They can be agglomerative (each individual instance starts as a separate cluster, with pairs of clusters merging as instances traverse up the hierarchy) and divisive (all observations start with one cluster, and splits are performed as instances traverse down the hierarchy). While descriptive, this approach is more complex and requires more memory. Thus, it may be unsuitable for larger datasets.

Neural Networks

Neural networks are computing systems inspired by the biological neural networks that constitute animal brains. A neural network consists of layers of connected nodes that are referred to as neurons. Neural networks can be either supervised or unsupervised by nature. Although the principles of neural networks were known for decades, they did not achieve mainstream interest and adoption until large quantities of data and computational processing resources that unleashed their true potential became readily available. At a minimum, a neural network consists of three layers; one input layer, a hidden layer (any layer located between the input and output layers), and an output layer. A neural network with more than a single hidden layer is referred to as a deep learning network. In contrast to other classification systems, neural networks outperform traditional machine learning approaches as the scale of data increases.

Various neural network systems have been implemented in response to a myriad of challenges. However, they are increasingly complex, making them harder to interpret than other classification models. This limits the application of neural networks in certain healthcare domains where the interpretability of a prediction is of significant importance. However, they are invaluable in analyzing images, data streams, and genomic datasets. Currently, neural networks are widely used for various tasks linked to clinical care delivery [28–30]. Listed below are several commonly used classes of neural networks.

- **Convolutional Neural Network (CNN)** A neural network approach focused on challenges involving visual imagery. These are commonly applied to analyzing images or videos.
- **Recurrent Neural Network (RNN)** Neural network approach where connections between nodes form a

Table 16.2 Potential clinical informatics-related use cases and hypothetical analytical solutions

Use case	Potential solution
Predict patient-level hospital readmission rates	Patient-level hospital readmissions may be predicted using existing clinical, behavioral, and demographic datasets and supervised learning [29] or neural network-based methods.
Identifying types of patients most likely to develop opioid addictions.	To effectively address the causes of opioid addiction, it may be useful to identify different subpopulations of patients at most risk. A variety of basic descriptive statistics, risk stratification methods, or more complex predictive modeling approaches may be used for this purpose.
Identification of notifiable conditions for public health reporting	Free text reports may be searched for evidence of notifiable conditions using basic string search functions, regular expressions, or other more complex NLP-driven methods.
Support clinicians in cancer detection	Deep learning models can be trained to detect a variety of cancers using patient CT scans.
Detect drug-drug interactions	A variety of methods ranging from basic rule-based systems to deep learning models and neural networks can be applied to identify potentially harmful drug-drug interactions

directed graph representing temporal sequences, allowing the model to exhibit dynamic temporal behavior. These are commonly used to predict sequences of events such as changing stock prices, patient heart rate, or other sequential measures.

- **Long short-term memory (LTSM)** A form of RNN capable of learning long-term dependencies, thereby enabling it to support sequential predictions. These are applied to similar use cases as RNN's.

Applications of Analytics in Clinical Informatics

In this section, we briefly discuss several use cases where analytics could be applied to clinical informatics. Table 16.2 presents several clinical informatics-oriented use cases that can be addressed using analytics.

Common Pitfalls and Challenges

Some common pitfalls and challenges associated with machine learning are as follows:

- **Overfitting** A decision model is said to overfit if it captures the underlying structure of a dataset too stringently and thus, fails to achieve consistent performance across a different dataset. Overfitting is caused by noise (irrelevant or incorrect data elements included in the dataset) that does not generalize across other datasets. Ensuring that a model does not suffer from overfitting is referred to as *generalization*. To protect against overfitting, models should be trained using broad representative datasets and evaluated across various heterogeneous patient populations.
- **Underfitting** A decision model is said to be underfitting if it cannot adequately capture the underlying structure of a dataset and thus, underperforms against both the current and other datasets. To protect against underfitting, models should be trained using various features that adequately represent a use case under test. Often, researchers must deal with a tradeoff between model overfitting and underfitting in delivering effective models.
- **Class imbalance** In many real-world classification problems, the outcome variable (class) may not make up an equal or reasonable proportion of the dataset. For example, the prevalence of HIV, AIDS, or Rabies may be significantly low across the general population. A classification model may not have enough 'signal' in the training data to deliver adequate predictive performance in such a scenario. Two sampling methods may be considered to address class imbalance; o*versampling* (supplementing the minority class/es with copies of minority instances) and *undersampling* (removing instances of the majority class at random to improve class balance).

Model Training, Evaluation, and Validation

Researchers may select from multiple model training approaches based on the availability of data. Below are three training methods; train and test, cross-validation and train, validation, and test (Fig. 16.2).

Model Training Approaches

- **Train and test method** A dataset is randomly split into two sets, a larger training dataset used to train a decision model and a smaller test dataset used to test the newly trained model. Based on dataset size and quality, a training dataset could range from 70–90% of the original dataset.
- **Cross-validation** A resampling approach where the dataset is split into k many randomly selected subsets, where the user defines the size (k). We randomly choose one of the k subsets as the test dataset while the remaining subsets as training datasets. A model is trained using the (k–1) training datasets and evaluated using the test datasets. This process is carried out k-many times, and performance

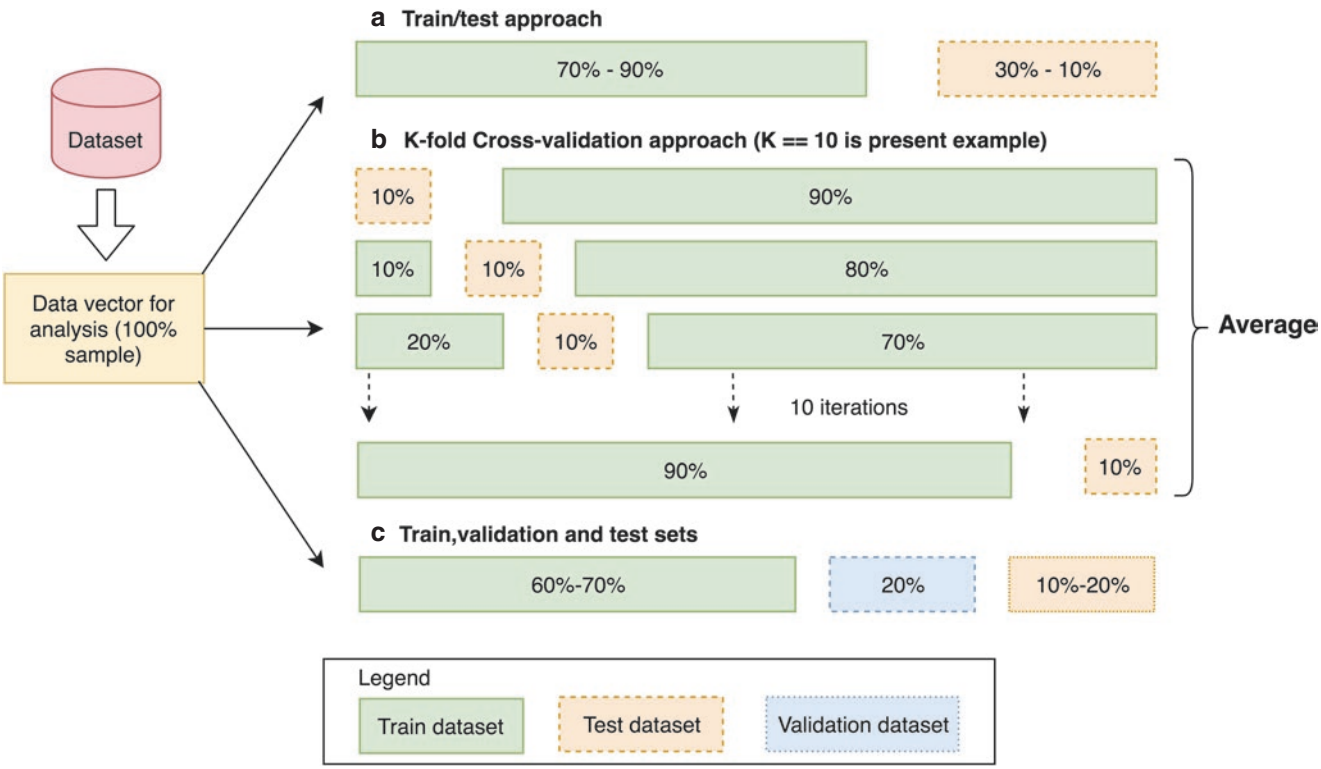

Fig. 16.2 Comparison of various training, validation, and testing methods for maching learning. (**a**) the dataset is divided into training and test subsets. (**b**) the dataset is resampled multiple times using random subsets of data. (**c**) the dataset is divided into training, validation, and testing subsets [1]

results for each iteration are averaged to produce less variable performance results. k = 10 is widely used, but values as small as five may be used based on the dataset at hand. Cross-validation methods are traditionally used on smaller datasets that require optimal use of data for training. However, this approach is vulnerable to overfitting.

- **Train, validation, and test sets.** This newer approach is more suitable for situations where a significant quantity of data is available. The dataset is randomly split into train, validation, and test sets. The training dataset is used to train the decision model. The validation dataset is then used to iteratively test the decision model and update its parameters for optimal performance. Once model parameters have been configured for optimal results, the model is evaluated using the holdout test dataset.

Performance Metrics

It is essential to evaluate the performance of a decision model using a variety of performance metrics.

- *Sensitivity (AKA recall)*: Proportion of actual positives that are correctly identified.
- *Specificity (AKA true negative rate):* Proportion of actual negatives that are correctly identified.
- *Precision (AKA positive predictive value):* Proportion of positive identifications that are correct.
- *F1-score*: Accuracy measure representing the *harmonic mean* (an average used for numbers that represent rate or ratio) between precision and recall
- *The Area Under the Receiver Operator Characteristic curve (AUC ROC)*: The Receiver Operator Characteristic (ROC) is a graphical plot that demonstrates the diagnostic performance of a classification model across various threshold configurations. The AUC ROC score measures the two-dimensional space underneath the ROC curve. Thus, the AUC ROC score can range between 0 (minimum) and 1 (maximum). An AUC ROC of 0.5 indicates that a model has no discrimination power.

It is also essential to identify the most appropriate performance metrics to evaluate model performance given a specific use case. For example, analytical methods that seek to predict the probability of high risk or high-cost events such as mortality or permanent injury should optimize sensitivity to increase the chances of identifying as many patients in need as possible. In contrast, solutions to identify the likelihood of a less risky event may focus on optimizing precision to reduce the burden of false positives on clinicians. Often it is helpful to compare tradeoffs between different perfor-

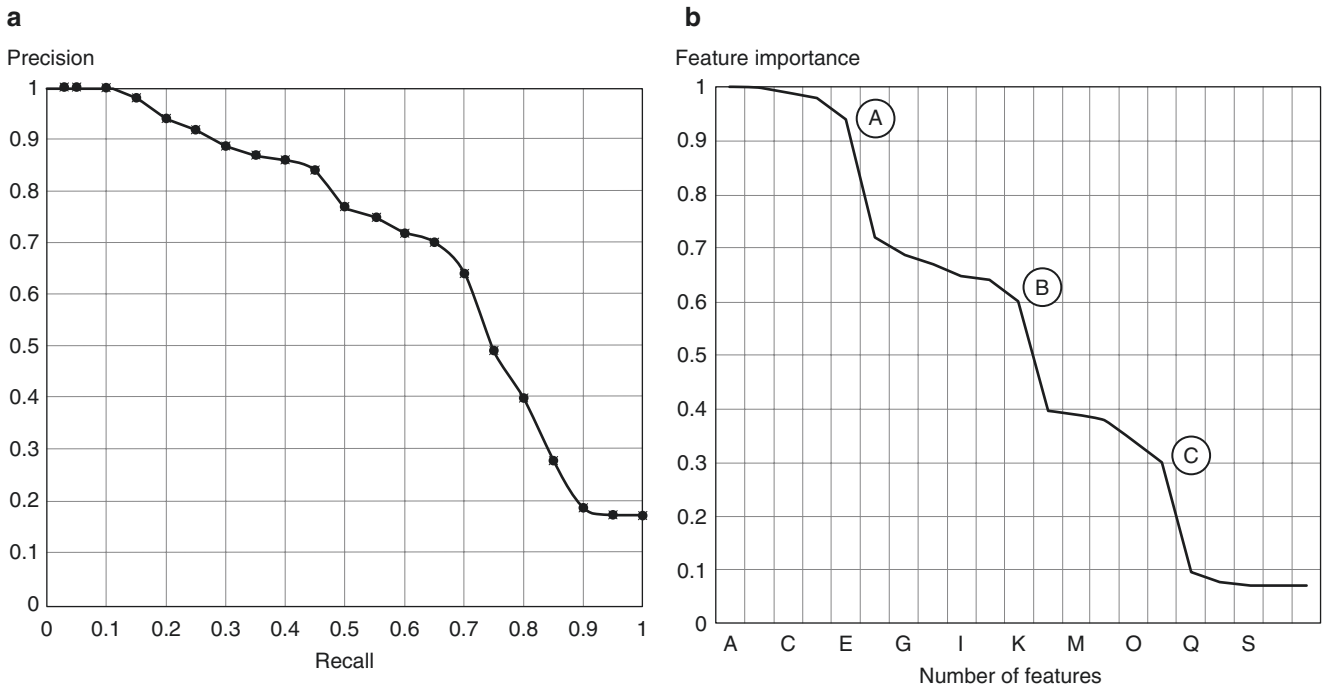

Fig. 16.3 (**a**) Precision-Recall curve demonstrating tradeoff between precision and recall at different cutoff thresholds, and (**b**) feature importance scores for each feature (ranked from the most important to least important). Adapted from [1]

mance measures to select the optimal model. Precision-recall curves compare variations in each metric across different cutoff thresholds, thereby enabling researchers to identify optimal thresholds based on the predictive performance of their choice. The sample precision-recall curve in Fig. 16.3 **(a)** presents variations of precision against recall. For example, this plot informs a researcher that 0.65 is the maximum precision achievable for a recall of > = 0.7. However, the maximum precision for a recall of > = 0.3 is 0.9.

Feature Selection Techniques

Feature selection, alternatively known as attribute selection or variable selection, is the process of selecting the most relevant features with the potential to contribute most towards a machine learning task. Proper feature selection can lead to numerous benefits, including reduced risk of overfitting, improved model accuracy, and reduced model training time and hardware requirements. Primary feature selection can be performed via manual review. A human expert with knowledge on a particular topic manually reviews a list of features and selects a subset of potentially relevant features based on their expertise. However, manual review becomes challenging with larger feature sets and also when investigating a lesser-known domain. Automated feature selection methods can be applied to address these situations. Automated feature selection methods can be classified as filter, wrapper, and embedded methods.

- *Filter methods*: Approaches that apply statistical measures to assign a score to each feature.
  - *Univariate selection*: Selects features with the strongest relationships to the outcome variable.
  - Information gain (AKA Kullback-Leibler divergence) [31]: Evaluates a feature's worth by measuring the information gain to the outcome of interest.
- *Wrapper methods*: Approaches that consider feature selection as a search problem using various combinations of features. Recursive Feature Elimination (RFE) is a greedy optimization (an approach that seeks to make a locally optimal choice at each stage) to identify the feature set with the best model performance by iteratively creating models.
- *Embedded methods*: Approaches that identify which features contribute most to the model's accuracy during its training process. Learning algorithms that support embedded feature selection perform feature selection as part of the model development process. Regularization or penalization methods such as the least absolute shrinkage and selection operator (LASSO), Elastic Net, and Ridge Regression commonly use embedded feature selection methods.

An example of automated feature selection would be when clinical data elements collected from an Electronic Health Record system or Health Information Exchange are being used to perform syndromic surveillance. In such an event, these filter methods can be applied to identify a smaller subset of the most relevant features to be used in machine learning, thereby ren-

dering the models more simplistic, with a lesser risk of overfitting. Further, a model that requires a limited number of features would be easier to operationalize in a clinical setting.

Figure 16.3(b) plots the importance of each feature, as identified by the feature selection method being used. How would a researcher identify the optimal number of features for model development? This depends on the ability to reach suitable performance metrics and considerations on model complexity. Assume that a model trained using the top 25 features (point A in Fig. 16.3(b)) does not yield adequate performance. In that case, expanding to include the top 55 features (point B in the plot) may do so. Alternatively, expanding further to include the top 85 features (point C in the plot) may be necessary. However, the inclusion of additional features results in a more complex model and may risk overfitting. Does the performance increase achieved by expanding to include extra features justify the risk of overfitting and increased complexity for the use case under study?

Model Validation

The core purpose of developing analytical models is to leverage them to predict outcomes for unseen populations. To do so, a model must demonstrate reasonable validity. A model is said to be valid if it demonstrates both internal validity and external validity.

- *Internal validation*: Testing a model's ability to replicate its predictions across the same population used to train the model. Internal validation can be performed by applying a model to a holdout dataset extracted from the original population and evaluating it using the performance metrics listed previously.
- *External validation*: Evaluate model performance against a dataset sampled from an alternative population not used in the initial training process. External validation serves as the gold standard for evaluating decision model performance. Unfortunately, external validation methods are rarely used due to the lack of access to datasets and the cost of performing such validation in the clinical domain.

Risk Stratification and Adjustment

Risk stratification is where clinicians assign patients to different tiers based on factors contributing to adverse health outcomes [31]. Different stratification methods may be selected based on each use case; as an example, one method might prioritize patients in most need (are sickest), while another may prioritize patients who are most likely to improve with care. Stratification methods result in distinct groups of patients with similar complexity and care needs. They help providers identify and mitigate patients' risks, effectively allocate healthcare delivery resources, and prioritize care for the right patients. In the most basic terms, risk stratification can be performed by using descriptive statistics to identify levels of risks and care needs based on patient demographics and the presence of chronic conditions. However, more successful approaches to risk stratification rely on complex predictive analytics [32] and phenotyping methods [33]. Risk stratification approaches are critical given value-based healthcare, which seeks to improve care outcomes while eliminating inefficiencies and reducing costs.

Data Visualization

Health systems process and analyze vast quantities of diverse datasets at a rapid pace. Effective mechanisms are needed to communicate the results of such analysis in a concise, easily understandable manner. **Data visualization** is an interdisciplinary field that integrates statistical and computing skills with design skills to enable the graphic representation of data and information. It helps reduce the burden of decision-making using complex datasets.

Basic types of health data visualization methods include various types of charts, tables, maps, scatter plots, timelines, and infographics created using various office application packages such as Microsoft Office or Apache Open Office. Alternatively, 3-Dimensional (3D) visualization techniques are widely used in clinical informatics to offer a clear rendering of the functionality of complex organs such as the human heart and aid in the diagnosis and effective delivery of various oncology, cardiology, and neurology procedures. Alternatively, geospatial visualization techniques can integrate relevant clinical or health information to geographic locations such as latitude and longitude, census tract, zip code, county, state, or country [34].

Data dashboards that incorporate one or many of these methods are used to visualize more complex datasets and interpretations in an easily accessible manner. Such dashboards may represent operational data (operational dashboards), presenting a real-time assessment of the use case under test, or strategic dashboards, representing trends or changes over time. Powerful, specialized tools such as Tableau or Power BI are widely used to create interactive dashboards or may be updated in real-time or at regular intervals. Notably, a variety of such dashboards were developed in response to the COVID-19 pandemic. Examples include dashboards built atop Indiana's statewide health information exchange for population-level surveillance and in support of pandemic response efforts across communities [35], as well as dashboards developed by Johns Hopkins University to provide timely information on COVID-19 cases and deaths worldwide [36].

Emerging Trends

The future of AI, particularly in the healthcare domain, continues to evolve in response to significant technological advances, uptake of tools and information systems, and emerging awareness of its value in driving healthcare delivery and outcomes. We highlight several notable trends in the clinical analytics domain.

Democratizing Access to Datasets for Effective Analytical Efforts

Widespread adoption of HIS has resulted in increased efforts to collect and curate clinical data. However, regulatory frameworks enforced by many countries limit the sharing of protected health information outside healthcare organizations. Limited or burdensome data access hinders the reproduction, sharing, and re-use of machine learning solutions across larger audiences and restricts inter-organizational collaboration addressing various healthcare challenges and building generalized machine learning models targeting diverse populations.

Efforts to enable better access to data include creating standardized data lakes with tools for effective access, use, and analytical efforts. Such attempts include the Observational Health Data Sciences and Informatics (OHDSI) initiative [37], a multi-stakeholder collaborative which seeks to improve health by empowering a community to collaboratively generate evidence that promotes better health decisions and better care, and currently boasts access to 600 million patients spread across 30 countries [38], as well as the National COVID Cohort Collaborative (N3C), which seeks to bring together clinical data and expertise from across the US to answer critical research questions to address the COVID-19 pandemic [39]. Other efforts involve using advanced analytical approaches such as Generative Adversarial Network (GAN) models to create large, realistic synthetic datasets that mimic original data sources but offer limited risk of re-identification [40, 41].

Awareness of Biases Present in Analytical Models

Most datasets used in healthcare research are not originally collected for research purposes [42, 43]. Such datasets are susceptible to **biases**, defined as systematic errors caused by prejudiced decision-making, poor representation of vulnerable populations, and incomplete data collection errors [44, 45]. Biases place privileged groups at a systematic advantage over unprivileged groups [44].

If used for analytics, such datasets may lead to the garbage in - garbage out problem [46], resulting in biased models harmful to vulnerable populations such as racial and ethnic minorities, older adults, or persons with special healthcare needs [47–49]. Biases can also be harmful to individuals with negative Social Determinants of Health (SDoH), defined as conditions in which people are born, grow, live, work, and age [50]. Such biases may present significant harm to patients and result in legal penalties and negative attention to healthcare systems [44]. There is increased awareness of the need to effectively identify and mitigate biases present in analytical models via effective data collection and curation methods that improve data quality and other analytical methods that improve fairness in models trained using messy data.

Summary

The popularization and adoption of analytical approaches for the healthcare domain continues at a rapid pace. To keep up with these advances, clinical informaticians must obtain a firm grounding in the fundamentals of analytics and the potential limitations and challenges that must be overcome to build and maintain robust analytical solutions. This chapter provided (a) a detailed description of the nature of data, information, wisdom, and knowledge, (b) key definitions associated with data analytics, (c) introduction to various machine learning algorithms, their advantages, and limitations, and (d) various evaluation methods to assess analytical performance. To support clinical informaticians in leveraging these lessons for practical use, it also included content on practical considerations, limitations, and challenges that may impede the implementation of AI tools in support of clinical care delivery. These lessons serve as steppingstones for researchers who wish to become familiar with the current analytics domain and support self-learning to keep up with the latest advances.

Questions for Discussion

1. Contrast various predictive performance metrics and identify clinical scenarios where you may favor one over the others. How would you explain these choices to your clinical team?
2. Contrast neural networks, classification algorithms, and clustering algorithms. In which use cases would you prefer each of these methods over the others? Why?
3. Identify common pitfalls and challenges of applying data science and analytics in clinical practice. How are emerging trends in clinical analytics addressing or bypassing these limitations?

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Cybersecurity in Healthcare

17

Bryan C. McConomy and Dennis E. Leber

Learning Objectives

- Describe the importance of cybersecurity in healthcare.
- Classify laws that involve data privacy and computer hacking.
- Differentiate methods of cyber-attacks and software employed to carry out attacks.
- Compare cybersecurity risk mitigation techniques.
- Develop a cybersecurity risk assessment and mitigation plan for an organization.

Practice Domains: Tasks, Knowledge, and Skills

- K001: Security threat assessment methods and mitigation strategies
- K002: Security standards and safeguards

Case Vignette

As hospitals were combating the coronavirus pandemic, another challenge was in the path. Healthcare systems around the United States faced ransomware attacks from a group known as UNC1878 or Wizard Spider [1]. A German hospital was attacked by ransomware which disrupted emergency services. A patient had to be routed to a hospital farther away and died. An investigation ultimately led to the conclusion that negligent homicide was not present, but it is likely a matter of time before ransomware leads to the death of a patient [2]. Cyber-attacks have become increasingly commonplace over the past decade and are now a multi-billion dollar industry internationally. Quick profits for the attackers and difficulty prosecuting these cases internationally mean that cybersecurity has to be a significant facet of all health systems.

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Introduction

Adopting a myriad of electronic components into the healthcare sector, including electronic health record (EHR) systems, has elevated the importance of cybersecurity in healthcare. In 2013, a report found that 94% of health systems had been the victim of a cyber-attack, and the number of attacks has steadily risen [3, 4]. It is estimated that there are 10–15 connected devices per bed in a hospital, allowing for multiple points of attack [5]. Although earlier attacks focused on credit transactions, cybercriminals have realized the value of hacking healthcare data [4, 6]. A data breach per record cost is estimated at $408 for healthcare and $206 and $170 for the financial and technology sectors, respectively [7]. Further, healthcare data has a high degree of necessary interoperability since it is shared with insurers, other clinicians and health systems, government entities, business associates, and patient portals allow for multiple access points to hackers [6, 8, 9].

Unsurprisingly, there has been a rise of attacks on healthcare systems, including breach of millions of patient records from Anthem and the WannaCry cyberattack on the Nation Health Service in 2017 [10, 11]. The WannaCry ransomware attack cost over £90 million and required a major overhaul of the NHS's information systems [10]. The ransomware exploited computers running older versions of Windows operating systems and systems that were not updated with the latest security patches. Hackers do not just attack large entities but also smaller health systems. Hollywood Presbyterian Medical Center in Los Angeles fell prey to *Locky* ransomware crippling their operations for a week before paying $17,000 in Bitcoin [12]. These are just a few examples of many cyberattacks that have become a major source of money for hacking groups and nation-states [13]. A retrospective study by Ronquillo et al. analyzed publically available data on data breaches (involving a compromise of 500 patients or more) from 2013 to 2017. During this time, 1512 incidents were affecting over 150 million patient records [14]. A total of 128 EHR breaches occurred, with

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25% of them through hacking, but accounted for 87% of the exposed patient records [14].

Cybersecurity in the healthcare sector has not kept pace with the amount of risk to organizations. Often, healthcare systems have not invested money and human capital into securing their computer systems [8, 15]. Most health information technology (HIT) budgets account for 4–7%, whereas other sectors spend around 10–14% of the total budget on cybersecurity [7, 8]. Healthcare executives may purchase cybersecurity systems without proper vetting, and many organizations have not developed a formal cybersecurity program or have a leader charged with an information security responsibility [16]. Surveys have found that only 40% of C-level executives show proficiency in cybersecurity mitigation techniques, and interaction between the Chief Information Security Officer (CISO) and senior leadership to be lacking [16]. The lack of investment leads to healthcare systems continuing to use antiquated legacy systems (e.g., Windows XP), which are vulnerable to attack [15]. Highly trained cybersecurity professionals are in short supply; thus, attracting top talent is difficult for most organizations [15–17]. Increasing reliance on networks to connect healthcare technology once been standalone-alone becomes yet another target for attack [8].

Laws Impacting Healthcare Information Privacy and Cybersecurity

Laws and policies regulating healthcare information privacy and the cybersecurity landscape are directed toward hacking, cyber-attacks, inadequate security affecting consumers, information privacy, and directives to improve cybersecurity resilience. A full explanation and detailed review are beyond this chapter. Still, we aim to provide information on many laws that informaticians should be familiar with and the impact on a healthcare organization.

Federal Trade Commission Act

One may not think of the Federal Trade Commission (FTC) Act as having much of anything to do with cybersecurity in healthcare since it was signed by Woodrow Wilson in 1914. Still, the FTC has interpreted Section 5 of this Act to regulate data security [18]. Section 5 mentions the prohibition of "unfair or deceptive acts or practices in or affecting commerce" through unfair (will substantially harm the consumer and consumer is unable to reasonably protect themselves) or deceptive practices (representation, omission, or practice misleads the consumer) [19]. The FTC considers the healthcare industry to be commerce, thus giving the FTC jurisdiction to bring enforcement actions against entities that fail properly secure consumer data or are not truthful about the degree of data security in the privacy policy or statements to consumers [18]. In 2016 a dental software company was fined by the FTC for misrepresenting their data security while using an inferior non-industry standard patient record encryption which the FTC considered to be a deceptive practice [20]. Several state-level data security statutes exist and could impact informaticians. It is incumbent on the informaticians to seek guidance on the local law in their geographic region.

Computer Fraud and Abuse Act

Congress first began debating how to address the legal issue of individuals attempting to commit untoward acts through unauthorized access to data on computers in the early 1980s [21]. In response, Congress passed the Comprehensive Crime Control Act of 1984 Section 1030, which made unauthorized access of classified information a felony, and access of financial records or credit information stored in a financial institution a misdemeanor [21]. Further debate in Congress led to the development of the Computer Fraud and Abuse Act (CFAA), signed into law in 1986. This law was written to limit jurisdiction to cases involving federal computers, certain financial institutions, and interstate crime [21]. Over the past three decades, over a half dozen amendments have been made that expand the scope of the law [21]. The CFAA added seven different actions to the penal code, (1) obtaining National Security Information, (2) accessing a computer and obtaining information, (3) trespassing in a government computer, (4) accessing a computer to defraud and obtain value, (5a) intentionally damaging by knowing transmission, (5b) recklessly damaging by intentional access, (5c) negligently causing damage and loss by intentional access, (6) trafficking in passwords, and (7) extortion involving computers [18, 21]. Over time, interpretation of the CFAA has expanded to include harms from loss of data confidentiality and/or integrity [18]. The other side of the coin is that the CFAA can prohibit companies from "hacking back" or aggressively pursuing perpetrators.

Cybersecurity Act of 2015

Rising numbers of cyber-attacks came to be viewed as a national security issue. Congress passed the Cybersecurity Act of 2015 to coordinate cybersecurity functions of the Office of the Director of National Intelligence and the departments of Energy, Commerce, Homeland Security, Defense, Justice, and the Treasury [22]. The Act directed

federal agencies to create procedures to share important cyber threat information with groups under threat of attack (e.g., state and local governments, health care, and critical infrastructure). Section 405 was specific to the health care industry and tasked the Department of Health and Human Services (HHS) to provide a report to Congress regarding cybersecurity readiness of the healthcare sector and convene a 1-year task force of healthcare industry stakeholders, cybersecurity experts, and federal agencies to develop an information-sharing plan free of charge to recipients [22]. Further, HHS must create a unified, healthcare-specific, and voluntary cybersecurity framework through coordination with the Department of Homeland Security, healthcare industry stakeholders, and the National Institute of Standards and Technology (NIST) [22].

HIPAA

The Health Insurance Portability and Accountability Act of 1996 was a monumental law for healthcare. The spirit of the law was to improve the portability and continuity of health insurance coverage, decrease healthcare spending and fraud, and improve access to long-term care services and coverage. HIPAA defined health plans, healthcare providers, and healthcare clearinghouses as "covered entities" and a person or organization performing a function or service to a covered entity that involves patient information as "business associates" [23]. The act was multifaceted, but from a cybersecurity perspective, the act sets forth regulations for the privacy and security of patient information, defined civil penalties for failure to comply with regulations, and applies to covered entities and business associates. The U.S. Department of Health and Human Services (HHS) published their Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) in 2000, amended it in August 2002, and required compliance by April 14, 2004. The Privacy Rule defined "individually identifiable health information" as protected health information (PHI) which included, (1) past, present, or future physical or mental health or condition, (2) care delivered to the individual, (3) past, present or future payment for care received by the patient [23].

In February 2003, HHS published the final Security Standards for the Protection of Electronic Protected Health Information (the Security Rule) that established national standards for protecting PHI held or transferred in electronic form (e-PHI) [23]. The Security Rule was enacted in response to the move away from paper to new electronic solutions. The general rules were "to maintain reasonable and appropriate administrative, technical and physical safeguards for protecting e-PHI." [18, 23] The Security Rule does not dictate the specific measures for the spectrum of organizations (e.g., single provider to large multi-state health plans); however, each entity must take into account their size and capabilities, hardware and software infrastructure, cost of security measures and potential for breach of e-PHI [23]. The administrative portion mandates that organizations perform a risk analysis process and document vulnerabilities and mitigation techniques implemented. Administrative safeguards include limiting access to e-PHI, designating a security official, providing workforce training, and evaluating administrative procedures. Physical and technical safeguards to be implemented are limiting facility and workstation access, perform e-PHI access audits to look for unauthorized e-PHI access, ensure that e-PHI is not improperly destroyed, and implement security measures that protect e-PHI transfer over electronic networks [23].

HIPAA did not define technical standards that an organization must adopt but does mandate that an organization investigate and implement policies and procedures to ensure privacy and security of PHI, and failure to do so would lead to hefty civil penalties. The civil money penalties originally set forth by HIPAA were $100 per violation and up to a maximum of $25,000 in a calendar year. In contrast, the criminal penalties were a fine of up to $50,000 and 1-year imprisonment [23]. The criminal penalties are harsher (up to $100,00 fine and 5 years imprisonment) if the violation was under false pretenses, and more severe if the violation involved the intent to sell, transfer or use PHI for "commercial advantage, personal gain, or malicious harm." [23] From 2008–2018, the five highest HIPAA violations settlements ranged from $4.3 million to $5.5 million [24]. Some have argued that the civil penalties are overly punitive and do not translate to improved adherence or outcomes [18].

Gramm-Leach-Bliley

Healthcare is not the only industry that routinely deals with sensitive personal information. The financial sector also has a significant amount of personally identifiable information (PII) or nonpublic personal information (NPI) that cybercriminals want to exploit. The Gramm-Leach-Bliley Act (GLBA) or Financial Services Modernization Act was signed into law by Congress in 1999. It was intended for financial institutions to explain their information-sharing practices to the consumer and safeguard information [25, 26]. Many in healthcare do not realize that the wording of the GLBA places healthcare under its umbrella. If a health system offers long-term payment plans with interest or sends patient information with a third party (e.g., credit reporting agency), then the health system is considered "significantly engaged" and needs to comply with the regulations in GLBA [25].

A health system is responsible for adhering to 3 facets of GLBA: a Privacy Rule, a Safeguards Rule, and a Pretexting Rule [25]. Complying with the Privacy Rule includes the health system notifying the patient of the organization's privacy policies. If NPI is shared with a third party, the patient must be given the option to "opt-out". Further, the patient must be given a "reasonable" way to opt out in a "reasonable" amount of time before sharing NPI [26]. The Safeguards Rule is put in place by the FTC (16 C.F.R. Part 314) and mandates that the health system have measures in place to safeguard NPI and ensure that affiliates and service providers also have safeguards in place [26]. An organization should create and implement a written information security program (WISP) which details the administrative, technical, and physical safeguards for NPI [25]. Within the WISP, an organization must have a plan to mitigate outside individuals from obtaining NPI under false pretenses to satisfy the Pretexting Rule [25, 27].

HITECH Act

The passage of the Health Information Technology for Economic and Clinical Health Act (HITECH) in February of 2009 profoundly affected the uptake of EHRs and provided incentives to meet "Meaningful Use" standards. HITECH pertains to cybersecurity in Sect. 13402, which mandates covered entities and business associates under HIPAA to report breaches of unsecured protected health information (PHI) [28]. Unsecured PHI is defined as "protected health information that is not secured through the use of a technology or methodology specified by the Secretary in guidance" [28]. Suppose the breach results in a compromise of <500 patient records. In that case, the covered entity or business associate must notify affected individuals within 60 days and notify HHS of the breach within 60 days of the end of the calendar year in which the breach occurred [28]. If 500 or more individual records are compromised, individuals, a prominent media outlet serving the state or jurisdiction, and HHS within 60 days [28]. Breaches of encrypted or destroyed and unreadable information need not be reported.

The HITECH Act also expanded on the civil and criminal penalties originally outlined in HIPAA. Business associates are now directly liable for compliance with HIPAA regulations. There are further limitations on the use and disclosure of PHI for marketing, fundraising, and prohibition of selling PHI without individual authorization [29]. Four different tiers of culpability and placed increasing penalties based on the infraction tier. The culpability tiers range from no knowledge (tier 1) to willful neglect without corrective action taken by the covered entity (tier 4). The maximum penalty is $50,000 with an annual limit of $1.5 million for all tiers [30]. However, this was amended in 2019 to annual limits of $25,000, $100,000, $250,000 and $1.5 million for tier 1, 2, 3, and 4, respectively [31].

GDPR

The General Data Protection Regulation (GDPR) was set into motion in May 2018 in countries part of the European Union (EU) [32]. Albeit this law does not have legal implications within the US, healthcare organizations that conduct business in EU member countries are affected, and this legislation may influence future health data privacy regulations in the US. The GDPR is an overarching data protection framework for all data use contexts compared to the US, where data privacy is regulated by sector (e.g., healthcare or financial). GDPR does not cover anonymized data [32]. GDPR regulations pertain to controllers and processors that collect, use, disclose or process personal data. A controller is an entity that collects data and determines how the data is used. This is akin to a covered entity in HIPAA [33]. A processor is an entity that the controller gives data to perform an action or service (e.g., data analysis). This could be thought of as a business associate under HIPAA [33]. Personal data is considered any information that could identify an individual. This includes not only personal information but also data such as IP addresses and cookie identifiers [32, 34]. GDPR (Article 9) also defines eight special categories of sensitive personal data with race or ethnicity, genetic data, health data, and sexual orientation being most pertinent for a healthcare organization [32]. This regulation aims to ensure that individuals understand why their data is being collected and how the data will be used. Controllers must be transparent with the purpose of the data, minimize the amount of data collected, ensure data accuracy, keep the data secure and specify the period of time data will be stored [32]. An individual must give consent for data acquisition, and the controller must make the consent process unambiguous, and the individual must be able to rescind consent [34]. It is possible to process data if the consent is unable to be obtained if it meets another lawful basis such as contract, legal obligation, necessary to save a person's life, performing a task in the public interest, or another legitimate interest. The individual does have the right to erasure ("right to be forgotten"), but this is not an absolute right. For example, the right to erasure does not apply for public health purposes or if the processing is necessary to provide health or social care [34].

Health systems providing treatment to an EU citizen in the US need not comply with GDPR because the GDPR

covers EU citizens located in the European Economic Area (but is subject to HIPAA). If an EU physician requested records from a US physician, GDPR would not apply here either since the US physician is not providing a good or service. In this instance, a US health system or entity that obtains personal data from an EU citizen over the internet, GDPR is applicable [33]. Although this regulation is meant to create a more uniform data protection framework for the EU, it does not describe a minimum level of security or technical standards that must be met to remain in compliance. Rather, it mandates that organizations take appropriate measures to manage risk, design robust cybersecurity systems and appoint a Data Security Office (DSO). The DSO is responsible for monitoring compliance with GDPR, train staff, and provide advice on data protection. The DSO must report to the highest level of management [34].

Anti-Kickback Statute and Stark Law

The Anti-Kickback statute, originally signed into law in 1972, prohibits offering, soliciting, or receiving anything of value to preferentially attract referrals from medical professionals [35]. The Stark Law was passed in 1989 and was intended to prevent physicians from referring Medicare or Medicaid beneficiaries (does not apply to private insurers) to another practitioner or medical establishment for which the originating physician has a monetary relationship [35]. This impacts cybersecurity because health systems are reticent to accept cybersecurity assistance or donation from other health systems for fear of violating these laws. A 2017 report published by the Health Care Industry Cybersecurity Task Force recommended that these laws be modified in a manner such that large healthcare organizations are permitted to share cybersecurity resources and information with their partners [36]. Allowing for the sharing of resources allows smaller health systems to bolster their cybersecurity by accepting assistance from industry or larger health systems and not fearing financial repercussions.

DEA Electronic Prescription of Controlled Substances

The impetus for prescribing medications in a readable electronic format from the point-of-care to the pharmacy began with the Medicare Modernization Act of 2003. It was supported by the 2006 Institute of Medicine's report on e-prescribing medications to reduce medication errors [37]. E-prescribing of controlled substances (EPCS) had not been allowed until the Drug Enforcement Agency (DEA) amended regulations in 2010 to allow for e-prescribing [38]. However, to use EPCS, the practitioner must be registered with the DEA (as enforced by the Controlled Substances Act), and the practitioner's identity must be verified [38]. The amendment allows healthcare organizations to perform their own identity verification, and from there, multi-factor authentication must be used (e.g., password, smart card, fingerprint, mobile authentication application). An institution must also have "logical access controls" in a place where the institution limits the ability of EPCS to only those that have privileges under the Controlled Substances Act [38]. Protecting user identities and preventing the ability of cybercriminals from usurping mechanisms in place to prevent illegal prescriptions is important.

California SB-327

An emerging threat to cybersecurity in healthcare is the rise in popularity and abundance of devices that are a part of the 'Internet of Things'. In response, California passed Senate Bill 327 in 2018 that took effect January 01, 2020, and required manufacturers of connected devices sold in California to comply with new security provisions [39]. This law applies to any primary or contracted manufacturer that sells their device(s) in California. A connected device is defined as an object that connects to the internet directly or indirectly (e.g., accessing the internet on the paired device) and is assigned an IP or Bluetooth address [39]. Manufacturers must have "reasonable security features" to prevent unauthorized use and not allow weak default login credentials (e.g., 'password' or '0123').

Methods of Cyber-Attack

It is difficult to know exactly the most common forms of attack since not all breaches are reported. Several studies have investigated publically available data from the Office of Civil Rights record of breaches involving more than 500 records and conclude that attacks on network servers are in the minority but lead to the largest number of records compromised [14, 40, 41]. Classification of cybersecurity threats has been proposed based on attack technique, threat impact, and hybrid models [42]. Jouini et al. recently proposed a branching multidimensional hybrid model that divides cyber-attacks by security threat source, threat agent, threat motivation, intent, and impact [42]. In this section, we will discuss types of cyber-attacks and the software employed to carry out attacks as described by Bhuyan et al. [43], summarized in Table 17.1.

Table 17.1 Delineation of cyber-attacks and malicious software types that commonly plague healthcare enterprises

Types of cyber-attacks
DoS
Privilege escalation
Cryptographic attack
SQL injection
Eavesdropping

Malicious software
Virus
Trojan horse
Ransomware
Worms
Phishing/spear-phishing/watering holes

DoS denial of service, *SQL* structured query language

Types of Cyber-Attacks

Denial-of-Service

A malicious actor generally carries out Denial-of-Service (DoS) attacks by inundating a host network with traffic preventing the host from responding or leading to a system crash, thus preventing users from accessing the system [43–45]. Several forms of DoS exist, such as smurf attack, SYN flood, buffer overflow, teardrop, and amplification attack [44, 45]. Increasing internet-connected devices has given rise to distributed denial-of-service (DDoS) attacks. Cybercriminals carry out DDoS attacks using botnets. A botnet is a group of compromised internet-connected devices controlled by a cyber-criminal and can flood a network with requests and leading to DoS. Even more concerning is the ability for low-skilled hackers to "rent" botnets to carry out a DDoS [44].

Privilege Escalation

Access controls prevent unauthorized persons from changing security settings and are a method to mitigate IT system compromise. However, hackers can carry out privilege escalation attacks in which they circumvent these controls through software vulnerabilities or gain control of an employee's credentials [43]. There are two different types of privilege escalation attacks, vertical and horizontal. A vertical attack occurs when the hacker can gain access to the account and perform actions as that person (e.g., a hacker sends an email impersonating a bank stating that you must click the link in the email and log in to keep the account active) [46]. The horizontal attack is slightly more involved but starts the same as a vertical attack and gaining access to an account. The hacker then uses more advanced software to exploit software vulnerabilities to gain higher access to the system [46].

Cryptographic Attack

A cryptographic attack is rather straightforward. The cyber-attacker attempts to use cryptography to decipher encrypted patient data. To transmit PHI over email and remain HIPPA compliant, enhanced encryption such as Advanced Encryption Standard (AES) must be used. A report from Intertrust, which evaluated mobile health apps, found that 91% of apps evaluated fail cryptographic tests [47]. This is especially concerning given the rapid rise in personal health applications and the internet of things in healthcare.

SQL Injection

Websites and medical records utilize Structured Query Language (SQL) to retrieve information from the database to display to the user. Suppose there are vulnerabilities in the application leading to no validation or scrutiny of the input. In that case, hackers can inject their own SQL code to change the parameters and request as much data as possible from the database. Not only can the parameters be changed, but the database can be modified such that data is inserted or altered [43, 48].

Insider Threat

An insider is a person that has access to an organization's sensitive information, networks, facilities, etc. The National Insider Threat Task Force has defined an insider threat as "the risk an insider will use their authorized access, wittingly or unwittingly, to harm their organization. This can include theft of proprietary information and technology; damage to company facilities, systems or equipment; actual or threatened harm to employees; or other actions that would prevent the company from carrying out its normal business practice" [49]. An insider threat can involve inappropriate access of patient information, such as a hospital employee that inappropriately accessed 1309 records between 2016 and 2017 or a hospital employee in a Texas hospital that created a botnet from computers and devices within the hospital to compete with other hackers [7, 50].

Man-in-the-Middle (MITM) or Eavesdropping

Healthcare data has to be shared between organizations, payers, third parties, and more. The transfer of information is vulnerable to a Man-in-the-Middle (Eavesdropping) attack. This occurs when a hacker has inserted themselves as a silent pass-through for the data flowing between two parties [45]. Hackers can gain access via an unencrypted WiFi access point, spoofing, address resolution protocol attack, and several more. Spyware is also another method of carrying out this type of attack. Encryption and hashing make deciphering the content stolen by the hacker extremely difficult and can also notify the receiver if the message has been altered [51].

Social Engineering and Phishing

Many of us have opened an email that looked a bit off but appeared to come from the IT department. The email stated

that our credentials would be revoked unless we confirmed our employee information and conveniently placed a hyperlink to direct us to the correct URL. You hover over the link and are about to click until you notice that it is trying to direct you to a .ru top-level domain. This is an example of social engineering and phishing. Social engineering is the art of deceiving a person (and, in this case, usually a healthcare employee) to divulge private information or perform an action that compromises security [45, 52, 53]. Social engineering is a form of human factors interaction that allows for technical hacking methods [52]. Phishing is the pursuit of obtaining passwords, usernames, and other privileged information, usually through email, and is a form of social engineering [54]. The example above is how about 78% of phishing emails appear to hospital employees [45]. Spear-phishing is a targeted form of phishing in which the attack is tailored for a specific person, and whaling is an attack on a high-level official or C-suite executive [45, 54]. When the unsuspecting victim clicks on the link, opens the attached file, or enters privileged information, the opportunity for ransomware, worms, viruses, and Trojans is present.

Organizations are working to boost their employees' cyber hygiene by performing phishing attacks to raise awareness of this type of attack. For example, a healthcare organization in the UK performed phishing attacks for 1 month, but no privileged information was gained. In addition to testing, email and internet traffic was monitored. The organization received 858,200 emails during the testing period, of which over 18,000 emails (2.2%) were suspicious [54]. Gordon et al. performed 20 different phishing campaigns and found that 65% of individuals that received phishing attempts from all campaigns clicked on at least two emails [55]. A retrospective review of phishing simulations found that employees clicked 14.2% of almost three million emails [56]. An important finding of many studies is that the more simulations are performed by an organization, the click rate on phishing emails decreases showing the value in being proactive in elevated cyber hygiene [54].

Malicious Software "Malware"

Virus

A virus is a bit of software (often an executable file) that can self-propagate between computers; however, to activate the virus, it takes user activation akin to a person's finger initiating the chain reaction of a series of dominoes falling [43].

Spyware

While a user often realizes that their system has been infected by a virus rather quickly, spyware is intended to be installed and run in the background without the user's knowledge. The goal of spyware is to transmit a user's actions and data to the hacker over an internet connection. Spyware often degrades the performance of a system due to it using resources to collect and transmit data [43].

Ransomware

An increasing number of attacks on healthcare organizations involve ransomware. This malware is designed to encrypt and/or deny access to the user's computer system until a ransom is paid. This type of malware was made famous from the attack on the National Health Service in the UK. As with many other types of malware, it takes activation from a user, typically from social engineering and phishing. Unfortunately, paying the ransom does not guarantee full use of the system again and restoration of data [43, 57]. Mitigation efforts specifically designed to limit the impact of a ransomware attack include backing up data and configurations and storing offline, segmenting networks to limit the amount of parallel spread, limiting privileges, apply patches and updates immediately, have a plan in place before a ransomware incident and asking for assistance from CISA, FBI and Secret Service in the event of a ransomware attack [57].

Worms

A worm is considered a type of virus but differs in that it does not require a user to initiate the program. Worms will spread from computer to computer, take up considerable system resources, and infect systems through social engineering or software vulnerabilities [43, 58].

Trojans

Trojan malware is designed to appear as a legitimate piece of software or an attachment in an email. It does not use a host software like viruses or worms and does not self-replicate. Hiding inside the Trojan is a virus, worm, or code that will allow hackers to have a "backdoor" into the system [43, 58].

Mitigation Techniques for Healthcare Cybersecurity & NIST Cybersecurity Framework

Mitigating cybersecurity risks requires resources. Resources include budget, knowledge, staff, and programs. The organization must prioritize mitigations to minimize the risks that impact the mission and goals of the business. A proven strategy for mitigation is aligned with best practices and security frameworks such as the NIST Cybersecurity Framework (NIST CSF). Mitigation strategies are paired with additional strategies creating a defense-in-depth security program.

Nefarious actors, also known as advanced persistent threat actors, nation-state actors, and criminal hackers, continually seek new tactics. The following mitigations are foundational, time-tested, effective steps to treat risks, but

mitigation is a living, breathing program, and the assistance of your cybersecurity leadership is required. Mitigating controls are both administrative and technical. Administrative controls are the policies and procedures your organization develops that support your risk appetite and goals. Because policies vary from organization to organization, this section focuses on the technical controls that are ubiquitous.

Updates
Keeping software and hardware up to date provides the most effective and simplest mitigation against risks. Attackers invest tremendous resources in seeking out and exploiting vulnerabilities and instantly begin to search these weaknesses out shortly after patches are released in hopes of finding software and machines not yet updated.

Equally important is managing the solutions provided by and managed by vendors or third party providers. The recent Solar Winds hack highlights the importance of validating the authentication of these updates entering your enterprise. A solution obtained by a vendor can still provide a delivery agent for infection.

Privileged Access
Criminal hackers target administrators who possess privileges to obtain their credentials via phishing attacks, hacking efforts, guessing based on social engineering, and other tactics so they may move freely through the enterprise and achieve the goal(s) they have. Privileged access is mitigated through adopting a least privilege approach; meaning giving folks just enough access to do their job, using privileged access management (PAM) solution that automates credential management and access control, and through tiered administrative access where each higher tier provides additional rights but is limited to fewer staff.

Certified Software Execution
Operating systems (OS), known to most as Microsoft, Linux, and other brands, require software to run and execute commands. Mitigating the risks of nefarious applications is accomplished through application allow and deny lists and signed with trusted certificates and execution policies that accommodate better controls. The recent Solar Winds hack presents another example of the importance and that all controls still pose risks. The hackers in this attack accessed the Solar Winds infrastructure and deployed malicious software through the trusted supply chain and delivery mechanism.

Disaster Recovery (DR) Planning
Preparing for breaches and attacks requires the ability to recover. Keeping your business running is paramount to success and essential to patient safety. Cybersecurity is patient security. Time must be allotted to create, review, and test a recovery plan. Elements foundational to such a plan include protection of critical data, configurations, backups, and logs. Backups must be encrypted, kept in triplicate, in separate locations, and protected from the disaster that requires their use. DR plans must be viewed as a living document and adapted as changes occur to your enterprise and/or new risks are presented that impact your organization.

Inventory
Take an inventory of all devices and software. This accommodates the ability to manage your enterprise. Working from this baseline reduces the attack surface and establishes control of the same. This enables the ability to identify and remove unwanted, unneeded, or unexpected devices and software that pose a risk to your organization. This provides the same control as the application allow list; a device allows program alerts to the anomalies in your environment and allows treatment.

Continuous Monitoring/Threat Hunting
Taking an active effort that detects, contains, and removes malicious presences in a network vastly reduces risks. Adopt a mindset of not if or even when but assume that a hacker is already inside your organization. There are several tools to assist and automate this mitigation step. Passive detection is obtained through logs, security information and event management (SIEM) tools, Endpoint detection and response (EDR) tools, and security orchestration, automation, and response (SOAR) tools, to name the top solutions.

Other resources such as active pursuits include threat hunting programs and penetration testing (PenTesting). The development of proactive programs transitions the organization to a mature, real-time detection and remediation strategy.

Use Built-in Modern Security Features
Modern hardware features include Unified Extensible Firmware Interface (UEFI) Secure boot, trusted platform module (TPM), and virtualization. Older hardware must be refreshed with a plan to refresh regularly. Modern hardware works to increase the integrity of the bootup process, provide system attestation, and support high-risk application containment.

Segregation of Networks
Separate critical networks and services, paired with application-aware network defenses that block improperly formed traffic and restrict content based on policies and regulatory requirements. The separation of networks reduces the ability for a successful attacker to move freely across your enterprise and access critical data and systems.

Reputation Services
Reputation services aid in detecting and preventing malicious events while allowing for a rapid response to threats. These services provide access to numerous sources of information that accommodate robust threat analysis in a multi-

channel sharing collaborative. There are numerous tools available that automate and correlate this for an organization. These tools are both free and paid subscriptions. They include H-ISAC, REN-ISA, MS-ISACA, InfraGard, and many others.

Multi-Factor Authentication (MFA)
All-access to organizational data and services must be behind multi-factor authentication. There are numerous solutions for MFA, and your organization must evaluate which solution best protects your business and enables folks to work. Multi-factor consists of supplemental knowledge-based factors such as passwords paired with a physical-based authentication system.

Security Awareness Training
Most organizations require annual security awareness training. This usually consists of a presentation about not clicking links, phishing attacks, and governing policies. Anything type of awareness which arms your users to remain diligent but unafraid is better than doing nothing and throwing your users into the deep end and hoping they know how to swim. Developing a human factors-based awareness program that incorporates behavioral analytics and adjusts to trending risks and activities provides a robust return on training investment. Your users are your first defense in the defense-in-depth, also referred to as a layer defense strategy. Remember the statement; people, processes, and technology, and people are listed first for a reason.

Following good cyber hygiene and best practices greatly reduce the risk to your organization. Remember that nothing replaces a good cybersecurity strategy, program, leadership, and staff backed by the organization and resources.

NIST CSF [59]

Several cybersecurity frameworks provide ample controls that aid in securing your organization. The National Institute of Standards and Technology (NIST) developed a widely accepted framework through a public-private partnership, the cybersecurity framework (CSF), simply known as the NIST CSF. The NIST CSF easily maps to all other frameworks and regulatory requirements, making it easy to demonstrate compliance regardless of the measurement.

About NIST CSF
The CSF is based on existing standards and guidance, particularly the NIST 880–53 (current version), to manage and reduce cybersecurity risks. An attractive feature of NIST CSF is the design to foster discussion between internal and external stakeholders with a common language.

The framework contains three components: The Core, Implementation Tiers, and Profiles. The Core defines the desired cybersecurity outcomes and guides the organization in managing risks. The Implementation Tiers puts into context how the organization considers the appropriate level of effort for their program and sets the foundation for discussions on risk appetite, priority, and budget. The Profile aligns the requirements and objectives, risk, and resources measured against the desired state of cybersecurity the organization sets to achieve.

The CSF contains five functions: Identify, Protect, Detect, Respond, and Recover. The functions are the foundational elements of the success of a cybersecurity program. Directly from nist.gov, the five functions are described as:

Identify
The Identify Function assists in developing an organizational understanding to managing cybersecurity risk to systems, people, assets, data, and capabilities. Understanding the business context, the resources that support critical functions, and the related cybersecurity risks enables an organization to focus and prioritize its efforts, consistent with its risk management strategy and business needs.

Protect
The Protect Function outlines appropriate safeguards to ensure the delivery of critical infrastructure services. The Protect Function supports the ability to limit or contain the impact of a potential cybersecurity event.

Detect
The Detect Function defines the appropriate activities to identify the occurrence of a cybersecurity event. The Detect Function enables the timely discovery of cybersecurity events.

Respond
The Respond Function includes appropriate activities to take action regarding a detected cybersecurity incident. The Respond Function supports the ability to contain the impact of a potential cybersecurity incident.

Recover
The Recover Function identifies appropriate activities to maintain plans for resilience and restore any capabilities or services that were impaired due to a cybersecurity incident. The Recover Function supports timely recovery to normal operations to reduce the impact of a cybersecurity incident.

The NIST CSF provides a plethora of information on its implementation and use. We highly encourage you to visit Framework Documents | NIST (www.nist.gov/cyberframework/framework). All organizations must review, evaluate, and determine what framework facilitates meeting their goals and missions then develop the resources and roadmap.

Emerging Trends

Internet of Medical Things

The internet has allowed the incredible connection between ourselves and the technology we use daily. Devices we use daily are no longer tethered with a cord for interaction but rather use the internet and APIs. These devices are considered to be the Internet of Things (IoT). It was estimated that there would be approximately 50 billion devices networked and connected by 2020 [60]. Unsurprisingly, the healthcare sector is now littered with a myriad of Internet of Medical Things (IoMT). One estimate puts the number of connected devices in hospitals to be 10–15 million in the US [61].

All IoMTs consist of essentially three layers; perception, network, and application layers [62]. The perception layer is the data collected by the device. The network layer is the process of transmitting data collected in the perception layer to the application layer. The network layer may consist of middleware, wired and wireless protocols. The application layer is how the end-user interacts with the data collected in the perception layer [62].

Patients using the Animas OneTouch insulin pump were warned about a security vulnerability in which hackers could take control of the pump. A known hacker, Barnaby Jack, demonstrated the possibility of a hacker taking control of a Medtronic insulin pump to deliver a lethal dose [15]. IoT developers are known for producing products with weak cybersecurity measures due to rushing these products to the market [63, 64]. The Mirai botnet DDoS attack in 2016 exemplifies IoT manufacturers' lackadaisical approach to cybersecurity. Three college students developed malicious software that scanned sought out open Telnet ports used for IoT devices. To penetrate the device, the software used a brute force attack to gain access using a list of 61 different combinations (e.g., admin or root 12,345) [65]. Once the device was overtaken, it could be used for DDoS attacks. These examples show healthcare organizations' vulnerabilities as new patient monitors come to market and become integrated into the EHR. Governance around IoMT is an evolving issue, and informaticians should lobby the industry to improve the security of devices.

Blockchain and its Application in Healthcare

Blockchain is often discussed in cryptocurrency and has spread to other industries (e.g., financial) [54, 66]. The power of Blockchain is in its ability to have a decentralized distributed ledger serving as the source of truth and automated logic that reduces transaction costs [66–68]. The ledger is not stored on a single server, so all participants can view transactions. There are public and private Blockchain instances. A public Blockchain is open to the public (e.g., Bitcoin), while a private implementation requires invitation (which would require a central authority), and the identity of all participants is known [67, 68]. Further, encryption is the cornerstone of its utility in healthcare since clinical data needs to be portable and secure. Blockchain links data together through the use of cryptographic hash such that the hash of the most recent block is dependent upon the prior block [69]. If someone were to try and alter one of the blocks, then the hash would change for the downstream block, and it would be obvious that tampering was attempted. A user must have a digital signature that provides an audit trail of transactions to add to the chain [66].

Gaynor et al. posit that Blockchain could be used in 3 main categories for healthcare, (1) data, (2) smart contracts, (3) and supply chain [66]. Having a decentralized ledger to securely store patient data would be useful for recording healthcare transactions in a patient's record, as well as health information exchanges (see Fig. 17.1). However, in its current state, Blockchain could not handle all the different types of medical data [66, 68]. Public health informatics could be augmented by using de-identified data in Blockchain to analyze emerging trends.

The second category, smart contracts, would include patient-provider relationships, clinical trial research, genomics, and more. A smart contract is a piece of code stored in the Blockchain that can execute an action (using if/when… then logic) when predetermined conditions have been met [70]. For example, readings from an insulin pump could be written into Blockchain and then uploaded to the patient's record in the EHR through an application programming interface (API). The transaction is faster because there is trust between the insulin pump wearer and the EHR record, and no intermediary is required to input the data into the patient's record.

The healthcare supply chain spans medications, organs, implantable devices, blood products, and wearable devices. Using a Blockchain ledger allows multiple parties to track the location and use of these products, which lowers coordination costs [66]. It is important to note that this technology remains in the proof-of-concept phase. Blockchain has size limitations and can become computationally challenging with a large volume of transactions. It has not been well studied that Blockchain meets the regulatory standards in the US or Europe with the GDPR. Health systems would need to agree on data standards for full interoperability, which is a significant hurdle currently. Lastly, the need for a private Blockchain implementation with a central authority to determine participants eligible to read and write to the ledger means

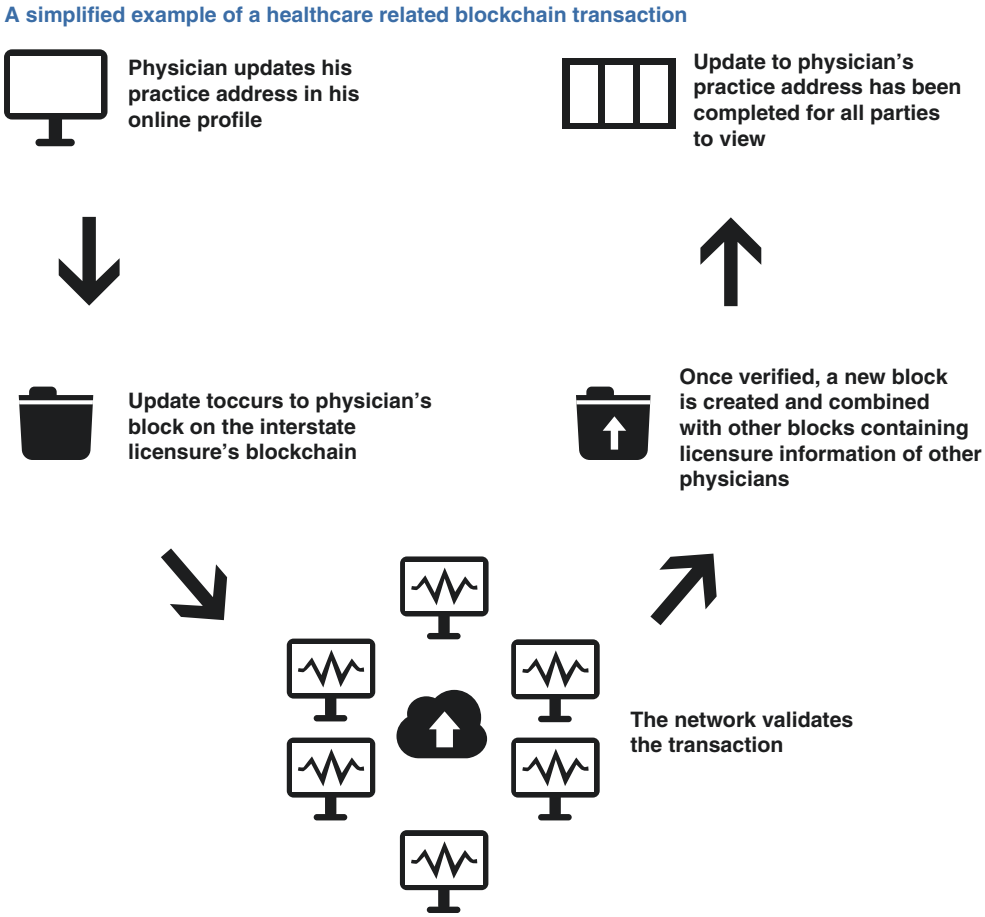

Fig. 17.1 Example of how Blockchain could assist in storing patient medical records, adapted from [68]

that compromise of this central authority via cyber-attack places privacy and security at risk [67].

Artificial Intelligence and Cybersecurity

Artificial intelligence (AI) began in the 1950s, and with the increase in computing power, it has advanced at a rapid pace [71]. Machine learning, decision trees, support vector machines (SVMs), k-nearest neighbor (k-NN), and artificial neural networks (ANN) are all different mathematical models that aim to classify internet traffic and/or software as legitimate or nefarious [71]. Security researchers can train these various models in a laboratory setting to learn and develop patterns that discriminate legitimate activity from cyber-attacks. The power in using AI for cybersecurity is that AI can rapidly ingest and process more data than humans and monitor for aberrant activity. Several security firms have created algorithms that can recognize malware, malicious code, and suspect network traffic to protect against cyber-attacks [72]. Methods of attacks on healthcare systems will continue to evolve, and AI is a tool that can adapt to these threats rapidly.

Twenty-First Century Cures Act

The twenty-first Century Cures Act was originally signed into law on December 16th, 2016, by President Obama [73]. At a high level, this Act was intended to modernize and standardize health technology to put patients' needs first. This section cannot cover all the sweeping changes it entails but will introduce a few key concepts and concerns from the healthcare community. The Act's goals include allowing patients to access their medical records via a smartphone app, improving transparency into cost and the outcome of their care, improving the transfer of data between EHRs, revising criteria for EHR certification, and preventing blocking of data from the patient [74]. However, implementation of the Act has been slow due to ambiguities of the text, rapid timeline for implementation, among other issues [75]. Furthermore, dates for compliance have been extended due to the Coronavirus pandemic. The Sequoia Project has provided significant comments on the law, including the desire for the ONC to heed feedback from clinicians and developers, set realistic implementation timelines, clarify definitions of access, exchange, use, electronic health information, and health information exchange versus health information net-

work [75]. The final rule does require that Application Programming Interfaces (APIs) use the Fast Healthcare Interoperability Resource (FHIR®) from HL7® [74]. Implementation of the rules in this Act is changing how healthcare systems are sharing data with patients and other organizations, and informaticians should familiarize themselves with these regulations to adhere to proper privacy standards.

Questions for Discussion

1. As a newly hired CMIO, how would you assess the organization's cybersecurity readiness?
2. Health-related connected devices (e.g., fitness trackers, blood pressure monitors, continuous glucose monitors, etc.) are becoming ubiquitous in today's healthcare landscape. How might you mitigate the security risks they pose?

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Telehealth

18

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Learning Objectives
At the end of the chapter, the reader should be able to:

- Describe four telehealth modalities.
- Identify policy considerations that impact telehealth uptake and ongoing use.
- Describe practical considerations for telehealth use.

Practice Domains: Tasks, Knowledge, and Skills

- **K051** Concepts and tools for care coordination
- **K053** Health information technology landscape (e.g., innovation strategies, emerging technologies)
- **K085** Telehealth workflows and resources

Case Vignette
As the first surge of the novel coronavirus became apparent, hospitals started providing Wi-Fi connected tablets to the inpatient and emergency departments staff for use during their clinical care. The separate inpatient floors and emergency departments were given education on the use of the tablets, e.g., how to turn on/off, how to place a 'call' with a patient. During this first pandemic, there is anxiety everywhere you looked in the hospitals. Each floor and emergency department took the tablets and did their own things with them. Some put them on iv poles. Others had cases that held the tablets on the patient bedsides.

There was an initial rollout of the tablets in the emergency department with the same education as those who brought the tablets to the clinical areas. Providers innovated with how they would use the tablets, such as interviewing a patient outside the room and decreasing the time spent examining patients who potentially were infected with the novel coronavirus. These tablets were thought to help conserve Personal Protective Equipment and potential exposure of clinical staff. It became apparent that there were gaps in the education and use of the tablets. First, providers started to complain that they were hoping to use the tablet; however, it pointed away from the patient. Other providers were asking about the best practices in using the tablets. There also were concerns about potential inequality around who could adjust their clinical work to use the tablets and who performed work that could not use this tool but had to expose themselves more than their colleagues. While ideally, workflows and education would have been figured out before rolling out these tablets, the urgency of the surge of the new and mostly unknown virus, decisions were made to provide the technology without evidence or plans for how best to use the devices.

Introduction

The purpose of this chapter is to provide an overview of telehealth. Telehealth is known by several names, such as virtual care, telemedicine, or connected care [1]. Use of the term varies but generally refers to interactive electronic information sharing for healthcare [1–3]. The uses for healthcare include direct patient care, provider to provider communication, and support. We will use the term telehealth broadly to cover a range of uses.

Telehealth can improve outcomes by improving access to care and enhancing **provider-to-provider communication** [3]. Improvements in both access to care and access to expertise can improve the quality of care delivery. Much of the United States has many providers of different types in large

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urban centers with fewer providers in rural areas. Telehealth can help provide consistent care throughout the country [4]. Provider-to-provider interaction can be improved by using technology to provide education and access to expertise that may not be accessible locally. Provider-to-provider interactions include education, consultation, care coordination, and case reporting.

Telehealth can improve access to care by **connecting providers and patients** who are not co-located. This saves patients from the burden of traveling great distances to see a provider in person [5], or if patients in urban centers lack transportation or availability during providers' office hours.

There are four primary types of telehealth [6]:

1. Synchronous or **real-time video visits** are essentially videoconferencing, though there are provisions for audio-only visits for special circumstances such as the coronavirus pandemic. These real-time interactions can be provider-to-patient or provider-to-provider. Examples include a real-time video-enabled urgent care visit where the patient is at home and the provider is in her office. These visits are also referred to as *virtual care* visits.
2. **Remote patient monitoring** involves using devices to monitor patients from a distance. Providers receive information from devices, such as continuous glucose monitors, and make changes to the care plan from a distance.
3. Mobile health or **mHealth** involves using the various applications and smartphones that are patient-facing to facilitate care or provide education. Examples include sharing patient-generated health information such as steps captured on a wearable or sending medication reminders to patients with diabetes.
4. **Store and forward** telehealth applications are asynchronous. This type of telehealth typically involves a provider reviewing an electronic transmission of patient health records sent from either a patient or a provider and sending recommendations or orders for the patient. Two of the most common examples include radiologists reviewing imaging studies that are not real-time and electronic consultations between a primary care provider and a dermatologist.

Each type of telehealth uses a different technology and has different organizational and policy considerations. The rest of this chapter will address considerations with telehealth implementation and use.

Telehealth and the Coronavirus Pandemic

Once the coronavirus pandemic spread across the United States, interest in telehealth increased. The rapid acceleration in its use was due to the need for physical distancing to prevent the novel coronavirus's spread and preserve healthcare facilities' capacity. As a result, many policy changes were made to promote virtual care.

The payor landscape changed significantly during the pandemic. The Centers for Medicare and Medicare Services (CMS) changed the physician fee schedule to expand reimbursement for telehealth [7]. Many private payers and state Medicaid agencies followed suit [1, 8, 9]. Reimbursement changes included expanding the type of reimbursable services, provider types who were eligible for telehealth reimbursement, and removal of geographic restrictions [9–11].

Expansion of the services included remote patient monitoring for both new and established patients and remote check-ins and visits via video or phone [7, 10]. Provider type expansion included reimbursing providers such as clinical psychologists, licensed clinical social workers, and speech-language pathologists for services via telehealth. Geographic expansion of the reimbursement policies increased the use of telehealth in both rural and non-rural areas as well as allowing the site of care to be the patient's home [7, 10].

Other changes included removing barriers to providing treatment. The Office of Civil Rights, which is responsible for HIPAA enforcement, temporarily allowed for consumer-facing technologies such as FaceTime and Skype to be used for visits so that providers could quickly implement video calls with patients [12]. Before the pandemic, providers were required to use secure platforms that met stringent HIPAA-compliant standards. Similarly, the Drug Enforcement Administration (DEA) activated the public health emergency exception to the Ryan Haight Act to prescribe controlled substances, including those used for Medication-Assisted Treatment of Opioid Use Disorder, via telehealth without an in-person exam [12].

Telehealth generally requires internet access, and there were policy efforts made to expand connectivity throughout the United States. The Federal Communications Commission offered grants to expand connectivity and encouraged telecommunications companies to keep people connected [13]. Similarly, the United States Department of Agriculture also invested in broadband in rural areas [14].

Overall, these updates resulted in an increased number of telehealth visits across payors. However, there was an initial sharp increase, followed by a decline [11]. In addition, the efforts did not address patient-related barriers to access, such as digital literacy and internet access [15]. Other items to address included providing organizational support so that providers know how to implement telehealth effectively [16]. Telehealth visits remained above pre-pandemic levels with generally high levels of patient satisfaction [17].

Practical Considerations with Telehealth

There are several aspects to consider when one wants to implement the tool telehealth. These considerations include service selection, organizational changes, and patient and provider acceptance of the modality.

As for service selection, this includes selecting the appropriate telehealth modality for the healthcare delivery challenge. Part of the decision-making must consider the limitations of the telehealth tool selected, the patient, and its feasibility. For certain conditions that require touch or palpation as part of the physical examination, it is unlikely that remote patient monitoring and health or an asynchronous visit would be appropriate. Depending on the physical exam that's required, even a video may not be appropriate for this patient. It may be difficult to perform a visit with a patient who does not have consistent access to the internet for patient characteristics. Depending on what technology is available to the patients, health conditions may increase the risk of morbidity. Any telehealth modalities would be safe to use in such high-risk patient populations. However, as technology advances and remote monitoring devices become more commonplace, patients or patient conditions who would not have safely been seen via telehealth in the past may one day have their entire inpatient hospital stay in their own home. Current limitations of telehealth are being mitigated by other workflows, such as video visits being enhanced by community paramedics who can be present at the patient's house during a video call, with the chance to obtain a robust set of vital signs and perform point-of-care laboratory testing and treatments.

The feasibility of a telehealth program depends on many factors, from the resources available to purchase software and/or devices, the human resources to oversee and providers to care for these patients virtually, to the ability to receive compensation for telehealth care. While reimbursement opportunities have increased during the COVID-19 public health emergency (PHE), it remains uncertain what telehealth reimbursement will be the PHE has ended. While there has been working through CMS to make some telehealth reimbursement permanent, these discussions are ongoing.

A successful telehealth program relies on secure and dependable technology and appropriate workflows for the use of such technology in clinical care. Workflows must include how telehealth care is going to be integrated into the care model. Such considerations in the workflows include if the providers will be seeing patients only virtually or if the telehealth care will be interspersed in an in-person clinic with one patient via telehealth and the next patient seen in person. Another example of workflow consideration is when a patient becomes unstable and how care is escalated. While many healthcare systems or healthcare practices considering telehealth may initially be concerned about how expensive the technology may be, they must realize that the most expensive aspect of the program will be the compensation for the providers and administrators of the program. Also, while many administrators and providers envision telehealth as an opportunity to improve burnout by enabling a provider to work remotely from a busy in-person clinic or hospital, the workflows for telehealth care must be thoughtfully created to not unnecessarily contribute to burnout. Poor workflows can lead to poor provider and patient experience and likely poor care.

Before the PHE and during the rapid acceleration of telehealth during 2020, many telehealth programs were started without formal integration into the local electronic health record. This has created situations where many telehealth programs are using multiple applications to provide telehealth care. For example, a virtual urgent care program may be running on one application for the ability to queue up unscheduled patients, obtain their payment and insurance information, and connect with live video with provider; however, this patient's documentation for the allowable reimbursement must be documented in the local electronic health record. Yet another telehealth service in the same program may use a different software application for the video connection and chat-based communication between the providers separate from the local EHR and its required documentation. To add to the providers' frustration, double documentation may be required with documentation in the telehealth application AND the local EHR.

Telehealth enables patients to be remote from the provider while receiving care, and it also enables the providers to be remote from the typical work office. If providers are working remotely from the clinical office, they will still need support for their telehealth activities, whether technical support or devices. There is no standard across the United States for remote telehealth providers regarding devices (e.g., computer, internet connection, tablets, phones); typically, providers use their own home devices and home Internet connection to provide telehealth care. When telehealth providers are not working remotely from a clinic, they may work separate telehealth shifts and see no patients in person, or there may be a mix of in-person and remote patients. The best format for this is still unclear, and thus will why attention to workflows are critical to the successful program.

Typically, telehealth video visits are not recorded and archived; however, patient-generated data used for clinical decision-making should be documented in the EHR. Similar to the lack of integration with telehealth care and the EHR, patient-generated data and mHealth programs still have gaps in how they are integrated into the EHR. Many opportunities exist in informatics to integrate telehealth care with the EHRs. As for health information exchanges (HIE), unless the telehealth visits and remote patient monitoring data are doc-

umented within the local EHR, HIE does not pull telehealth-specific data.

Patient and provider acceptance of telehealth has been mixed. This is not unsurprising, as telehealth, in general, is multifaceted, and depending on the implementation, there could be varied perceptions on its usefulness. After a year of increased telehealth care in the PHE, it appears that patients have been quite satisfied with telehealth and many patients hope that their providers continue to offer telehealth services after the pandemic [17]. Providers, in general, have seen the usefulness of telehealth; however, many may choose to go back to in-person care only. While there may be many reasons for this, such as opportunities for higher reimbursement for in-person care or frustration with the lack of integration of the applications, there is a potential for the patient demand to continue the growth of telehealth.

While telehealth has the potential to increase access to care for patients, it also can increase healthcare inequalities. Sometimes the inequalities occur because a telehealth program requires a smartphone to report patient-generated data or conduct a video call. Other applications may require a patient to have a certain broadband speed that may not be available for some patients. Some telehealth programs cannot care for non-English speakers or patients with certain disabilities. While designing programs, care must be taken to account for how the program may exacerbate access issues and find ways to remedy these issues.

Emerging Trends

Telehealth has many possibilities into the future, with new care models coming onto the scene. For example, integrated mobile health (MIH) community paramedicine programs with specially trained paramedics go to a patient's home and treat the patient in place while under video medical direction with a physician or advanced practice provider. Telehealth innovations in care delivery will include episodes of care that are substitutive for in-person care and ways to augment or enhance the current in-person care models. More reimbursement opportunities likely will emerge for telehealth as more evidence demonstrates where the value in telehealth lies. Broadband access will increase, and technology will inevitably improve and likely become less expensive.

It will not be surprising that the policy landscape will be changing drastically over the next few years as more and more experience with telehealth informs these decisions. One of these policies may be the creation of a 50-state medical license. Before the PHE, providers could only provide care to patients within the state where the provider has a medical license, restraining the growth of telehealth practices. The Interstate Licensure Compact, which at the time of this writing includes 17 states within the United States, allows telehealth providers to care for patients in states within this compact. Credentialing by proxy may become more widespread throughout the United States. Telehealth providers caring for patients in a healthcare facility (including skilled nursing facilities) must be credentialed at that facility. Credentialing by proxy allows a facility to recognize the credentialing provided by another institution, decreasing the source verification and other necessary credentialing processes. Reimbursement policies will continue to evolve as new care models involve using telehealth. The medical, legal aspects of care will also continue to evolve. Currently, there are risk management concerns that legal defense teams could choose to use the laws in the jurisdiction of either the patient's or provider's location during the telehealth encounter, even if the provider has the appropriate medical licensure to conduct the call.

Summary

In summary, while telehealth has been available for decades, it has seen an accelerated rise during the coronavirus pandemic. Telehealth can solve several challenges in the healthcare system, as well as enhance the care process. Telehealth also can make things more disjointed, exacerbate inequalities in access to care, and worsen burnout. The thoughtful application of telehealth is key. There are several opportunities in informatics to improve telehealth, including system integration of telehealth into electronic health records.

Questions for Discussion

1. What are the types of telehealth?
2. What are the parameters for telehealth service selection?
3. What is the role of telehealth for acute versus chronic care?

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Part IV

Leading and Managing Change

Leadership Models, Processes, and Practices

19

Robert C. (Bob) Marshall

Learning Objectives

- Identify and discuss common leadership principles, models, and methods in contrast to those with management.
- Identify how effective negotiation and conflict management strategies methods and techniques are critical to the role of an informaticist placed in a supervisory position.
- Provide guidance on motivational strategies, methods, and techniques that will help you get the most out of your team and allow everyone to be successful.
- Provide guidance on the methods needed to appropriately and effectively assess how well your training and competency development achieve the goals set out for the people you supervise and the organization as a whole.

Practice Domains: Tasks, Knowledge, and Skills

Domain 5: Leadership Models, Processes, and Practices—Tasks and Knowledge Areas

- T5.03. Participate in the development of organizational health informatics goals, strategies, and tactics in alignment with the mission and vision of the organization
- T5.04. Improve care delivery and outcomes and advance the mission of the organization through effective communication, negotiation, and conflict management
- T5.05. Build support and create alignment for informatics best practices to ensure all stakeholders are active, visible sponsors of informatics within their respective roles
- T5.08. Engage, educate, supervise, and/or mentor clinicians and other healthcare team members in their use of clinical informatics tools, systems, and processes
- K118. Strategy formulation and evaluation
- K119. Approaches to establishing Health Information Technology (HIT) mission and objectives
- K123. Negotiation strategies, methods, and techniques
- K124. Conflict management strategies, methods, and techniques
- K128. Motivational strategies, methods, and techniques
- K131. Leadership principles, models, and methods
- K133. Coaching, mentoring, championing, and cheerleading methods
- K134. Adult learning theories, methods, and techniques
- K135. Teaching modalities for individuals and groups
- K136. Methods to assess the effectiveness of training and competency development

Case Vignette

George Linksys has split his time between clinical practice and clinical informatics as a 0.5 FTE in the Clinical Informatics Department. He recently applied for and was selected to become the Chief Medical Informatics Officer (CMIO) for the hospital. In his new role, he leads a department of 30 people…trainers, clinical workflow analysts, data analysts, and two other clinical informaticists. Due to potential budgetary realignment, he has been tasked with evaluating both the value of the training his department provides and devising a way to assess competency development both within his department and within those departments his people train. He has also been assigned to develop and implement a governance process that will require all departments to submit new software application requests and any equipment purchases that come with software through the governance process. This will put him at significant risk for conflict with various department heads and require solid conflict management and negotiation skills. This will require solid leadership skills to ensure success for everyone, including the organization as a whole.

Introduction

This chapter focuses on multiple necessary skills that fall under the general heading of leadership. It begins with laying out different leadership models that have been accepted

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within business and industry and differentiates those from management models, which are also essential skills but different than leadership. Organizational culture is covered because your effectiveness as a leader is often dependent upon the organization's culture in which you work. If you do not understand your organizational culture, it is doubtful you will be effective as a leader. We then go on into subcategories of leadership skills such as negotiation, conflict management, and motivational strategies. We then delve into the realm of training effectiveness and competency development, which are essential to both develop and measure. It is also crucial to determine what competencies are required to succeed both within and outside the informatics realm. Finally, we touch on emerging trends in leadership principles, which gives you an idea of how leadership changes over time and how you might need to change due to changes in workforce composition, worker expectations, and the need to lead virtual teams with new technology tools.

Definitions of Leadership/Leadership vs. Management/Leadership Models

There is not a single definition of leadership. In this chapter, we use a combined definition drawn from multiple sources:

1. Leadership is a process of social influence in which a person can enlist the aid and support of others in a small group or an entire organization to accomplish a joint task/mission [1].
2. Leadership involves the following: [2]
   (a) Establishing a clear vision
   (b) Sharing that vision with others so they will follow willingly
   (c) Providing the information, knowledge, and methods to realize that vision
   (d) Coordinating and balancing conflicting interests of all members and stakeholders

Leadership vs. Management

Management is a set of well-known, well-defined processes, such as planning, budgeting, structuring, staffing jobs, measuring performance, and problem-solving. These processes help organizations to predictably do what they know how to do and do them well. Management helps an entity produce products and services of consistent quality, on budget, day after day, week after week. This is a difficult, complex task; however, it is not the same as leadership.

Leadership is associated with taking an organization into the future, finding opportunities that are coming at it faster and faster, and successfully exploiting those opportunities. Leadership is about vision, people buying in, empowerment, and producing useful change. Leadership is all about behavior, not attributes. In the ever faster-moving world of today and the future, leadership is increasingly needed from more people, no matter where they are in the organizational hierarchy [3]. See Fig. 19.1 for a summary comparing leadership and management traits/behaviors [4].

Leadership Models

Leadership models may be defined as guides that suggest specific leadership behaviors in particular environments or situations. There are multiple leadership models in the literature with various research and internal/external validity levels to support them. Some of the more common general models include the following: **leadership/managerial grid**; four framework approach; **situational leadership**; **servant leadership; and action-centered leadership**. Within the healthcare field, some of the accepted models include: **functional results-oriented healthcare leadership model**; **healthcare quality professional leadership development model**; **National Center for Healthcare Leadership competency model**; **Healthcare Leadership Alliance model**; and the **Center for Creative Leadership six-part model**.

Leadership/Managerial Grid

The leadership/managerial grid model was developed from work by two researchers, Robert Blake and Jane Mouton, in 1985. Based on a questionnaire given to leaders about how they approached tasks and people, the model placed the leader in one of four quadrants: authoritarian; country club; impoverished; or team leader [5].

According to Blake and Mouton, the ideal team leader is strong on task and people skills/relationships. These leaders lead by positive example and foster a team environment to assist members in reaching their full potential, both as team members and as individuals. A key characteristic is encouraging the team to achieve goals as effectively as possible while also strengthening the interpersonal bonds among team members [5].

The authoritarian leader is highly task-oriented and hard on his/her workers. A synonym would be autocratic. There is little room for cooperation or collaboration with this style.

The country club leader predominantly uses reward power to maintain discipline and encourage the team to accomplish its goals. This leader is almost incapable of exerting punitive, coercive, or legitimate power for fear of jeopardizing relationships.

The impoverished leader uses a “delegate and disappear” style, showing almost no commitment to either task accomplishment or relationship maintenance. They pretty much allow their teams to do whatever they want.

Subject	Manager	Leader
Make up of role	Stability	Change
Decision making	Makes	Facilitates
Approach	Plans detail around constraints	Sets and leads direction
Vision	Short-term - today	Long-term - horizon
Control	Formal influence	Personal charm
Appeals to	The Head	The Heart
Culture	Endorses	Shapes
Action	Reactive	proactive
Risk	Minimizes	Takes
Rules	Makes	Breaks
Direction	Existing direction / keeps status quo	New direction / challenges norm
Values	Results	Achievement
Concern	Doing the thing right	Doing the right thing
Focus	Managing work	Leading people
Human Resource	Subordinates	Followers

Fig. 19.1 Summary table comparing leadership and management traits/behaviors: [4]. Candy L. Leadership versus Management: What is the difference? Available at: http://www.educational-business-articles.com/leadership-versus-management.html. Used by permission

Blake and Mouton emphasized that the team leader model is preferred and allowed for situational use of the other models to be appropriate in specific settings [5].

Situational Leadership

Situational Leadership, which was initially developed in 1977 by Paul Hersey and Ken Blanchard, is based on two continuums: (1) the required level of supervision (directing); and (2) the arousal (support) required to coach workers in specific situations so they can develop into great performers. Each level of supervision and arousal (support) is driven by the worker's skill and knowledge level, also referred to as the maturity level [6].

The levels of directing and supporting are driven by the employee's skill and knowledge level for a given task or situation. This requires ongoing assessments of the employee's abilities as new tasks are assigned, or situations arise. Of note, in this model, the leader's assessment of the employee's knowledge and skill level is based on Gestalt or an interview. It is not based on a formal learning or training needs assessment. The goal is to provide the needed direction/support to ensure task success and continued employee growth/development [6].

According to the theory, and continued in the current version, are four styles of leadership and four levels of maturity. The four leadership styles are Telling (S1), Selling (S2), Participating (S3), and Delegating (S4). The four maturity levels are simply numbered 1–4. M1 is low maturity. M2 is medium maturity and limited skills. M3 is medium maturity and has higher skills but lacking confidence. M4 is high maturity. Each maturity level is matched with the similarly numbered leadership style [6, 7].

This model was refined in 1985 by Ken Blanchard, and it is now a four-step model, but still dependent on the situation/task and employee's maturity level. The leader can jump into any step dependent on how well an employee can perform and is motivated to perform [7].

The four steps of Situational Leadership are: Directing, high direction, and low support; Coaching, decreased direction and increased support; Supporting, further decreased

direction and similar support as for Coaching; and Delegating, providing guidance and support as needed [7].

George the Situational Leader

George has studied different leadership models, and he feels that situational leadership best fits the new responsibilities the Informatics Department personnel will need to take on. George takes each new task (governance, cross-training, expanded roles), evaluates who might serve in that role, and determines their current skill level for that task. He uses a skill/role matrix to determine this and then uses the situational leadership curve to determine the type of leadership he should apply for each person and task. This will allow him to better allocate his time and personnel resources to accomplish the new mission.

Servant Leadership

While servant leadership is a timeless concept, dating as far back as 570 BC, the phrase "servant leadership" was coined by Robert K. Greenleaf in "The Servant as Leader", an essay that he first published in 1970 [8].

A servant-leader focuses primarily on the growth and well-being of people and the communities to which they belong. While traditional leadership generally involves the accumulation and exercise of power at the "top of the pyramid," servant leadership is different. The servant-leader shares power, puts the needs of others first, and helps people develop and perform as highly as possible [8].

The servant-leader (SL) believes himself/herself "first among equals." This idea is at the very core of servant leadership. A servant leader does not consider himself/herself *above* those he/she leads. The SL sees those he/she leads as peers to teach and to learn from. He/She is willing to lead others to reach an agreed-upon goal and does not believe that being the leader makes him/her better than others.

Because of this, the servant leader is a consummate team builder. He/She will draw on followers' strengths and be a follower *himself/herself* when appropriate. Such a leader doesn't lead by decree or dictate. Instead, he/she leads by allowing everyone to do what they do well [9].

Principles of servant leadership defined by the Alliance for Servant Leadership are:

1. Transformation as a vehicle for personal and institutional growth.
2. Personal growth as a route to better serve others.
3. Enabling environments that empower and encourage service.
4. Service as a fundamental goal.
5. Trusting relationships as a basic platform for collaboration and service.
6. Creating commitment as a way to collaborative activity.
7. Community building as a way to create environments in which people can trust each other and work together.
8. Nurturing the spirit as a way to provide joy and fulfillment in meaningful work [10].

George, the Servant Leader

George has long been a believer in servant leadership. He has practiced this style with his people for as long as he has been in leadership positions in his clinical department and practice. As he assumes the role of CMIO, simultaneous to the change in personnel and scope, he realizes that the only way to help his people not have significant morale issues (and possibly leave) and create a supportive atmosphere to help people succeed in their new, expanded roles, is to apply servant leadership techniques to the department as a whole. Servant leadership nicely dovetails with situational leadership to help subordinates feel supported and valued by focusing on their success and personal needs.

Action-Centered Leadership

The following model is called Action-Centered Leadership. It is from a book of the same name, published in 1973 and authored by John Adair [11]. In this model, leadership is represented by a set of behaviors that assist/support people or a group in performing tasks and reach goals. It is focused on meeting needs in three areas: task, team, and individual [11].

Functional Results-Oriented Healthcare Leadership Model

Another model, more focused on healthcare, is the Functional Results-Oriented Healthcare Leadership model. It is based on Adair's action-centered model. It adds a results element onto the foundational elements of an individual, team, and task to emphasize leadership's responsibility for measurable outcomes in healthcare, including patient outcomes [12].

Healthcare Quality Professional Leadership Development Model

The National Association for Healthcare Quality published a leadership model in 2008 focused on professional leadership development. In this model, the primary tenets are fostering positive change, organizational awareness, performance improvement, communication, self-development, self-management, professionalism, and professional values [13].

National Center for Healthcare Leadership Competency Model

The National Center for Healthcare Leadership published a model, also in 2008, based on three domains: transformation, execution, and people. The transformation domain deals with visioning, energizing, and stimulating change processes that bring together communities, patients, and professionals around new healthcare and wellness models. The execution domain focuses on translating vision and strategy into optimal organizational performance. The people domain is about creating an organizational climate that values employees from all backgrounds and provides them with an energizing environment [14].

Within the three domains are 26 competencies. Eight are skills and knowledge competencies, and they include communication skills, financial skills, human resources management, information technology management, performance measurement, process management, organizational design, project management, and strategic orientation [14].

Healthcare Leadership Alliance model

The American College of Healthcare Executives published a leadership model in 2013 called the Healthcare Leadership Alliance model and includes a competencies assessment tool [15].

The primary domains for this model and the competency assessment tool are leadership, communication and relationship management, professionalism, knowledge of the healthcare environment, and business skills and knowledge. Each domain has its own set of associated competencies, which can be assessed using the competency tool. Only the leadership domain overlaps the other four [15].

Center for Creative Leadership Six-Part Model

The Center for Creative Leadership has created a six-part model for collaborative healthcare leadership focused on transformational change and the requirement for cross-organizational collaboration [16].

The six organizational capabilities considered essential for this model include collaborative patient care teams; resource stewardship; talent transformation; boundary spanning; capacity for complexity, innovation, change; and employee engagement and well-being. Within each of these six areas are key leadership practices needed to maximize effectiveness [16].

Dimensions of Effective Leadership

As with leadership models, numerous theories attempt to explain the dimensions of leadership. Most of these theories have various levels of primarily qualitative research providing some level of evidence supporting them.

McKinsey Global identifies five dimensions of effective leadership based on their research. These five dimensions constitute what they call "centered leadership": [17]

1. Meaning: finding meaning in work
2. Positive Framing: converting fear or stress into opportunity
3. Connecting: leveraging connections and community
4. Engaging: acting in the face of risk
5. Managing Energy: sustaining the energy that is the life force of change

McKinsey's research has shown that meaning has the most significant impact on work and life satisfaction of these five dimensions. Meaning's contribution to life satisfaction is five times more powerful than any other dimension [17].

Another theory based on research by Sugerman, Scullard, and Wilhelm [18] proposes eight dimensions of leadership. The eight dimensions are pioneering, energizing, affirming, inclusive, humble, deliberate, resolute, and commanding in this theory [18].

The authors state that all leaders need to stretch beyond their primary leadership dimensions to have their greatest impact. They need to understand how their personalities play a part in their leadership styles. This understanding allows them to incorporate other dimensions and thus optimize their leadership capabilities [18].

A third and final leadership dimension theory comes from Douglas Reeves [19]. Dr. Reeves uses a variety of published research to support his proposed leadership dimensions model. While the book is focused on school leadership, the dimensions are generalizable to other fields, including clinical informatics [19].

One crucial aspect of this model is that a deficiency in one leadership dimension is not necessarily a prescription for focusing on and improving that deficiency but rather a suggestion that the leadership team is broadened to include complementary dimensions. Reeves argues that leaders need not be experts in every dimension themselves. However, the effective leader can and must ensure that some leadership team member provides every leadership dimension [19].

The leadership dimensions included in this model are visionary, relational, systems, reflective, collaborative, analytical, and communicative [19].

The leader with systems intelligence must understand each interaction within the system under their purview and its impact on the entire system. They then must communicate this complexity to enable each organization member to understand and consistently use these critical interconnections. Systems leadership is not just about complexity. The more significant challenge is converting that complexity into simplicity for others to understand and act upon [19].

Communication and Leadership

There are all kinds of communication models, some basic and some complex. For our purposes, communication can be described as CREATING UNDERSTANDING.

You send many messages about yourself and your organization through words, actions, body language, voice tone, and other processes. This constitutes one-half of the communication process. The second half consists of verifying that the message you intended to send was received and interpreted the way you intended.

Remember:

1. Although you communicate in a way that seems clear to you, the receiver of the communication filters the information through pre-conceptions that can distort the message received.
2. Receivers listen selectively. They hear and process some things and gate out other things. It is likely that the whole message was not received.
3. The ONLY way you can ensure that you have created a common understanding is by asking the other people what they have heard and their reactions to it [20].

Verbal communication is the most obvious form of communication. Research has shown that people pay much less attention to the words that are said and much more attention to the actions and nonverbal cues that accompany those words. Nonverbal cues include facial expressions, use of hand motions, body posture, and eye movements. Leaders should always strive to match nonverbal cues to their words. When they do so, they are more believable and trustworthy [21].

Skills acquired and/or knowledge gained about good communication are only valuable to the extent they can be practically applied when needed. The number one thing great communicators have in common is they possess a heightened sense of situational and contextual awareness. The best communicators are great listeners and astute in their observations. Great communicators are skilled at reading a person/group by sensing the moods, dynamics, attitudes, values, and concerns of those being communicated with. Not only do they read their environment well, but they possess the uncanny ability to adapt their messaging to said environment without missing a beat. The message is not about the messenger; it has nothing to do with the messenger. It is 100% about meeting the needs and the expectations of those with whom you are communicating [22].

You know you are a good communicator when you consistently use the following ten principles in your interactions with others:

1. Speak not with a forked tongue—earn/build trust
2. Get personal—engage people; think dialog, not monologue
3. Get specific—simple and concise communication
4. Focus on leave-behinds, not the takeaways—focus on contributing more than you receive (servant leadership); transfer ideas and inspire action
5. Have an open mind
6. Shut-up and listen—know when to talk and when to just listen
7. Replace ego with empathy—communicate with empathy, transparency, and caring; get rid of any ego-driven façade
8. When you speak, know what you are talking about—develop technical command over your subject matter; address both the "what" and "how"
9. Speak to groups as individuals—hard to do; work to establish credibility, trust, and rapport with the individuals in a group
10. Read between the lines—understand what is not said, witnessed, or heard; keep your eyes and ears open and your mouth shut (as appropriate) [22].

Whenever you have a message to communicate, make sure the message is true, correct, well-reasoned, and substantiated by solid business logic that is specific, consistent, clear, and accurate. Most importantly, keep in mind that communication is not about you, your opinions, positions, or circumstances. It's about helping others by meeting their needs, understanding their concerns, and adding value to their world [22].

George, the Communicator

It is easy for people to get the wrong idea about your intentions. This is even truer with the more impersonal modes of communication we often employ today: e-mail and text messaging. You must carefully craft e-mail messages to ensure you and your intentions are not mistaken. Whenever possible, it is best to resort to phone or in-person communication to ensure the message received is the one you want to send. Even then, if there is a lack of consonance between the spoken word and body language or subsequent actions, the spoken word is ignored in favor of the other. Given George's new role as CMIO and department head, he must engage in careful, face-to-face (F2F) communications to ensure his message to others is clear. He must back up that communication with action to reinforce the message and build trust. When trust is built, and transparency is maintained (i.e., the motivators for actions/words), communicating by less personal modes is possible without worrying too much about misconstrued intent. Phone conversations are an acceptable alternative to F2F communications but should be intermixed with F2F discussions if trust is being built. E-mail and texting are convenient, but they are much less effective modes and more likely to be misconstrued by the recipient.

Strategic/Tactical/Analytical/Innovative Thinking

It is vital to have a deliberate, systematic process for making decisions and managing work to guide individuals, teams, and organizations towards desired outcomes. Those decisions must be made with an awareness of the future and its implications, organize teams and individuals to execute those decisions, and measure the results against expectations [23].

This is called strategic thinking, and it is the ability to step back from day-to-day activities and develop a long-term plan for sustained growth and development. Strategic thinking is called for when considering organizational goals, management plans, and the long-term development of people. Using strategic thinking allows for systematic and efficient strategic planning for the organization, teams, and people [23].

Liedtka observed five major attributes of strategic thinking that resemble competencies.

These five competencies are:

1. A systems perspective—ability to understand implications of actions
2. Intent focused—more determined and less distractible than others/competitors
3. Thinking in time—being able to hold past, present, and future in mind simultaneously to create better decision making and speed implementation
4. Hypothesis-driven—ensuring that both creative and critical thinking are incorporated into strategy creation. This competency explicitly includes the scientific method into strategic thinking.
5. Intelligent opportunism—being responsive to good opportunities and not losing sight of alternative strategies as they present themselves [24].

People often confuse strategic thinking with tactical thinking. Strategic thinking is focused on the long term, which can vary based on the organizational and competition dynamics. It challenges the status quo, looks at future ROI (return on investment) and considers the preparation/level of effort needed to reach the long-term goals. Tactical thinking is more immediate or "in the moment", often safe, conservative, and maintaining the status quo. It looks for a quick payoff and involves the automatic and routine execution of a task. It is the immediate "what to do and how to do it" mode of thinking [23].

Several factors can drive tactical thinking:

1. Culture—the biggest driver of tactical thinking, especially when strategy execution drags out and the organization misses targeted opportunities.
2. Lack of strategic clarity—middle managers often make tactical decisions when they do not fully comprehend the intended strategy and its implications.
3. Renegade managers are relatively rare—managers who make tactical decisions counter to strategy they do not accept and/or have their own agenda.
4. Onetime events—if only happening once, the strategic impact will not likely be a big one
5. Small investments—small in terms of time and resources; they can be revised later to align with strategy
6. Idea testing—new ideas can support the current strategy or challenge it; either way, these new ideas are good and should be nurtured. Cutting them off because they challenge/do not fit the current strategy is a tactical error [25].

George, the Strategist

George understands that he will never be successful in his new role and his department's new set of responsibilities if he only focuses on short-term goals (tactical thinking). While he needs to ensure that he accomplishes day-to-day responsibilities, the success of his and the department's mission (as well as that of the organization) depends on him working with his people to create and accomplish a long-term strategic plan. He accomplishes this by engaging in critical thinking and working with both the organizational leadership and his people to ensure a strategic plan that supports his departmental mission and the organization as a whole. Creating such a plan allows George to work with other department leaders to harmonize their department strategic plans by focusing on the organizational mission (shared values).

Analytical/Critical Thinking

Analytical thinking skills are critical because they help gather information, articulate, visualize and solve complex problems. Some people make the incorrect assumption that analytical thinking and critical thinking are the same. That is not true, and it is important to differentiate the two to understand when to think critically and when to think analytically [26].

When thinking critically, one decides whether or not an event, object, or situation appears to be right or wrong. Once provided information, one evaluates the data and determines how best to interpret it. Conclusions and assessments are made based on one's perception of the information and knowledge of the world, often looking at other pieces of data

that might be relevant. Critical thinking takes facts and uses them to form an opinion or belief [26].

Analytical thinking is used to break down complex bits of information, thinking step-by-step to develop an overall conclusion, answer, or solution. Analytical thinking uses facts to support conclusions or a train of thought. Analytical thinking may require you to think about some (or all) of the following: [26, 27]

1. Cause and effect
2. Similarities and differences
3. Trends
4. Associations between things
5. Inter-relationships between the parts
6. The sequence of events
7. Complex systems and how they work
8. Ways to solve complex problems
9. Steps within a process
10. Examples of what is happening

Innovative thinking is rooted in creativity and would be considered the other side of the creative thinking "coin". Creativity is bringing into existence an idea that is new to you. Innovation is the practical application of innovative ideas. Creative thinking is an innate talent we were born with and a set of skills that can be learned, developed, and utilized in daily problem-solving. Innovative thinking is taking the same skills like creative thinking and applying them to practical solutions [28].

There are multiple cultural and physiological barriers to both creative and innovative thinking. Such things as making assumptions, following the rules, over-reliance on logic, and fear of failure restrict the ability of the left brain (analytic), right-brain (creative), conscious and subconscious to properly collect information needed, choose and calculate which information is essential, communicate those ideas to our consciousness and provide an innovative solution [28, 29].

As stated, one of the prime reasons to engage in creative or innovative thinking is to solve problems. The first step in solving problems is to define them. There are well-studied tools for defining problems. These include the Kipling Method, the Problem Statement, and the Challenge Method. The Kipling Method (from Rudyard Kipling) uses questions, the 5 W's and the 1 H, to help trigger ideas and solve problems. The Problem Statement method is self-explanatory and not easy to accomplish in many cases. This method works when everyone identifies the problem for them and then collaborates/negotiates to arrive at a single best problem statement for all. The Challenge Method works well to get people out of a thinking rut. It is good for testing idea validity. It starts with identifying a problem or situation and then challenging it, or some component of the problem domain, with deep questions about concepts; assumptions; boundaries; the 'impossible'; the 'can't be done'; the 'essential'; and the "sacred cows" [28].

There are several well-studied tools for creating new ideas or innovating. Three of the more common ones, out of more than 27 known tools, are: attribute listing; brainstorming; and visioning [28, 30].

Attribute listing is a good technique for ensuring all possible aspects of a problem have been identified and examined. This tool breaks the problem down into smaller and smaller bits, allowing one to see/discover the details. The steps in attribute listing are the following: list the attributes; consider the value of each feature; and modify the characteristics to increase value, reduce negative value or create new value [28, 30].

Brainstorming, also called "Classic Brainstorming", became popular in the 1950s as a way to come up with new ideas. Various versions have been developed since to overcome perceived deficiencies in "Classic Brainstorming": Brainwriting 6-3-5; Harvey Cards; Imaginary Brainstorming; and Reverse Brainstorming. The steps in brainstorming include the following: [30]

1. Arrange the meeting for no more than 4–8 people
2. Write a well-defined, clearly stated problem where everyone can see it
3. Ensure that everyone understands the problem/issue to be addressed
4. Review the ground rules (there are at least five)
5. Have someone (or two people) facilitate the discussion, enforce the rules and write down all ideas as they occur
6. Generate ideas via unstructured or structured methodology—the goal is complete participation by all in attendance
7. Clarify and conclude the session, combining identical ideas and obtaining consensus on the next steps/actions and a timeline

The last of the three methods/tools for creative/innovative thinking is called Visioning. It works by imagining the desired future and what the organization, team, or individual is trying to achieve. Visualize what that future state holds, and describe it to others in dynamic and emotive words (like 'sharp', 'now', and 'value') to paint a picture. Phrase it in the present tense and use action verbs that talk about what is happening in the vision. Test it against others to ensure that the vision works for them as well. Visioning works because humans are imaginative and motivated by what we perceive as a possible and/or desired future [28].

George, the Brainstormer

George understands that he must engage his people to help define the best approach to accomplish the strategic plan for the department. He, fellow department heads, and his people have already engaged in critical thinking to develop a strategic plan. Now they must engage in innovative thinking to determine how best to carry out that strategic plan in an ever-evolving Health IT environment. George engages his people in several brainstorming sessions to develop ideas to best approach and accomplish the tasks ahead. Each brainstorming session is facilitated by one of the Human Resources Department's persons trained to do so. He limits his group to no more than eight people to allow brainstorming success. He does this by breaking down the sessions to focusing on a particular area…training, workflow analysis, implementation, and governance. For the governance brainstorming session, he engages department heads from other departments to make them owners of the process to minimize conflict.

Decision Making and Accountability

Clinical Informaticists engage in decision making in two distinct realms: medical or shared medical decision making; and leadership/business decision making. The former is covered in an earlier section of this book. This section will deal with the latter, which has much less scientific literature dedicated to it than the former.

The role of the leader, or manager, is to make decisions. The better leaders and managers make effective decisions, and they generally do so repeatedly. Research has shown that there are four basic decision-making styles: decisive (little information, one course of action); flexible (little information, many options); hierarchical (lots of data, one course of action); and integrative (lots of data, many options) [31].

Both the decisive and flexible decision-making styles focus on speed in making the decision. Still, they differ in that decisive values efficiency and consistency, while the flexible style focuses on adaptability and quickly changing course based on conditions encountered. Hierarchical and integrative styles are analysis-based. Here the focus is on getting both lots of information and lots of input from others. The difference between these two styles is the final decision process. Hierarchical decision-makers will challenge others' input to ensure they are valid, make the final decision, and expect it to stand the test of time. The integrative decision-maker tends to frame decisions very broadly and often includes perspectives and choices that are very different than their own. They do not delegate the decision-making process, but it is close [31].

There are other styles of decision-making in the literature that somewhat align with those above. Some common terminology used includes: command or autocratic (leaders make decisions with total control of the input and ownership); collaborative or collective/participative (leaders gather their teams/member of the organization and asks/encourages feedback before making the final decision themselves; this is also called evidence-based decision making); consensus or democratic (leader gives up ownership and control of the decision and everyone votes on a course of action; majority rules; there is no responsibility for the decision); convenience or delegation (this is where the leader does not make the decision, instead of delegating that to others) [32, 33].

Research has found that leaders and managers, especially those who are considered effective/successful, change their decision-making styles over time. What was found is that there is a steady progression towards openness, diversity of opinion, and participative decision-making as one moves up the ranks in the organization (flexible/integrative). Conversely, there is a step-by-step, corresponding decrease in the use of more directive, command-oriented styles. At the same time, the leaders/managers exhibited a progression in their thinking (private) styles different from their leadership styles, showing a marked increase in their analytic, maximizing styles (hierarchical/integrative) but a significant decrease in the flexible style [31].

Decision-making is about much more than styles. It is also about how to make decisions in a world that does not always follow the Newtonian-based scientific management assumptions that a certain level of order and predictability exists in the world. Things often become more complex, and simplifications fail [34].

One model of complex decision making is called the Cynefin (pronounced Ku-*nev*-in) framework, which allows executives to see things from new viewpoints, assimilate complex concepts and address real-world problems and opportunities. The Cynefin framework sorts all issues into five contexts defined by the nature of the relationship between cause and effect. Four of the contexts require leaders to diagnose situations and act in contextually appropriate ways. These four are simple, complicated, complex, and chaotic. The fifth context, disorder, applies when it is unclear which of the other four is predominant in the situation [34].

Complicated and straightforward contexts assume an ordered universe. Here, the appropriate actions are to sense, analyze and respond for complex and sensitive, categorize and respond for the simple context. Complex and chaotic contexts are unordered. The appropriate responses here are probe, sense, respond for the complex context, and act sensibly and respond to the chaotic context.

The disorder context is just as it seems from the name. The only way out of this mess is to break down the situation into constituent parts and assign each to one of the other four realms. Then decisions can be made in contextually appropriate ways [34].

Other models for decision-making are based on emotional intelligence, managing uncertainty and choices, and trusting one's intuition. None is perfect, including the Cynefin framework, but all are viable options for making decisions [35].

George, the Decisionmaker

As the department head and organization CMIO, George is now thrust into a position of both decision-making authority and accountability. George can assume similar or different decision-making styles based on his level of control. Within the department, George is the boss. He can choose to make unilateral decisions based on his desires/needs, elicit ideas/inputs from the department members and make a unilateral decision, or engage the group and make a shared decision. Depending on the situation, one of the latter two decision-making styles is the most functional from a long-term leadership perspective. Given lots of time and full engagement, the shared decision-making style is best. George must employ a shared decision-making style with the Governance Committee or face a significant backlash from the other department heads, who are his peers. It takes more time, and it also takes employing all the previously discussed tools: negotiation, conflict management, motivation, strategic thinking, the appropriate leadership style, and more. The only thing more challenging than leading a group of peers is leading from behind (i.e., leading your boss).

Understanding, Surviving, and Changing Organizational Culture

Organizational culture is a system of shared assumptions, values, and beliefs, and they govern how people behave in organizations. Every organization develops and maintains a unique culture, and each of these unique cultures is composed of seven characteristics that range in priority from high to low. Every organization has a distinct value for each of these characteristics. When combined, these characteristics values define the organization's unique culture. Members of each organization use these values to adjust their behavior to match the culture [36, 37].

The seven characteristics of organizational culture are: [36]

1. Innovation (Risk Orientation)
2. Attention to detail (Precision Orientation)
3. Emphasis on outcome (Achievement Orientation)
4. Emphasis on people (Fairness Orientation)
5. Teamwork (Collaboration Orientation)
6. Aggressiveness (Competitive Orientation)
7. Stability (Rule Orientation)

To implement change in an organization, which informaticists must do regularly, it is critical to first understand the organizational culture. Here are some basic guidelines to help with that task: [37]

1. Understand the major types of cultures. Research efforts into organizational cultures have identified four major types: academy culture; baseball team culture; club culture; and fortress culture.
2. Describe the culture of your organization. Consider what you see and hear, not what you feel or think. Answer the following questions:
   (a) Who seems to be accepted, and who doesn't? What is different between the two groups?
   (b) What kinds of behaviors get rewarded? What kind seem to get punished?
   (c) What does management pay the most attention to? These would be things like problems, successes, crises, etc.
   (d) How are decisions made? Are they made by one person, discussion, and consensus, or are they made at all?

Be aware that there may not be close alignment between what the organization espouses as its values and what others see within and outside the organization. This is a common disparity and can create internal confusion. It is essential to discuss this disparity with other, trusted leaders. An ideal time is during strategic planning discussions [37].

Changing the culture of an organization is never easy, but it is possible. The best and most enduring method to change organizational culture is to change behavior, not by changing structure. To change behavior, one must change the underlying mechanisms that drive existing behavioral patterns: norms, social values, identity structure, and mental models. Culture is resistant to change because many of the cultural control mechanisms become mentally internalized by organizational members. Changing culture often means changing members' entire social identity [38].

While often difficult, organizational culture can change. The key lies in symbolic action, dealing with important symbols of values, norms, and assumptions. Here are some general guidelines:

1. Change social values
   (a) Role modeling and emphasizing what's important in terms of desired social values.
   (b) Symbolic action—actions speak louder than words; leaders' actions let the organization know what is valued and what is not. Reward members whose behaviors reflect what is essential and discourage behaviors that do not reflect what is necessary by providing feedback, warnings, or termination (that does not mean punish or cause prolonged discomfort).
   (c) Selective hiring—social values are often changed through the selection process, which tends to support current or new values [37, 38].
2. Changing mental models and basic assumptions
   (a) Single loop learning—maintains current mental models and basic assumptions because people do not question them when something goes wrong. They simply question their inputs.
   (b) Double-loop learning—in this setting, people question both the mental models and basic assumptions when things go wrong. To accomplish this, it takes a concerted effort from leaders to outline, challenge, and agree on changes to the shared mental model [38].

George, the Culture Manager

While Health IT, clinical workflow analysis, and implementation are already components of the organizational culture, governance is not. George will have to change the previous culture of departments purchasing whatever clinical software and hardware they wanted to one where all purchases of clinical software, and any purchase of clinical hardware with a software interface, go through a governance process that prioritizes and ensures compatibility with existing systems and the network. He will need the support of the senior leadership, and he will need to educate other departments/department heads as to why this is a better idea for both the organization as a whole and for them as a department. He does this by focusing on hypothetical comparisons between governance and non-governance processes and their relative costs to the departments and the organization. The intent is to change mental models and basic assumptions about governance versus non-governance for purchases. He will need to demonstrate good negotiation skills to be successful.

Negotiation Strategies, Methods, and Techniques

Negotiation is a dialogue between two or more people or parties, where each person/party involved tries to gain an advantage for themselves by the end of the process. Negotiation is intended to aim at compromise [39].

Barriers to negotiation: [40]

1. Die-hard bargainers
2. Lack of trust
3. Informational vacuums and negotiator's dilemma
4. Structural impediments
5. Spoilers
6. Culture and gender differences
7. Communication problems
8. The power of dialogue

Rules for effective negotiations: [41]

1. Background homework: before negotiations, begin understanding the interests and positions of the other side in relation to your own. Look at things from the other side.
2. Do not negotiate against yourself during the process, especially true if you do not fully know the other side's position. Stay firm on your initial positions, explain your rationale, and do not give up too early on points. Wait until you better understand the other side.
3. The stalemate: this often occurs in negotiations. There is usually some negotiation "currency" (something they really want for something else you really want) outside of the stuck negotiation focus area.
4. To close or not to close: the uber golden rule of negotiation is to always let someone else walk away. Be honest and straightforward on what you are willing to do and give the other person an honorable "out" if your best does not work for them.

There are several negotiating pitfalls to avoid. A list of seven common ones are: [42]

1. Poor planning
2. Thinking the pie is fixed: it usually is not. This is common when both parties want the same thing, but they fail to discuss it thoroughly. Faulty assumptions are made.
3. Failing to pay attention to your opponent: this comes from failing to understand what biases the other party brings to the negotiation
4. Assuming that cross-cultural negotiations are just like "local" negotiations: understand and address cultural differences
5. Paying too much attention to anchors: anchors and adjustments are a normal part of the negotiating dynamic. Everyone needs to clearly understand the

other party's anchors and what adjustments can and will be made.
6. Caving in too quickly: no matter what the offer, even if fair, always make a counter-offer
7. Gloating: never a good thing. Stay professional at all times

Negotiation theorists generally distinguish two types of negotiation, though different theorists use different labels. The two types are: [43, 44]

1. Distributive negotiation: also called positional or hard-bargaining negotiation. Distributive bargainers conceive of negotiations as a process for distributing a fixed amount of value.
2. Integrative negotiation: also called interest-based or principled negotiation. Integrative negotiation often involves a higher degree of trust and relationship formation. It can also involve creative problem-solving to achieve mutual gains. It is sometimes called Win-Win negotiation.

George, the Negotiator

As stated previously, George is faced with internal and external issues that will require both conflict management and negotiation to be successful. Conflict will be covered below. George will need to negotiate with senior leadership to determine the right number of personnel for the Informatics Department and pay for those remaining commensurate with their increased roles and responsibilities. He will have to negotiate with his own people to determine who will stay and who will go. His values and servant leadership style should help make those negotiations go more smoothly. He will have to negotiate with other department heads to get them on board with the new governance model and their participation in the governance process. George will look for shared values and collaboration wherever possible. He is willing to compromise if needed. He follows the principles of integrative negotiation, and he knows that dealing with hard bargainers will be challenging at best. That is why he will engage senior leadership to officially support the governance model to create openings for negotiation with those most opposed to the governance model.

Collaboration

According to Baggs and Schmitt (1988), collaboration involves coordinating individual actions, cooperation in planning and working together, and sharing goals, planning, problem-solving, decision-making, and responsibility. Collaboration can happen between two people representing the same or different disciplines or among small groups of people representing one or a range of disciplines [45].

Collaboration is a recursive process towards shared goals. Collaboration is NOT cooperation … it is more than the intersection of common goals but a collective determination to reach an identical objective by sharing knowledge, learning, and building consensus [46].

Leadership is a critical ingredient in effective collaboration, be that the leader of a team or an entire organization. Some of the key leadership skills for effective collaboration include the following: [46]

1. Build trust—build it through actions and evidence
2. Expect conflict to reach consensus—as stated, conflict can be an opportunity to grow, as long as the emotions are kept out of it and facts/evidence are kept the priority
3. Embrace change—initiate change rather than react to it; give the team clear and factual reasons why change is necessary
4. Establish a level of analysis, structure, and control—balance is essential here; if out of balance, chaos can result; be careful not to stifle innovation and creativity
5. Make decisions—a blended approach (between independent and collaboration) factoring in the best team input works best
6. Foster continuous communication—communication is the glue that forms the bond between team members and between leaders and teams; credibility is required—and that means honesty and integrity
7. Provide recognition—recognition drives motivation and human behavior; human behavior drives results; recognition validates people and their purpose
8. Create learning experiences—all people have a desire to learn a grow; the best learning opportunities are experience and sharing

Organizations can benefit from an atmosphere of collaboration that rewards teamwork. Creating a collaborative, team-oriented work community helps an organization stay competitive. People, who might otherwise leave for various reasons, will stay in a collaborative environment where they are challenged (in a good way) to grow both personally and professionally.

Several habits have been shown to create such an environment of collaboration within an organization: [47, 48]

1. Lead by example
2. Focus on individual benefit versus corporate benefit when communicating collaboration
3. Strategy before technology—understand the "why" of collaboration before pursuing the solution

4. Learn to get out of the way—provide general guidelines and best practices, but don't stifle collaboration with policing/enforcement
5. Listen to the voice of the employee and not just the customer—employees must be a valued part of the process
6. Integrate into the flow of work—collaboration must naturally fit into the flow of work for those engaged
7. Create a supportive environment for collaboration—goes back to rewarding and recognizing people for collaborating
8. Measure what matters—to the team, to the organization, to the individual as part of the team
9. Persistence—make collaboration an organizational initiative; make collaboration THE option for working
10. Adapt and evolve—collaboration is perpetual and ever-evolving; keep ahead of it and anticipate/innovate
11. Employee collaboration also benefits the customer—be they internal or external, customers
12. Collaboration makes the world a better place—both at work and away from work; a collaborative environment leads to less stress at work and generally happier employees…which leads to less stress at home.

Conflict Management Strategies, Methods, and Techniques

Conflict Management

Conflict arises from differences, both large and small. It occurs whenever people disagree over their values, motivations, perceptions, ideas, or desires. In most cases, conflicts arise from differing needs.

1. A conflict is more than just a disagreement. One or both parties perceive a threat.
2. Conflicts continue to fester when ignored
3. People respond to conflicts based on personal perceptions, not necessarily based on facts
4. Conflicts trigger strong emotions
5. Conflicts are an opportunity for growth [49]

The key to managing conflict well is choosing and executing the strategy that best fits the situation. Thomas and Killmann proposed five styles of conflict management in 1972. These are: [50–52]

1. Forcing—using formal authority or other possessed power to satisfy one's concerns without regard to the concerns of the other party
2. Accommodating—allowing the other party to satisfy their concerns while neglecting one's own concerns
3. Avoiding—not paying any attention to the conflict and not taking any steps to resolve it
4. Compromising—attempting to resolve a conflict by identifying a solution that only partially satisfies each party's requirements (also known as Lose-Lose)
5. Collaborating—cooperating with the other party to find a solution that is wholly and mutually satisfactory (also known as Win-Win)

Regardless of whether one uses the traditional conflict management styles of Thomas and Killmann, or one of the newer styles proposed by Khun and Poole (2000), DeChurch and Marks (2001), or Rahim's meta-model (2002), the key is to match the style and strategy to the situation [50, 53–55].

1. Time pressure—if there were never any time pressures, collaboration might always be the best approach to use
2. Issue importance—the extent to which essential priorities, principles, or values are involved in the conflict
3. Relationship importance—how important is it that a close, mutually supportive relationship is maintained with the other party
4. Relative power—how much power each party engaged in the conflict has relative to the other

If the conflict is over important issues, collaboration is best unless time pressures intercede. If they do, and there is markedly unbalanced power, forcing is more appropriate. However, always use forcing with caution, as there may be long-term damage to the relationship unless the other party feels their concerns received adequate consideration.

With only moderately important issues, compromising can be appropriate. However, remember that compromising means neither party gets what they really want. If possible, collaboration is still the best approach.

When the conflict involves relatively unimportant issues, the accommodating strategy can quickly resolve and not strain existing relationships. Collaboration is still the best approach if it is worth the time investment (and you have the time to invest).

Avoiding should be reserved for those situations where there is a clear advantage to waiting for conflict resolution. Too often, avoiding results in worsening of the conflict and increasingly strained relationships. Avoidance is a poor strategy if the issue is important, or even moderately important, to either party [50].

George, the Conflict Manager

George knows that the personnel reduction requirement in his new department will likely create some conflict, both within the department and between him and the people he must let go of. He will use the previously mentioned leadership style and negotiation methods to address the real or expected conflicts that may arise in his department. He will be as transparent about the process as possible, and he will be as supportive as possible for the people he must let go of to get them past the denial and anger phases of job loss grief. That will go a long way towards reducing the potential department-level conflict. Getting senior leadership sponsorship and public support for the governance process will help reduce conflict between George, the face of governance, and those department heads who may be (or feel) most adversely affected by the governance process. George will need to engage in collaborative negotiation (and possibly brainstorming) with all of the department heads to best engage them in the process and collaboratively (as much as possible) work towards a process that they can embrace. George must address the concerns that underlay the potential conflict to successfully manage it. Here again, shared organizational values can help find common ground and overcome conflict.

Methods to Assess the Effectiveness of Training and Competency Development

Before one can assess the effectiveness of training or competency development, some baselines must be established, starting with an understanding of what you are trying to assess. Starting at the beginning, competency is a combination of knowledge, skills, and abilities (KSA) required for successful job performance. Skill is about doing something well, which translates to your ability to choose and perform the right technique at the right time. Skills are usually developed through training and practice. Knowledge is the information that you know, including theories, facts, and procedures, and the ability to apply this information in different situations. An attribute is an inherent characteristic or quality and is often expressed through what you think, do, and feel. Competencies are described in ways that are: (1) observable; (2) measurable; (3) linked to the workplace, academic environment, and other life experiences; (4) transferable; and (5) based on performance [56].

Strongly related to the definition of competency is a concept called a competency model. Competency models define what performance success should look like within the organization for each individual job. The model is applied to recruitment practices, talent management training, and performance assessment. This is different than the job description, which is a general summary of the skills required for the job. The competency model provides specific behaviors that employees must do on the job to be successful [57, 58].

Once a competency model has been developed for different positions within the organization, one can go about determining what competencies need to be developed on both a general and individual basis, and a needs assessment can be performed to understand and define which training is necessary to develop each of the needed competencies.

We will start with the competency development cycle/framework, which will drive which training is required. It will also lead to assessing the training effectiveness based on the success or failure and competency development outcomes. A competency development cycle is a framework to help staff think through, manage, and facilitate effective and efficient staff competency development. It involves a continuous process of action-reflection learning that can identify strengths and development needs, develop an action plan to effectively engage staff in competency development activities, support, monitor competency development progress, and evaluate the impact on behavior and work performance [59–61].

When creating the competency framework, three principles are critical to ensure the best chance for success. These three principles include the following: (1) involve the people doing the work and look for best practices across the organization; (2) communicate the reason for developing the framework, how it will be created and how it will be used; and (3) use relevant competencies for the roles being evaluated [62].

There are four main steps to developing a competency framework. Each staff has key actions to encourage engagement with and use of the framework components. Step one is preparation, where you define the purpose and create a competency framework team. Step two is collecting information which you will do through observation, interviews, questionnaires, and work analysis. The next step is to build the framework; this is accomplished by grouping the behavior statements, creating subgroups/subcategories of related behaviors, refining the subgroups, and then identifying and naming the competencies. The fourth and final step is the implementation of your framework. Some tips for implementing this include: Link to business objectives; reward the competencies; provide coaching and training; keep it simple; and finally, communicate openly and frequently.

Now that you have developed your competency framework, the required competencies for each person or position within the organization have been defined, along with the KSA's for each competency. Now it is time to determine what knowledge and skills gaps exist and outline/develop

training that will give people those competencies and an assessment of the training effectiveness and the competency development outcomes/assessments [57, 62].

The most common way to assess the knowledge and skills gaps is the learning needs assessment (LNA) or training needs assessment (TNA). They can be used interchangeably. As stated, through a series of knowledge and/or skill-based questions, the existence of a gap can be identified, and the exact nature of the deficit can determine what training is needed to close/reduce that gap. The LNA/TNA seeks to identify the current situation regarding the KSA's of the desired competencies. That identifies both the gaps and outlines what additional training is needed. Additionally, LNA/TNA is the process of collecting information about an overt or tacit organizational need that might be met through focused training. The need could be a performance that does not meet the current standard. It means that there is a prescribed or best way of doing a task and that variance from it is creating problems. The LNA/TNA can be formal, such as surveys or interviews, or informal [63–65].

Once you have conducted your training needs assessment, you are ready to develop your training plan based on both your competency KSA's and the knowledge and skills gaps identified through the LNA/TNA. Your training plan will include both the topics to be covered and the methods used in the training sessions. That is beyond the scope of this chapter. However, the next step, which is to assess the effectiveness of your training, is our next topic.

Assessing training effectiveness, also known as training evaluation, refers to obtaining relevant information on the effects and outcomes of a training program. It is considered an essential aspect of any training to reflect, analyze and improve effectiveness and efficiency. The primary objective of evaluating any training program is to understand whether that training has achieved its stated objectives. There are several methods for assessing training effectiveness, and those will be covered below.

Training evaluation benefits include the following: (1) accountability; (2) transparency and feedback; and (3) cost efficiency. These also allow calculating a return on investment (ROI) since training is expensive, with an estimated total cost of $80 billion per year in the United States alone [66].

There are several types of training evaluation methods to measure the effectiveness of enterprise training. Tools such as surveys, post-training quizzes, participant case studies, and official certification exams are among those methods. There are at least five proven methods that can be used to measure training effectiveness. These include the Kirkpatrick Taxonomy Model, the Phillips ROI Model, Summative and Formative Evaluation, Kaufman's Five Levels of Evaluation, and Anderson's Model of Learning Evaluation [66–70].

The Kirkpatrick taxonomy model is one of the most widely used methods for evaluating training effectiveness. The framework offers a comprehensive four-level strategy to evaluate the effectiveness of any training course or program. The four levels used in this are: (1) Level 1—Reaction; (2) Level 2—Learning; (3) Level 3—Behavior; and (4) Level 4—Results. Level 1 is where you gauge how the participants responded to the training they received. In Level 2, the goal is to assess what the participants learned from the training at the end. In Level 3, which takes place after the training is completed, the goal is to assess whether the participants put what they learned in the training session into practice in their normal job roles. In level 4, the goal is to evaluate whether the training met the stakeholders' expectations by assessing their return on expectations (ROE).

The Phillips ROI Model is very similar to the Kirkpatrick model in its approach. However, it has added an extra step to evaluate the program's return on investment by measuring the difference between training costs and training results. Since the initial steps are remarkably similar to those in the Kirkpatrick model, the focus will be on calculating the ROI. The steps to accomplish this include the following: (1) collect the pretraining data as a baseline measure that allows for calculating pre-and post-metrics; (2) collect the post-training data in the same fashion that you collect the pre-training data; (3) as best possible, isolate the effects of the training program, attempting to remove confounders; (4) convert the data to monetary gains, based on parameters provided by your Resource Management Department; and (5) calculate the return. The formula for the calculation is the following: ROI (%) = (Net Program Benefits/Program Costs) × 100.

The summative and formative evaluation method looks to provide feedback on the training program, both while it is being developed (formative) and after it has been delivered (summative). The steps to conducting a formative evaluation are the following: (1) review the training materials with one or more potential trainees; (2) use material in a simulated environment that closely approximates the actual training program to assess the impact of the material; (3) hold group discussions with the simulated environment students to gain feedback; and (4) review and assess the material with managers and supervisors who oversee the potential trainees.

Some of the steps performed to conduct a summative evaluation are the following: (1) test students who have completed the training on how well they grasped the information provided; (2) asked the students for their opinion about the training program after delivery; (3) measure changes in production and quality of work post-training; and (4) conduct surveys or interviews with the students to gain a better understanding of what it is they learned from the training.

Kaufman's Levels of Learning Evaluation is another popular training evaluation method. The levels and considerations for this method are as follows: (1) input, which are the kind of resources and learning materials the training teams have at their disposal to support the learning experience; (2) process, which focuses on the delivery of the learning experience, both in terms of student acceptance and response; (3) micro-level results, which take into account whether or not the learner or the learning group acquired the knowledge and applied it to their respective jobs; (4) macro-level results, which take into account whether or not the performance improvements are due to the learning and application of new skills, and what kind of benefits participants gained from learning on an organizational level; and (5) mega level impact, which considers the kind of impact that the learning has on society or larger external stakeholder groups.

Anderson's Model of Learning Evaluation is another popular type of training evaluation method. There are three stages to the Anderson model, and they include the following: (1) Stage I, which evaluates recurrent training programs against the strategic business priorities; (2) Stage II, which is where one measures the contribution of training to strategic business results; and (3) Stage III, where one finds the most relevant approaches for the organization and determine whether the ROI is worthwhile. Of note, if not satisfied with the results of the ROI measurement in Stage III, an evaluation of the training program needs to be undertaken [66–70].

Motivational Strategies, Methods, and Techniques

Motivation is defined in the Business Dictionary as internal and external factors that stimulate desire and energy in people to be continually interested and committed to a job, role, or subject or try to attain a goal [71].

Motivation and motivation theory have been the subjects of many experiments, studies, and published papers since the 1930s when Elton Mayo studied the effects of motivation on productivity in the Hawthorne Works of the Western Electric Company (Hawthorne Effect). Mayo's experiments showed that workplaces are social environments where people are motivated by recognition, security, and a sense of belonging, not purely economic interests or the physical environment [72].

Since the Hawthorne experiments, multiple theories have been developed to better characterize motivation. Each has strengths and weaknesses. Each has limits in generalizability. What is universal is that the factors influencing motivation can be identified in two main categories: intrinsic factors and extrinsic factors.

1. Intrinsic factors—come from the work itself and the goals and aspirations of the individual (achievement, the possibility for growth, social relationships, etc.)
2. Extrinsic factors—depending on the surrounding environment or basic human needs (salary, office space, responsibility, etc.) [72]

Three of the more prominent motivation theories are Abraham Maslow's hierarchy of human needs, Frederick Helzberg's theory on motivators and hygiene factors, and David McClelland's achievement motivation theory [31, 72].

Maslow's hierarchy of human needs defines five levels of human needs. Higher-level needs become motivators only after lower-level needs are satisfied. From lowest to highest, the hierarchy of needs, with examples from the business world, is: [72]

1. Physiological—salary, office space, appropriate facilities, lighting
2. Safety—job security, pension scheme, medical insurance, sick leave
3. Social—interactions with colleagues and customers, teamwork
4. Self-esteem—reputation, recognition, and appreciation from colleagues, subordinates, and supervisors
5. Self-actualization—realization of the full potential of the individual

Herzberg's motivators and hygiene theory rely on different assumptions. In this theory, some factors increase motivation (motivators) that align with intrinsic factors. Some factors help to avoid de-motivation but do not motive in and by themselves. These are the hygiene factors and are aligned with extrinsic factors.

In this theory, motivators include such things as (in order of importance) importance, achievement, recognition, work itself, responsibility, advancement, and possibility for growth. The hygiene factors relate to more basic biological needs. These include such things as (not in any order) company policy, office space, supervision, personal life, and salary [72].

McClelland's achievement motivation theory is focused more on a particular group of people: those with a strong desire to achieve. In this theory, achievement-motivated people exhibit the following characteristics: [31]

- Like difficult but potentially achievable, goals
- Like to take calculated risks
- Are more concerned with personal achievement than with rewards for success
- Have a strong need for concrete, job-relevant feedback, so they know how well they are doing

Herzberg's extrinsic (hygiene) factors correspond to the lower level of Maslow's hierarchy, and the intrinsic (motivator) factors correspond to the higher levels. Achievement-motivated people tend to be more motivated by Herzberg's intrinsic (motivator) factors, as the achievement itself is an intrinsic factor.

In general, intrinsic factors tend to be much more effective than extrinsic factors in motivating people, at least within the workplace [72].

George, the Motivator

George is faced with the spectre of downsizing his department almost as soon as he assumes his new leadership role. That is not an enviable position for any new leader. We have already discussed how George will engage his people for negotiation, strategic planning, critical thinking, and conflict management. Through all the changes, one component that must be maintained is motivation. George must motivate his people to keep morale and assume greater roles and responsibilities while seeing their co-workers be retired or terminated. Many of his department members likely have some level of intrinsic motivation, but that is not enough by itself. George must determine what other motivators are important to his people and deliver on some or all of them, to at least some degree. That will require advocacy and negotiation with senior leadership to entice George's people to deliver more with fewer personnel resources. He will also need to find motivating factors for the other department heads to participate and fully engage in the governance process. Inspiring others often requires a needs assessment (what motivators they desire/what motivates them) and then negotiation to deliver on those needs.

Emerging Trends in Leadership

Even before 2020, there was concern that leaders were holding onto behaviors that might once have worked but are felt to now stymie the talents of their employees. Because of the pandemic, the need for virtual work, and the ongoing social upheaval, leadership approaches have been forced on leaders worldwide.

The 2020 future of leadership global executive study and research report indicated that organizations must empower leaders to change their ways of working to succeed in a new digital economy [73]. The report identified a series of leadership behaviors labeled as eroding, enduring, and emerging. The emerging leadership behaviors included the following:

- Being purpose-driven
- Nurtures passion
- Makes data-driven decisions
- Demonstrates authenticity
- Demonstrates empathy
- Employs an inclusive approach
- Shows humility
- Works across boundaries

Some of the recommendations from the report, which was a collaboration between MIT Sloan School of Business and Cognizant, include the following:

- Articulate a powerful leadership narrative that lays out what you believe is important for digital economy leadership.
- Build communities of leaders by empowering employees at all levels.
- Align your talent, leadership, and business strategies.
- Do not just embrace inclusion and diversity; demand it [74].

Another challenge that is now facing leaders is the requirement to be able to lead across generations. With the "graying out" of the Baby Boomers, the new generation of leaders must deal with a multigenerational workforce that often has different expectations regarding work than do the leaders themselves. Some trends in leadership that can help lead across generations include the following:

- Learn from each other
- Flex the hours
- Share values and show respect
- Be a trustworthy leader
- Address office politics
- Communicate change
- Understand the context of loyalty
- Do the right things to retain talent
- Create a learning environment
- Build coaching skills [75, 76]

While virtual teams have been around for several years, the advent of the pandemic and the rapid progress in collaboration tools such as Zoom, Microsoft Teams, and others have ushered in a requirement for leadership style adjustment. Some of the recommendations for leading virtual teams in the digital age include the following:

- Have a good understanding of the unique challenges associated with virtual teams, such as cultural and time zone differences as well as still imperfect education and collaboration technology tools that are the only interface for them to interact.

- The importance of leadership style on virtual teams' productivity is greater than that with traditional co-located teams.
- The leader needs high levels of techno-socio-emotional capabilities
  - Transactional leadership
  - Transformational leadership
  - Situational leadership [77–79]

Chapter Summary

This chapter covers leadership models, processes, and practices, found under Domain 5 of the revised clinical informatics core content.

In this chapter, we have covered definitions of leadership, provided a comparison between leadership and management, and reviewed multiple leadership models, some of which are general business models, and others are healthcare-focused. There are important differences between leadership and management, and these are summarized within the text and laid out nicely in a table that accompanies the chapter. The most important business-associated leadership models include the leadership/managerial grid, situational leadership, servant leadership, and action-centered leadership.

Communication and leadership focus on the fact that actions are much more important than words, and leadership by example has a greater impact on followers than other forms of communication. There are ten principles to good communication, and these are covered in detail.

The importance of strategic thinking when in leadership positions was discussed and how that is an important concept to remember even when focused on tactical problems. To be a good leader is essential to be able to both think strategically and tactically simultaneously. We discussed the five major attributes of strategic thinking proposed by Liedtka: systems perspective, intently focused, thinking in time, hypothesis-driven, and intelligent opportunism.

When trying to understand, survive, and change organizational culture, it is critical to understand what organizational culture is, a system of shared assumptions, values, and beliefs that govern how people behave. Surviving in any organization means understanding the culture and generally abide by its rules. Changing organizational culture is not easy, but it is possible. The best and most enduring method to accomplish this is by changing behavior, not by changing structure.

We define negotiation as a dialogue between two or more people or parties, where each person or party tries to gain an advantage for themselves by the end of the process. The basic rule is negotiation is intended to aim at compromise. Barriers to negotiation and rules for effective negotiation were covered, as well as seven negotiating pitfalls to avoid.

Conflict can arise from differences, both large and small. It occurs whenever people disagree overvalues, motivations, perceptions, ideas, or desires. One of the most common methods for managing conflict is utilizing the Thomas and Killmann styles of conflict management, of which there are five. Whether you use the Thomas and Killmann management style, or a different one, the key is to match the style and strategy to the situation.

When trying to assess the effectiveness of training and competency development, the most critical first step is understanding what you are trying to assess. That includes understanding what you mean by competency, skill, and knowledge and how those are demonstrated. There are four main steps in developing a competency framework which is important and developing the competency development cycle. When starting to develop training, one of the most important first steps is to understand knowledge and skills gaps within your workforce. This is assessed by performing either learning needs assessment or training needs assessment. Once you have assessed the skills and knowledge gaps, you can start your training curriculum development. At the same time, as you develop your curriculum, you need to evaluate how effective your training is. There are several methods to accomplish this. These include the Kirkpatrick taxonomy model, the Phillips ROI model, Kaufman's levels of learning evaluation model in Anderson's model of learning evaluation.

Motivation is defined in the Business Dictionary as internal and external factors that stimulate desire and energy in people to be continually interested and committed to a job, role, or subject. Motivation and motivation theory has been around since the 1930s when Elton Mayo studied the effects of motivation at the Hawthorne Works of the Western Electric Company. Three more prominent motivation theories include Abraham Maslow's hierarchy of human needs, Frederick Helzberg's theory on motivators key factors, and David McClelland's achievement motivation theory. In general, intrinsic factors tend to be much more effective than extrinsic factors in motivating people, at least within the workplace.

Questions for Discussion

1. Why is leadership an essential skill for a clinical informaticist?
2. Describe a leadership model you have observed in practice. Did the leader meet all the criteria as outlined in the model definition?
3. Which motivational theory or aspects of motivation would work best when implementing a clinical decision support (CDS) module into a department or clinic? How

about when implementing a medication reconciliation module? Would the motivating factors be the same in these two scenarios?
4. Is it possible to communicate well but be a poor leader?
5. What role does negotiation play in leadership?
6. Think about scenarios in which you've observed conflict management. Describe one scenario in which the conflict was resolved well and another where the conflict was resolved poorly. What could lessons from the first scenario have improved the second?
7. What are the five common characteristics of competencies?
8. What is the purpose of a competency framework?
9. What are the main components of the Kirkpatrick model of training assessment?

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Effective Interdisciplinary Teams

20

Titus Schleyer, Sarah Zappone, Candace Wells-Myers, and Todd Saxton

Learning Objectives
At the end of this chapter, readers should be able to:

- Explain how human resources management intersects with and contributes to the achievement of an organization's mission and goals.
- Discuss the activities necessary to recruit personnel for and build staff for clinical informatics organizations.
- Assess how job applicants match the requirements of a particular job description.
- Determine when forming a team to perform work that is useful and appropriate, identify the factors that contribute to (or hinder) team effectiveness, and apply strategies to address those factors.
- Apply a structured, 7-step process for planning, conducting, and managing meetings in support of organizational objectives.
- Describe some "out-of-the-box" ideas to create productive and efficient meetings.

Practice Domains: Tasks, Knowledge, and Skills
- K113. Consensus building, collaboration, and conflict management
- K120. Communication strategies, including one-on-one, presentation to groups, and asynchronous communication
- K121. Effective communication programs to support and sustain systems implementation
- K124. Conflict management strategies, methods, and techniques
- K137. Principles, models, and methods for building and managing effective interdisciplinary teams
- K138. Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles, team management, identifying and addressing challenges)
- K139. Group management processes (e.g., nominal group, consensus mapping, Delphi method)

Clinical Vignette
You have recently been hired as the first Chief Medical Information Officer at Kensington Community Hospital in Philadelphia, a 550-bed facility that offers emergency, primary, and specialty care, inpatient and outpatient services, and prevention and rehabilitation. For many years, the hospital has used various systems to serve its healthcare information technology (IT) needs. Registration, admission, discharge and transfer; billing; laboratory; and medication ordering functions are provided by McKesson; scheduling and a patient portal by RelayHealth; outpatient electronic medical records by eClinicalWorks; and nursing documentation by ePowerDoc. The computer-based physician order entry system in inpatient and outpatient settings was

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custom-written by a local software company working with Kensington for a long time. In addition, the hospital uses about 25 other applications in areas such as radiology and diagnostic imaging, several specialties, and its rehabilitation service.

Recently, the CEO and her executive team decided to move to a comprehensive, vendor-based system. Maintaining the current suite of disparate, non-integrated applications from many vendors had put undue strain on the organization and its IT support. Managing the data center with its growing number of dedicated and virtual servers, establishing the many, mainly HL7-based, interfaces among the applications, and troubleshooting problems had become an unsustainable and expensive endeavor. The IT staff alone had grown from 30 people in 2007 to over 80 in 2012. In addition, end-users complained about having to log into multiple systems for common tasks and that very often, the same information in different systems was out of sync.

Since you just completed your clinical informatics fellowship and passed your board certification, the hospital is placing all its hopes for a renewal of its health IT infrastructure and processes on you. After six months on the job, you have, together with the hospital senior administrative team, gone through a vendor identification and selection process that resulted in Kensington selecting Cerner as its future system. Due to the timing of the next stage of meaningful use, you now have 16 months to implement the fully functional system in your hospital. You also would like to phase out most standalone applications and replace their functions with Cerner or compatible packages.

One of your immediate priorities is to constitute a hospital-wide implementation team composed of clinical, administrative, and technical personnel to manage the transition. In addition, you are enlisting 25 consultants from Cerner for the implementation period and sometime after that. In total, you anticipate that about 150 people will be involved in implementing the new system.

Here are some questions for you to answer:

- What types of people, as well as how many, should be on your hospital-wide implementation team? How would you organize your team at the strategic, tactical, and operational levels?
- Many of your IT employees have been with Kensington for a long time and have rather idiosyncratic and, to a degree, outdated technical skills. How can you leverage them for the new implementation, and what opportunities and challenges do you face?
- While Kensington is in a somewhat economically depressed area of Philadelphia, the Philadelphia economy is booming. Competition for skilled IT personnel in healthcare is fierce. What can you do to ensure you can hire enough skilled IT staff?

Introduction

Clinical informatics is not a technical discipline; it is a sociotechnical profession. It combines technical knowledge with procedural, organizational, and personnel assets to achieve its objectives successfully. Therefore, clinical informaticists must recruit qualified people, organize them into high-functioning teams, and use meetings to effectively orchestrate operational efforts within the clinical enterprise. The chapter begins with developing a human resource plan, defining jobs and job descriptions, recruiting and hiring employees, developing, evaluating, and compensating them, and, finally, maintaining a highly productive workforce.

Next, the chapter describes how to leverage teams and teamwork because more than one person performs clinical informatics in the organization. The chapter discusses forming teams, defining a team charter and ground rules for the work, and aligning team members and task structure for maximum effect. The chapter also covers how to manage teams for maximum performance and how to handle inevitable conflicts. Key tenets for highly functioning teams include empowering members, defining responsibilities clearly, communicating transparently and effectively, and adapting rapidly.

Finally, the chapter discusses how best to use meetings for maximum effect. While holding meetings is one of the most hallowed traditions in organizations, meetings are also among the most reviled business activities. Effective meetings require thorough planning, conscientious execution, and diligent follow-up. If a meeting needs to be held, attendees need to know the purpose of the meeting, how they can contribute maximally, and the action items resulting from the meeting. Holding meetings is an expensive but essential activity. Therefore, they should be treated with the attention they deserve.

Understanding the material in this chapter should help you leverage personnel, teams, and meetings optimally to pursue your clinical informatics objectives.

Human Resources Organization Planning and Development

In the current knowledge era, and especially in the informatics industry, intellectual capital is one of the most important assets of an organization. **Intellectual capital** is the sum of the unique knowledge and skills that employees contribute to an organization. The importance of intellectual capital does not only manifest itself at the level of the individual but also in teams. Teams can synergize and leverage individual intellectual capital into high collective contributions and performance toward a goal.

Employees have evolved from being "a" resource in production in the industrial economy to "the" resource in the knowledge economy. Managing human capital for high performance and results has become one of the most differentiating competitive advantages today.

However, clinical informatics is not just a knowledge-centered activity but also a socio-technical activity. Bringing together, developing, and challenging the right people and teams is a key factor in supporting the vision and goals of clinical informatics.

Therefore, clinical informatics must partner effectively and strategically with talent management professionals who focus on recruitment, retention, and development. Do not treat your human resources (HR) department as a "service" used to "procure" workers when needed. Instead, engage all relevant parties, including your informatics organization and its stakeholders, as well as talent management professionals, in the process of seeking, acquiring, and managing talent. The earlier you get ahead of your organizational challenges by hiring the right talent and engaging them in your long-term goals, the faster collective efforts multiply on themselves, which increases capacity and ability to achieve beyond any one person's potential.

The Human Resources Process

Figure 20.1 shows a general overview of the human resources process, which we will use to map our discussion.

- **HR Planning**: Be clear about your goals, timelines, process, and stakeholders. Once you have a plan, you can go about determining what kind of staffing you need.

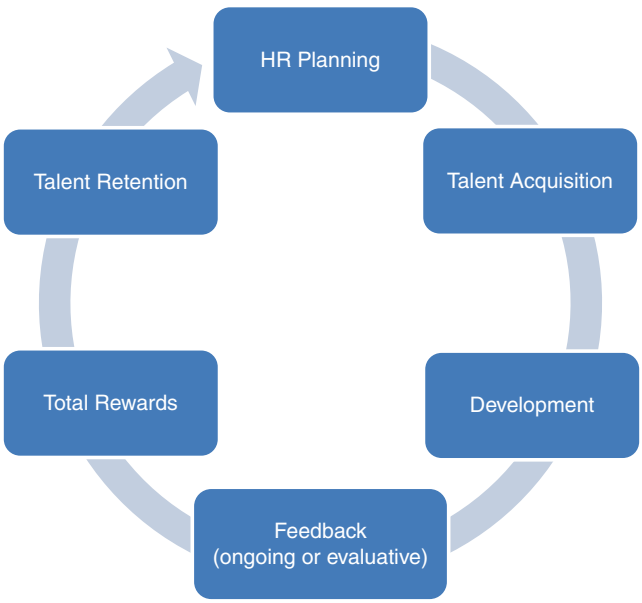

Fig. 20.1 General overview of the human resources process

- **Talent Acquisition**: With your plan in hand, you can set out to staff your organization. Talent Acquisition is a set of activities to attract and select individuals for positions to facilitate organizational goals, balancing short-term against long-term objectives.
- **Development**: Once you have staff, you can't just sit back and watch the work being done. While you strive to hire staff with the right qualifications based on your needs, you also have to make sure that employees develop continually. Help your employees acquire and maintain the skills and knowledge needed for higher productivity, better efficiency, or their next assignment. An essential part of development is continually assessing successes and failures and learning from them. Professional know-how is developed most rapidly through repeated exposure to complex, real-world problems.
- **Feedback**: While it is common to focus on results and solving problems and ignore the individual contribution of skills and knowledge to this effort, it is very important to provide ongoing feedback and evaluation. You need to identify and share how well each individual applies their knowledge, skills, and experience to fulfill the requirements of their position. The most effective feedback programs focus first and foremost on coaching and development. Feedback programs can include informal channels like coaching and regular informal sessions and formal channels like designated mentor programs and regular performance appraisals. Coaching, feedback, and mentoring are designed to help employees improve and develop their knowledge and skills. Performance appraisals are a formal process that usually includes numeric ratings and are often used to determine pay increases. All types of feedback, both for reinforcement and improvement, are important in the development of employees.
- **Total Rewards**: Total reward is a term used to define the entire package of salary and benefits offered to employees. A total rewards package includes:
  - Salary
  - Bonuses (if applicable)
  - Benefits (medical, dental, vision, etc.)
  - Paid Time Off (vacation, sick time, etc.)
  - Retirement Plans (401k, 403b, etc.)
  - Other ancillary benefits (parking, pet insurance, wellness incentives, disability insurance, life insurance, tuition assistance, etc.)

    Many people focus on salary, but it is important to recognize the value of other non-salary benefits provided to an employee as part of their total rewards package. Initially, salary is set based on various factors, such as position requirements, candidate qualifications, external market value, and internal equity considerations. External market value is determined by supply and demand for the skills required for the role, usually

within your geographic location. However, as more organizations embrace remote work, the competition for talent is beginning to blur the lines related to geographic location. Internal equity is how roles like work, responsibilities, and impact are balanced against similar roles in the organization. Generally, salary should reflect performance evaluations, external market trends, internal equity considerations, and available funding. As individuals apply knowledge and produce results, they become more effective, produce higher-value results for the organization and, as a result, position themselves for higher salaries. Rewarding top performers is key to increasing productivity and greater value for your investment. Ultimately, the goal is to create as many winning equations as possible. The organization must get a return on investment in the talent and vice versa. This is rarely just about salary.

- **Talent Retention**: Maintaining the workforce is a constant process of promotion, reassignment, recruitment, and termination to make sure your workforce is supporting your staffing plan. Keeping a team that has the right mix of skills, experience, and education is key.

Human Resources Planning

Few managerial decisions are as important as hiring the right talent. The quality and capabilities of the people you choose to bring on to your team will greatly impact its success—as well as yours as a manager. Maximizing staff contributions to the organizational mission requires a solid HR plan. Given your goals, what kind of people do you need to achieve them? How do various staff roles complement each other for maximum effect? How do expected staff transitions, such as retirement, affect your talent management needs? Having a solid HR plan in place prepares you well for creating jobs and recruiting for them.

Jobs

So, how do you create a job? The first step is to complete a job analysis. **Job analysis** is the systematic study of a job to determine what tasks and responsibilities are expected, the qualifications required to successfully meet those expectations, the conditions under which the work is performed, and who the position is accountable to. The following aspects need to be identified:

- **Purpose of the position**: a two to three sentence explanation of the primary role or function of this position and how it relates to other positions
- **Major duties and responsibilities**: a list of the primary deliverables and responsibilities
- **Job specifications/qualifications**: These include the knowledge, skills, and abilities required for a person to have a reasonable chance of successfully performing the job. Job specifications should list the minimum requirements for the role as well as preferred requirements. Minimum selection criteria should **not** include knowledge, skills, and experience that are not directly required to do the job successfully and should generally not include skills or experience that can be taught in a relatively short time frame.

Job analysis is a time-consuming and demanding task. It can be difficult to show statistically the extent to which a job analysis is valid or reliable, particularly as jobs get more complex. For best results, focus on the following:

- obtain information directly from the job incumbent if possible
- collect data from multiple incumbents, managers, and other stakeholders with knowledge of the role
- select a technique that allows information to be obtained, summarized, and processed with minimal effort. For example, coded, concise data are easier to process than narrative information
- select a technique that is easily updated to avoid repeating the entire process from the beginning

Your job analysis provides the information required to create a document called a job description.

Developing Job Descriptions

A **job description** is an important tool serving a variety of functions. In addition to supporting recruitment and selection, it facilitates training, safety, compensation, performance evaluation, clarification of handoffs, deliverables, and scope of responsibility. It can support a vision for career paths and the transition of workflows and functions, allowing for effective change management in line with the organization's evolving needs.

Formats vary greatly but typically contain the following elements:

- **Title:** The title often becomes the primary identity of a position. Titles alone can be a very effective management and development tool. Choosing titles that align with industry titles can also be important for external benchmarking purposes.
- **Organizational Relationship**: who the position reports to and how the position relates to various functional areas of the organization
- **Position Purpose**: a few sentences describing the primary function of the position

- **FLSA Status**: FLSA (Fair Labor Standards Act) status determines if the job can be exempted from overtime pay. For a job to be exempted from overtime pay for work over 40 h in a workweek, it must meet the qualifications outlined in federal wage and hour laws. A position classified as "exempt" (sometimes listed as salaried) does not require overtime pay for working more than 40 h in a workweek. If a position does not meet the federal requirements to be exempt, it is classified as "nonexempt" (sometimes listed as hourly), which means an employee must be paid overtime for hours worked over 40 h in a pay week. To be classified as exempt, an employee must meet all the requirements of the FLSA duties test as an exempt employee and meet a minimum salary test. Learn more about FLSA status by going to www.dol.gov/whd/.
- **Position Essential Duties and Responsibilities**: These are the essential functions and responsibilities of the job. This may also include nonessential functions which are desired but not necessary aspects of the job. Appropriately documenting the essential duties and responsibilities of the job is critical to ensure the FLSA status is set appropriately.
- **Qualifications**: A statement of skills, abilities, education, and previous work experience as well as desired skills that would be beneficial. This is typically a bulleted list.
- **Physical Demands and Working Conditions**: The job's environment and where it is performed, especially if in any unpleasant conditions. Lifting and standing requirements are often listed in this section. Any exposure to hazardous materials or conditions is also listed.

Sample Job Description

JOB DESCRIPTION

POSITION TITLE: Director, Business & Clinical Intelligence

SUPERVISOR'S TITLE: Executive Director, Decision Support & Analytics **FLSA STATUS:** Exempt

Position Purpose

The Director, Business & Clinical Intelligence, is responsible for developing and leading the business and clinical intelligence teams and enabling healthcare innovation through information delivery, self-service enablement, and visual analysis tool development. These responsibilities will be achieved by creating and maintaining common business intelligence (BI) framework, end-user training, and developing big data and analytics solutions.

Position Essential Duties and Responsibilities

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

- Participate in the Decision Support & Analytics leadership team, with the ability and desire to assume responsibility beyond the immediate role
- Lead the business and clinical intelligence teams, as well as provide support for research and health plan analytics
- Work with the enterprise architecture group to develop and maintain the system-wide business intelligence and analytics framework
- Support data-driven decision-making, and apply continuous improvement and the use of key performance metrics to improve existing processes
- Collaborate with all levels of senior leadership, providing coaching, development, and educational programs as needed. Facilitate the development and growth of leadership within a comprehensive and geographically dispersed integrated healthcare system.
- Cultivate an environment of collaboration, responsibility, and accountability, resulting in highly successful outcomes that the institution becomes the benchmark. Instill and inspire accountability and empowerment as part of the overall patient-focused, performance-based culture.

Qualification Requirements

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

Education and/or Experience

- MS or Ph.D. degree in computer science, information science, big data, or a closely related field is required.
- At least three years of practical experience with managing and analyzing large complex healthcare data sets is required.
- Experience must also include standard business intelligence and analytics tools, such as Tableau and Qlikview.

- significant experience in information systems, analysis, and quality improvement
- familiarity with clinical operations & healthcare information management, and the healthcare reimbursement environment
- strong matrix leadership skills (inspiring, problem solving, communication across multiple organizations, executing)
- a proven leader of people, able to recruit, develop and mentor a top-notch team capable of supporting future growth
- knowledge of industry issues
- adherence to system Leadership Competencies: Commitment to Purpose, Setting Healthcare Business Strategy, Leading Change, Driving for Results, Emotional Intelligence, Executive Disposition, Aligning Performance for Success, Coaching and Talent Development, Building Partnerships and Collaboration, and Team Leadership

Language Skills

- superior ability to communicate (in both verbal and written form) both abstract and concrete ideas and results to individuals with highly variable technical backgrounds
- ability to effectively present information in one-on-one and group situations to customers, clients, and other employees of the organization
- able to work and effectively communicate in a "team setting" as well as independently with minimum direction, use time efficiently, and problem-solve

Reasoning Ability

- able to translate business needs and requirements into appropriate analyses and visualizations
- superior capability to conduct data manipulation and data analysis

Technical/Computer Skills

- knowledge of relational and no-SQL databases
- experience with appropriate ETL and data management procedures to prepare data for analyses
- proficiency in conceptualizing and implementing analyses and visualizations in Tableau and/or Qlikview
- ability to operate office equipment, including copiers, fax machines, and phones

Physical Demands

The physical demands described here represent those that must be met by an employee to successfully perform the essential duties of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

- This position requires the physical ability to work 40 h per week, including the flexibility to work extended hours as necessary to meet organizational needs.
- This position requires the ability to sit and/or stand for extended periods.
- This position requires the manual dexterity to operate a keyboard and pointing device.
- This position requires the ability to travel around system facilities or to outside meetings as necessary.
- This position requires the ability to perform focused work with close attention to detail.
- This position requires excellent speaking, writing, and listening skills.
- This position requires some physical activity, such as pushing, pulling, lifting, carrying, and moving (up to 20 pounds).

Work Environment

The work environment characteristics described here represent those an employee encounters while performing this job's essential duties. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

- This work takes place in both an office environment and a healthcare environment for meetings, interactions with customers, and training purposes.
- This work is fast-paced and deadline-oriented, and requires a flexible work schedule.
- The use of a computer, business office equipment, and other machinery is necessary.
- This position requires working as a team member and also independently.
- This position requires working and interacting with others, both in person and through phone, email, and written correspondence.

There is a current trend towards broad descriptions without specific details regarding tasks assigned to specific positions. This allows the transition of tasks within the same job title or career path and facilitates effective internal equity management without constantly updating individual job descriptions.

Staffing

Attracting top talent is a competitive proposition. Top talent working in your organization attracts and fosters more top talent. The goal of your **recruitment strategy** should be to entice a large pool of qualified candidates. Deciding whether to recruit internally or externally has its advantages and disadvantages (see Table 20.1). How feasible internal recruiting depends somewhat on your organization (size, job diversity, etc.) and the availability of appropriate talent pools. Many experts advocate for a balance of the two.

Ultimately, the appropriateness of recruiting internally or externally depends on the organization's needs, capacity for training and development, culture, and specific project demands. It also depends on where the more talented candidate can be found.

Internal Recruiting Sources

Filling job vacancies through promotions and transfers can capitalize on the organization's investment in recruiting and developing its existing talent. Effective sources for internal recruitment include job postings, skill tracking systems, and employee referrals.

Table 20.1 Merits and drawbacks to recruiting internally and externally

	Recruiting internally	Recruiting externally
Advantages	• motivation for learning and development • reward for superior work of current employees • cost-effective • can improve morale • can assess known past performance • can result in successive promotions • reduced onboarding time as an incumbent is already familiar with the organization	brings in new ideas into the organization • helps organizations get needed competencies • provides cross-industry insights • may reduce training costs
Disadvantages	• can produce organizational inbreeding; candidates may have a limited perspective. • may place a heavy burden on training and development • may cause political infighting for promotions	• may result in misplacements • increases recruitment costs • may cause internal morale problems • requires longer orientation or acclimation time

External Recruiting Sources

The use of external labor sources varies with various factors, such as the type of job, geographic locality, state of the economy, and others. In periods of high unemployment, an adequate supply of qualified candidates can often be obtained through local advertising and networking. If unemployment is low, organizations may need to advertise more broadly, and seek assistance from sources such as employment agencies and search firms.

External supply or recruitment channels:

- advertisement
- employee referral
- headhunters/recruiting agencies
- Web
- social media including text, audio, video, images, podcasts, and online multimedia applications
- walk-in
- job fairs
- former good employees interested in returning from retirement or after life changes
- previous applicants
- trade and professional organizations

Networking

Informal recruitment networks often yield a level of professional, social, and personal compatibility between organizations and applicants that is difficult to obtain through general advertising. Sharing your staffing needs at lunches, conferences, and professional organizations can yield quality talent. You can exploit informal recruitment through social networks such as Facebook, Twitter, and LinkedIn.

Diversity

Achieving greater diversity in the workplace has become a priority of many organizations—and clinical information system departments are no exception. Diversity is essential given the increasingly collaborative and team-based structure of modern organizations. The evidence is clear that organizations that can effectively recruit and manage a diverse workforce have a clear competitive advantage. Therefore, your talent acquisition strategy needs to include specific steps for achieving and maintaining diversity.

Employment Branding

Employment branding is the process of positioning an organization as an "employer of choice" in the labor market. A good employment brand creates an image that draws and

retains the right talent. An organization's value proposition is the foundation of employment branding. Generally speaking, an organization's value proposition is the value that an organization can deliver to customers and other constituent groups within and outside the organization.

Recruitment Effectiveness

Evaluating the success of an organization's recruitment efforts is crucial. Without metrics and assessment, organizations tend to recruit the way they always have, possibly missing out on improvements they could make. Table 20.2 shows some useful short- and long-term metrics.

Table 20.2 Selected short- and long-term metrics for recruitment effectiveness

Time horizon	Criteria
Short-term	• average days to fill a position • acceptance rates • cost per applicant hired • ratio of qualified to unqualified candidates • EEO and Affirmation Action program implications
Long-term	• performance of hires • turnover • absenteeism per hire • training costs

Selection Process

Selection is the process of identifying the most suitable candidate for a position. The process involves a series of filters designed to narrow the field of candidates progressively down to a select few. At each stage, more information is gathered so that prospective candidates can be matched with the position's requirements.

Step 1: Analyzing Application Forms

Applicants typically use resumes to portray themselves in the best light given a particular job opportunity. Application forms, however, tend to be more structured and complete than resumes, and require the applicant to attest to the integrity of the information. If employees are found to have lied on their application form, they can be terminated for falsification of information. The organization's HR function will often review applications to ensure they meet all minimum qualifications for the position before they are eligible for consideration.

Step 2: Prescreen Phone Call

A verbal conversation can be helpful and efficient in clarifying information. In a few minutes, an interviewer can ascertain the candidate's background, characteristics of interest, and availability. It is also an opportunity to describe the job in greater detail so that both parties can determine whether continued interest in the position is warranted. The organization should keep applicants informed of their status and avoid significant time lapses between communications whenever possible.

Step 3: Selection Interviews

Selection interviews are intended to allow the interviewer to probe areas of interest to determine how well the candidate meets the position's needs. Unstructured interviews typically have relatively low reproducibility and validity. While structured interviews are better, semi-structured interviews are the most common. The interviewer uses a set of prepared questions as a guide but explores and focuses on questions as needed.

Situational interview questions are questions designed to elicit stories and examples from the applicant's experience that demonstrate the applicant's skills and qualifications. Hypothetical questions can also be used to learn how a potential employee might react in a given situation.

Both situational and hypothetical questions are valuable because they do not have canned answers and require an applicant to think on the spot. The goal of these questions is to predict future behavior based on the application of prior experience.

The following are helpful techniques for interviews:

- **Plan for the interview.** Be familiar with the job requirements to be able to assess how the candidate matches them. Review the candidate's application before the interview.
- **Establish and maintain rapport.** Try to create an environment where the candidate feels as comfortable as possible and is more ready to provide honest and open answers.
- **Listen carefully.** You are trying to learn as much as possible about the candidate**.** The applicant should talk the majority of the time. Once you have determined they are a viable candidate, you can sell them on the position later. Be disciplined about asking the same questions of every candidate.
- **Observe nonverbal behavior**. Be aware of facial expressions, gestures, body positions, and look for inconsistencies between the candidate's verbal and nonverbal cues. While eye contact is sometimes considered a key indicator for truthful responses, it is important to recognize that cultural norms and neurodiversity traits impact lower eye contact behavior (and other nonverbal cues).
- **Ask questions**. Plan ahead and ask open, probing questions that encourage candidates to tell you as much as possible. Make sure you have a question that targets each critical success factor or qualification of the position you are trying to fill. Examples of open, probing questions include: "tell me about…" or "describe a time when…."

- **Provide realistic information.** At the end of the interview, provide the candidate with specific information about the job and the organization's philosophy and culture. Do not promise or predict outcomes. Offer enough time for candidates to ask questions. You can learn what is important to them and whether they have prepared for the interview. Realistic job previews help improve good matching between the candidate and the role.
- **Take notes**. Note-taking is strongly recommended to document the qualifications of the candidate. It is not necessary to ask permission. Documentation should only contain information relevant to the requirements for the position. Do not document non-job-related information, even if it is volunteered by the candidate (family status, religious or political affiliations, etc.).
- **Summarize.** Conclude the interview with a summary, telling the candidate what will happen next.

Step 4: Pre-Employment Tests

Some organizations test applicants before in-depth interviews, others afterward, and many do not test at all because of legal risks. Tests must be valid and reliable and measure job–related predictors. Pre-employment testing may involve the risk of litigation because the tests discriminate against minorities, the disabled, or other applicants if improperly conducted. Within the guidelines, care must be taken to comply with applicable federal employment laws such as the Civil Rights Act of 1964 and 1991, the Americans with Disabilities Act, and any state laws that restrict pre-employment tests. In 1978, the Equal Employment Opportunities Commission (EEOC) created guidelines to ensure that the knowledge gained from testing is applied with impartiality to protect underrepresented applicants from discriminatory employment procedures, even if the adverse impact was unintentional.

Pre-employment tests may be broadly categorized in the following manner:

- *Cognitive ability tests* measure individuals' verbal and mathematical skills, logic, reasoning, and reading comprehension abilities.
- *Personality tests* attempt to measure a person's social interaction skills and patterns of behavior.
- *Aptitude tests* measure the general ability or capacity to learn or acquire a new skill, such as software applications, programming languages, and healthcare terminology.
- *Honesty/integrity tests* measure an applicant's propensity toward undesirable behaviors such as lying, stealing, taking drugs, or abusing alcohol. Such tests have been criticized for their possible invasion of privacy and self-incrimination.

Step 5: Pre-Employment Checks

Assuming that the best indicator of future performance is an individual's past performance, it is important to check references carefully. Some states limit the use of certain types of pre-employment checks, so it is important to know how and when you may use them in the hiring process. Many HR departments conduct all relevant pre-employment checks before the candidate's start date in compliance with all regulations.

The following are common types of background checks:

- **Work reference.** Generally, the most informative references are those given by former and current supervisors who are likely to know the candidate's work and have observed the candidate performing a job similar to the one for which the candidate is applying. Always obtain permission from the applicant before contacting a reference. This can be included in the application form and/or provided upon request by the candidate.
- **Verification of academic credentials**. Employers can request copies of grade transcripts or verification that the applicant attended the educational institution listed on the application form.
- **Credit history checks**. Credit checks should only be conducted for positions of financial responsibility or for positions that involve handling significant amounts of currency or other valuables. It can be considered discriminatory toward women or minorities to conduct credit checks without a business reason.
- **Motor vehicle record checks**. Motor vehicle records are maintained by departments of motor vehicles in all 50 states for up to five years. These records contain moving violations, motor vehicle accidents where a police report was filed, revoked or suspended license, and driving while impaired. Motor vehicle checks should be conducted on candidates for positions requiring the use of a company-owned vehicle or personal vehicles required for the performance of the job.
- **Criminal background checks**. Checking the criminal record of candidates reduces the possibility of theft and embezzlement, and the risk of workplace violence.
- **Drug screening**. Drug screens are used to help ensure a drug-free workplace.

Step 6: Employment Offer

An employment offer should immediately follow the final decision to hire a candidate. It makes the hiring decision official and is formally communicated through an offer letter. Employment offers should be worded carefully. They should never include language that could imply an employment contract. Obtain standard language approved by HR and/or legal counsel. Set a reasonable acceptance deadline taking

into consideration situations involving relocation or issues with higher-level positions.

The process we have described for staffing is very common in many organizations. However, some approaches may outperform traditional methods in terms of helping you recruit a high-performing workforce. For instance, in *Who: The A method for hiring* (2008), Smart and Street describe how you can source talent by building and cultivating a rich, multi-faceted set of long-term relationships [1].

Development

Hiring and New Employee Training Process

Hiring is just the first step in acclimating a new employee to the organization. Most organizations follow a comprehensive new employee training process to bring new individuals on board and help them develop as professionals. The following items are commonly found in new employee training processes.

Onboarding Effective onboarding is a critical aspect of retention and sets the stage for a high level of productivity. Supervisors should prepare in advance to ensure a positive first day on the job. Supervisors should make room in the calendar to spend time with new staff or assign a leader within your team.

First day of work Developing a working relationship in the first days is paramount. Introduce the employee to key team members they will work with, important stakeholders in their work, and administrative staff available to help them. Ensure the tools they need for the job are working, such as computing equipment, electronic accounts, email, badges, etc. Either you or a peer should accompany them to lunch. Arrange to obtain feedback from the employee at the end of the first day.

First week Verbally present a written description of the job and responsibilities, roles, and tasks. Offer job shadowing opportunities. Show new employees what to do, watch them do it and then ask them to show you what they are doing. Greet the individual each day in person or by phone. Inform them of department goals, objectives, and current projects. Make a coworker available to answer questions. Ensure the employee is set up to receive organization-wide information (e.g., membership in email lists and important directories).

First month To maximize acclimation during the first month, the employee should learn about:

- the organization, culture, vision, mission, and values
- the organizational structure
  - roles and responsibilities of each department in the organization
  - organization communication channels such as an intranet
  - their individual training outline or checklist

Frequently follow up with the employee to answer questions and remove barriers to his/her success. Make sure to assist the employee in developing relationships with peers and others.

First three months Highly structured management in the first three months can be a good thing to facilitate the continued development of the employee's knowledge of their roles and responsibilities. Create appropriate assignments, team participation, and decision-making opportunities. Let the employee work more independently as they become more familiar with the job and gain confidence. Consider assigning a mentor to the new employee so the individual has a regularly available resource for questions.

Throughout this training time, it is important to assess whether a good hiring decision was made. Be as open and honest as possible as you learn how an individual's skills and experience match the job expectations.

First year When an employee has completed their first year in the position, it is time to begin discussing longer-term professional development. Seek evidence to validate:

1. Is the job description a realistic and accurate reflection of what is being accomplished?
2. Have you reached maximum capacity or productivity as expected?
3. Does the individual hired have the skills, knowledge, and experience to fulfill the responsibilities as you expected?
4. Has the job evolved differently than expected?
5. Finally, what needs to change?
   (a) Revise the job description. Engage the employee in this process.
   (b) Implement training and development plans.
   (c) Think about how to increase the capacity and efficiency of this position.

Assign tasks that bring more value to the job, such as a larger scope of responsibility, more complex information processing, or responsibility for guiding other talents.

Most jobs are not static. Requirements tend to evolve, especially in dynamic, growing organizations. It is very important to grow the employees with their jobs.

Evaluation, Compensation, and Maintaining the Workforce

Performance management is the process of maintaining or improving employee job performance through performance assessment tools, coaching, counseling, and providing continuous feedback. Individual contribution drives business results that accomplish the goals of the organization. The performance management process allows the employee and the performance manager to discuss development goals and jointly create a plan for achieving those goals. Development plans and individual actions then contribute to organizational goals and the professional growth of the employee.

Ways to foster a high-performance team:

- provide a positive and challenging work environment
- attend to employee engagement activities
- hold performance managers accountable for their role
- provide continual feedback from managers, peers, customers, and others
- convey consistent management practices

Annual Evaluations

Regular performance evaluation can:

- improve productivity through effective written and verbal feedback and coaching
- provide a framework for allocating rewards and opportunities
- identity opportunities for development and training needs
- communicate expectations and determine employee aspirations
- foster commitment and mutual understanding

The most commonly used rating method is a categorical scale. The appraiser checks the appropriate place on the scale for each task or behavior listed. A typical example is a five-point rating scale where (1) is significantly below standard, (3) is standard or competent, and (5) is significantly above the standard. Frequently, a comments section is included in which the performance manager can provide more detail about the employee's performance.

Evaluations are trending towards a formal process for collecting feedback from peers, subordinates, and key stakeholders (e.g., 360-degree review). Also, evaluations tend to provide feedback on individual contributions to achieving specific results, projects, and/or metrics versus behaviors.

Compensation

Regular evaluation of compensation can ensure that:

- productive talent is financially recognized in an equitable way internally
- conscious recognition of where there is not a good return on investment in talent so that plans can be put in place to increase productivity, skillset, and results in those resources
- a conscious focus on the external market and external value of the talent in the labor market

Managing the compensation of talent is a difficult challenge. If available, you should seek guidance from the HR department in your organization. It is common for HR to have access to external labor market data. An increase in salary and career growth can come in merit increases, promotions to new and open positions, or upgrades to existing positions.

Merit pay budgets are affected by the cost of living and market demand for talent. There may be circumstances where market adjustments, in addition to merit adjustments, are necessary to retain your top talent. Good external market data should include a job description with the title, qualifications for the position, and several incumbents. Do not make pay decisions simply based on salary data with a title and no job description, or information on the number of incumbents.

The availability of promotions and upgrades are affected by the demand for higher-level competencies in your workgroup. Promotions are applicable when current work done by this individual must be shifted to a new hire or someone else in the group to make room for new responsibilities. Upgrades are applicable when an individual has developed and produced results that bring a higher level of value to the position than the position in which they were originally hired. Upgrades should only occur if a full-time position at the new level exists, the individual has demonstrated the knowledge and skill required to perform the upgraded position, and funding is available. All upgrades and promotions should require an updated job description and a clear understanding of new expectations associated with increases in compensation.

Departure of Staff

The movement of talent outside the organization is a natural part of the healthy evolution of the workforce. Whether employees voluntarily leave or are involuntarily terminated, their experience with the organization should end in a mutually respectful manner. The ultimate goal is to keep high performers and to transition out low performers.

- **Voluntary terminations** are generally categorized as resignations and retirements. It is not a bad thing when an individual gets promoted into a position outside of your organization. Your goal is to be aware of all team mem-

bers' aspirations so that those skills can be applied internally with the natural growth of the organization if possible. It is a given that you will not have opportunities for all, and departures can open opportunities for others to grow and develop.

- **Involuntary terminations** should involve counsel from your HR or legal department. You want to steer clear of accusations of wrongful terminations. Employees are protected by several laws that prohibit discrimination and unlawful employment practices. Documentation is extremely important and employment laws can vary among states.

  Common causes of involuntary resignations are not meeting performance expectations or violation of work rules. A progressive process of coaching, verbal warning, written warning, and final written warning is common. Timeliness and consistency in these communications are extremely important, as is consistent and unbiased documentation. State the facts, be clear, and do not exaggerate. It is not uncommon for employees to believe that they can miss deadlines, make mistakes, or bend the rules and keep their jobs. This might be true if one deadline is missed, or one mistake is made periodically, or they are occasionally late to work. When multiple deadlines are missed, multiple mistakes are made, or a rule is regularly violated, it is important to be clear that they cannot continue this behavior and retain their job.
- **Layoffs/Reductions in Force (RIFs)** occur in essentially all organizations as they need to reduce or adjust their workforce at one time or another. The most common reasons include the following:
  - mergers and acquisitions
  - downturn in business
  - reorganization or restructuring
  - financial difficulties
  - technology developments

  When determining which employees should be laid off, organizations should consider skills, work record, and seniority. In organizations where intellectual capital is the driving force, less consideration is given to seniority and more to the performance and skills of the individual as matched against the requirements of the post-layoff organization.

  Possible alternatives to labor reductions include asking employees to sustain pay cuts, offering voluntary termination or retirement with additional benefits, or asking employees to accept a reduced work schedule.

Legal Framework

There are several federal, state, and local laws that govern employment practices. Below are some key laws to be aware of:

- Title VII of the Civil Rights Act of (1964); amended 1972: prohibits discrimination based on race, color, religion, sex, national origin.
- Age Discrimination in Employment Act (ADEA) of 1967 prohibits discrimination in employment against persons age 40 and over. It forbids limiting or classifying employees in any way that adversely affects their status because of age.
- Pregnancy Discrimination Act (1978) amended Title VII to prohibit discrimination based on pregnancy, childbirth, or related medical conditions. It requires employers to treat pregnancy like any other temporary disability.
- Americans with Disabilities Act (1990) prohibits discrimination against a qualified individual with a disability because of his or her disability. A qualified individual with a disability can perform the job's essential functions with or without reasonable accommodations.
- Older Workers Benefit Protection Act (1990) requires that voluntary waivers of rights or claims under ADEA are valid only when such waivers are "knowingly and voluntarily" made. The Act requires waivers in writing, and employees considering signing a waiver must receive severance payments or some other thing of value, be advised in writing to consult an attorney, and be given at least 21 days to consider the agreement and be able to revoke the agreement for up to seven days after signing.
- Equal Pay Act (1963) prohibits discrimination on account of gender in the payment of wages.
- Family and Medical Leave Act (1993) entitles eligible employees of covered employers to take unpaid, job-protected leave for specified family and medical reasons with continuation of group health insurance coverage under the same terms and conditions as if the employee had not taken leave. Eligible employees are entitled to up to twelve workweeks of leave in a 12-month period for: the birth of a child and to care for the newborn child within one year of birth; the placement with the employee of a child for adoption or foster care and to care for the newly placed child within one year of placement; to care for the employee's spouse, child, or parent who has a serious health condition; a serious health condition that makes the employee unable to perform the essential functions of his or her job; any qualifying exigency arising out of the fact that the employee's spouse, son, daughter, or parent is a covered military member on "covered active duty."

Retention

Retention is the ability to keep talented employees in the organization. Organizations should aspire to keep high performers and to transition out low performers. High performers are employees who consistently achieve superior levels

of performance and contribute value to the organization. Value is unique to an organization. It is aligned with the organization's goals, customer's satisfaction, and productivity. High performers outperform their peers and demonstrate a strong capacity to grow and succeed in their careers.

Forming and Maintaining High-Performing Teams

Teams consist of a group of people who, working as one unit, perform organizationally relevant work organized around one or more common goals. Teams vary in size and location. However, regardless of whether the team is made up of two people or several dozen, there should be an established set of goals that define why the team has been formed, what the team is expected to accomplish, who will be on the team, and how the team's work will be performed. Additional considerations might include the expected length of engagement (e.g., weeks, months, years), the geographic distribution (e.g., in-person, virtual, hybrid), and the formality of the team structure (e.g., tightly structured and part of the company organization chart, loosely affiliated with not direct lines of report). In the case of the Kensington CMIO, the 150 people are likely to be organized in several teams addressing different subtasks, with characteristics varying across all these dimensions.

Task forces, development teams, committees, and working groups are several types of teams that you will be called on to organize and lead or participate in as a member. A major advantage of a team is that the team can operate on greater scales, broader scope, and longer timeframes than one person. Interdisciplinary teams that bring together participants with diverse knowledge, experience, and expertise can solve problems and be innovative in ways that are not feasible for a single individual. At the same time, teams can be too large—for example, the 150 people in the Kensington case would be unwieldy as a single team.

Yet, despite their importance and ubiquity, it is not uncommon to encounter unproductive, dysfunctional, dormant, or failed teams. A diverse group of people working together can foster greater creativity and innovation, which often means more work can be completed. However, working together can also increase debilitating conflict, often causing coordination and communication challenges for the team leader. Ignoring these trade-offs during the formation and management of teams is an important cause of many problems and failures.

One good way to view team composition is to think about teams as a decision-making entity. Essentially, a team is a group of people who are successful (or not) as they make a series of right (or wrong) decisions. John Hollenbeck and colleagues [2] have studied this and created a multilevel theory of team decision-making. They note that nearly all teams have expertise distributed across team members—i.e., all members do not have the same information and expertise. This is particularly true in a healthcare context. What drives successful teams and better decision making includes three components:

- Team Informity. Do all team members share their information as necessary to make a good decision?
- Team Validity. Do team members have the right information and expertise to address the problem or opportunity?
- Hierarchical Sensitivity. Does the team leader effectively draw out all information and weigh input appropriately?

So, when thinking through team composition, it is important to include members with a range of experience and expertise and encourage their full participation. The team leader should be someone with experience in managing a team and bringing diverse perspectives together—not necessarily the person who knows the most about the problem or opportunity.

It is also important to think about the stages of team decision-making. Most decisions go through distinct phases:

1. **Problem identification**. What is the problem we are trying to solve? What does success look like?
2. **Information gathering**. What additional data do we need to make an informed decision? Where do we have gaps?
3. **Options generation**. What are the possible paths forward? This is a key and often underdeveloped step.
4. **Selection and implementation**. Of the options, which do we choose, and how do we move forward?

Interestingly, research has shown that diversity of background, experience, culture, and demographics significantly improves decision-making through the first three steps. Encouraging diversity of thought and sharing improves team informity and validity—more and broader ideas and information are better. But when it comes to implementation, the whole team must be aligned and help execute the plan. In the Kensington case, it would be wise to include diversity across clinical experience (e.g., in- versus out-patient), technical, billing, workflow, different levels of care providers, and IT personnel when scoping new system demands and opportunities. Such diversity may not be as productive when installing and implementing the system. These considerations show how team diversity is intimately connected to diversity in talent management in your organization. In an organization with low diversity, it is difficult, if not impossible, to assemble diverse teams.

Another common model in team dynamics was developed by psychologist Bruce Tuckman decades ago. His research captured the evolution of team dynamics through four phases:

1. **Forming**. In the initial phase, team members will be uncertain about the goals and objectives and interpersonal relationships. The team leader must make all members feel comfortable and help establish the initial culture of the team.
2. **Storming**. At this stage, member disagreements and differences begin to emerge. This may lead to friction and challenging of authority. The team needs to lead, manage, and remain open to diverse perspectives while helping establish the team culture and relationships.
3. **Norming**. Now team members begin to understand and respect their differences and different areas of expertise. Teams establish norms of shared values and behavior.
4. **Performing**. Now teams are ready to begin realizing their potential and delivering. They begin to address their objectives and even take on new and complementary roles within the team. This also sets up a united front for execution.

There are some great tools to help manage team composition, stages of decision-making, and team dynamics. We mention them briefly here and encourage you to explore these resources further. We cover some of the technological solutions for team management later in the chapter.

- **DeBono's Six Hats**. Have you noticed that some teams have their established nay-sayers, devil's advocates, and optimists who seem to play the same role at every meeting? Over time, this tendency can erode effective contribution and decrease the diversity of perspective. The Six Hats approach has team members all take on the same role at the same time to form a team perspective on what is known (facts), what is possible, what is problematic, how team members feel, where creativity and innovation play a role, and what processes can/should be used to govern team progress.
- **Johnson's Farsighted**. Steven Johnson's book "Farsighted" distinguishes between shorter-term tactical decisions he calls narrowband decisions versus complex decisions with far-reaching and possibly unanticipated consequences he calls farsighted decisions. Most of this chapter assumes teams have at least some element of farsighted decisions to make—like implementing a new EHR system for Kensington. Following Johnson's advice to thoroughly explore possible alternatives and options is particularly salient here.
- Other tools such as mind maps, the business model canvas, and case studies can be used at different decision-making stages to help guide team idea development.

As you lay the groundwork for a team, launch it and lead the team through the development and the performance of its work, you must balance the needs of the team and its members while at the same focusing on the purposes and goals, in essence, the reason the team has been formed.

Forming a Team

Determining that a team is the most appropriate solution to accomplish an established goal requires an evaluation of the goals' scope, scale, and timeframe. As the team lead, you will need to establish the team's purpose, which provides direction and expectations. Team members need to be identified and establish how the team will be organized and operate as it develops and performs the necessary tasks.

The best way to lay the groundwork for an effective team is to create a Team Charter. A **Team Charter** is a document that establishes why the team is needed, what it will do, who will be part of the team, and how it will function. The Team Charter needs to be explicit about the team's purpose, the team members, processes for working together, and necessary recourses. Once the Charter is documented, stakeholders and team members need to give their buy-in. This support gives the team the green light to get started and brings forward specific information about how the team will need to function to work effectively together.

A Team Charter may have many parts, but it is imperative to include the following:

- **Purpose**—Why does the team exist, and what is it expected to accomplish?
  - **Statement of Work**—The Team Charter should start with the Statement of Work, identifying the overall purpose of the team, what it will accomplish, and the expected outcomes.
  - **Duration**—The timeframe expected for the team to exist provides team members and other stakeholders a common understanding of how long the work will occupy the team members and allows for a better understanding of what resources will be needed to support the team.
  - **Scope of the team**—The beginning and ending scope of the team sets the parameters which allow the team leads and members to identify the tasks that are both in and out of scope for the team processes.
  - **End result**—Documenting the final product at the beginning will help the team establish meaningful goals throughout the process and allow the team to dis-

band at the appropriate time rather than continue without a definitive ending.

- **Members**—Who is involved in and affected by the team?
  - **Team members**—Each member should be individually listed, including team leads and members. If a specific team member has not been identified, the necessary expertise or role should be described.
  - **External stakeholders**—Parties who are not directly part of the team but are interested in the team operations and accomplishments should be identified. Explicit consideration of these critical stakeholders facilitates future communication and coordination of the team.
- **Structure and Process**—How will the team be organized and operate?
  - **Roles and responsibilities**—Identifying critical activities and indicating who is responsible for the tasks are crucial for everyone to understand and should be documented in the beginning and updated as the team works together. As new roles and responsibilities emerge, it is important to update the Team Charter.
  - **Meeting plan**—Documenting how often, when, and where the team is planning to meet should be clearly stated in the Charter to establish team member expectations. The frequency of meetings should be selected to establish an appropriate rhythm for the team while avoiding meeting overload.
  - **Reporting plan**—In addition to the meeting schedule, a reporting plan should be established. This specifies how the team members will communicate progress and issues, who will receive the reports, how the reports will be distributed, and where the communal documents will be stored.
  - **Deliverables and Timetable**—Team deliverables are the outputs created by the team that are identifiable indicators of its successful performance. These should be documented along with when the deliverables are due so that there is no confusion or misunderstandings about the timeframes of each task.
- **Resources**—What is needed to support the team, and where do those resources come from?
  - **Financial resources**—The funding needed by the team should be identified and documented. These resources do not typically come from the team members directly, so this aspect of the Team Charter often requires explicit approval and oversight of budgets by one or more external stakeholders.
  - **Technology** (see further details below)—Technology is the lifeline of teams these days. Since teams are often distributed geographically, all members must have access to the technology designated as the main source of communication. When setting up a team, a careful review of the needed and available technologies will provide insight into the best forms of communication for the team. Identifying what technology each member needs will help significantly reduce logistical problems and ensure that all team members can participate when needed.
  - **Support**—Identifying administrative and management support that the team will need to develop and function effectively allows for a realistic assessment of the cost of forming the team.

A comprehensive Team Charter will lay the foundation for an effective team by clearly documenting its purpose and tasks, composition, structure and process, and the necessary resources.

As previously noted, technology is a vital resource in supporting efficient and successful teams. Electronic tools can perform various tasks and activities such as communicating, collaborating, sharing, and storing information. Some electronic tools only provide one function, while others are more encompassing.

Communication can occur in many ways, and variables such as accessibility and urgency should be considered when choosing which form is most appropriate. Email is a simple method of communication that allows for easy referencing, sending mass messages, and instant access to information and files. Phone calls and web calling foster quick, effective and clear communication. Instant messaging, or chatting, supports short asynchronous rapid exchange of information while video and web conferencing replace in-person communication, such as meetings, which provides flexibility. Commonly used services and platforms include:

- Microsoft Outlook, Gmail, Yahoo
- WebEx, Zoom, and GoToMeeting
- Skype, Slack, and Microsoft Teams

Collaboration software solutions and applications go beyond offering communication-only capabilities and are designed to support teams collectively. They serve as a one-stop-shop, eliminating the need for multiple tools by providing users with the ability to communicate in various ways in addition to sharing and storing information. Seamlessly integrated tools provide functionality in real-time across different devices, supporting better visibility and efficient work processes. Microsoft Teams and Google Workspace are examples of software solutions that serve as a centralized hub for teams.

Common features of collaboration software include:

- The ability to establish a centralized, private and secure environment.

– Integrated communication tools that include chat, calling, video conferencing, screen sharing, and file-sharing functions.
– Storage capabilities serve as a repository, allowing documents to be easily accessed and remain current and synchronized.

When deciding which solution is best for your team, the following considerations are important:

– ease of use; training required
– scalability and ease of integration
– organizational standards
– external collaborator access
– disaster recovery services (backups or prevention of loss)
– project management features
– cost
– privacy and security to ensure compliance, especially if your team will be using the platform to share or present protected health information.

Last, it is important to remember that while electronic tools offer many benefits, they do not guarantee team success!

Initiating a Team

Once the charter is established, the team is beginning to take shape. However, at this point, the team has not been formed. You will need to bring in the team members, guide them in developing a shared understanding of the goals and tasks, build relationships, and understand the team's structure and roles. Articulating these with the team during the team's initial meetings will help develop the cohesion the team needs to function efficiently and effectively.

Relationships

- As discussed in previous sections, following the necessary steps to gather the right people is key to creating a high-functioning team. The team's organization will affect the relationships between the team members in terms of responsibility and authority. A well-designed team will promote good communication between team members, which can help make the team more productive. In addition, the relationship between the tasks and the workflow process is affected by the organizational design of the team.
- Although job titles may be duplicated throughout the team, each member will contribute uniquely based on their knowledge and experience. The more variety the team has, the more views are likely to be articulated. It is very important to have all points of view represented. However, the composition is more than just having the right people; it has a good combination of people. Some combinations can contribute to creativity, and others can set a team up for nasty conflict. Having the right inputs is a critical condition for forming and running successful teams. Lack of purpose and goal clarity, unrecognized fault lines, and ambiguously defined connections with external sponsors and stakeholders can undermine a team and make performance difficult or impossible. Recognizing and mitigating issues such as these early on and having a good organizational design will create an environment for the team to work effectively with one another.

Team Structure

The structure and roles documented in the Team Charter need to be expanded to include shared processes, interdependence, and boundaries. Establishing and documenting these parts of the team structure allows the team members to relate to the overall structure. An understanding of their roles, in addition to others' roles, can help decrease downstream confusion. Since many of the requirements for a team to be fully functional may not be included in the established team, external parties may need to work with the team to complete the tasks. This is often referred to as Boundary Spanning, where the team leader needs to actively manage these external relationships and should also be documented in the team structure.

Often, people will be part of more than one team. You will need to work with the team members to understand what type of time commitment they can give to your team by providing you what percentage of their time will be dedicated to your team. This is a very important step, as it will determine which tasks can be assigned to team members.

Task Structure

Team interdependence and task structure are extremely important to establish in the initial stages of forming a team. Task structure lays out each task, who will accomplish the task, and when the tasks will be completed. The larger tasks will need to be systematically decomposed into smaller tasks, assigning these smaller tasks to appropriate team members. Be sure to carefully evaluate the time and effort needed for each task and relate to the team member assigned.

Task interdependencies should be documented and shared with all the team members so that each person has a clear understanding of which outcomes will affect the activities and timelines of other team members.

Group Management Processes

Working with the members during the initial stages of forming the team creates an environment where all members feel comfortable will help the team work smoothly, having a major impact on the goal. The initial interactions (forming to

storming) of a team are extremely important in establishing motivation and understanding. This helps establish team empowerment, allowing each member to understand how their expertise will contribute to the team and the outcomes. Key actions to be taken when initially developing the team character include:

- **Kick-off meeting**. During initial interactions when the team is forming, the team members need to develop interpersonal relationships. Providing time for the team members to get to know each other will help build this rapport. Gathering team members for an initial kick-off meeting is extremely important for articulating a shared mission and clearly understanding the goals and activities. As icebreaker activities, each member could share a success story and a frustrating team experience, an interesting personal fact about themselves that others are unlikely to know, or the "Two Truths and A Lie" game. Developing these initial relationships can lead to a discussion about the best way for the established team to conduct itself. Setting these expectations early on will create an environment where the members will feel included and will be more likely to contribute regularly.
- **Team expertise**. In between meetings, there are likely to be questions and issues that need to be addressed. Since each member will bring their expertise to the team, including areas where members have more experience than the team lead, the team should be encouraged to share their knowledge and utilize it when appropriate. When the team is initially forming, set aside time for the team members to share areas of expertise and document the areas that they will be willing to provide guidance about for fellow team members. Having a wide variety of expertise is a very positive feature, as it provides a wealth of information.
- **Problem solving**. Establish how problems will be solved. It should be understood that there will be problems on the team, ranging from miscommunications to outside resources not following through to disagreements between team members. While the team should develop an internal process for how team problems will be solved, you, as the team leader, will need to provide general problem-solving rules. To extend this exercise, allow the team members to provide examples of possible problems to practice addressing the established team problem-solving processes.

Now that the team has been introduced, roles and responsibilities have been established, and the tasks have been laid out, you have the beginning of a working team. These initial interactions were extremely important to how the team will function once the process begins to norm and perform.

As you lead the team, you will be responsible for managing the work process and ensuring everything runs smoothly. This coordination is continuous, and you will often need to refer to the Team Charter to help the team stay on track. You will also need to establish a plan for external communications. Although you have put together a team with various talents and expertise, the team will need outside assistance and information. This wide variety of talents and expertise on the team may cause conflict at various times that will need to be handled professionally, working to keep the conflict constructive.

Coordination

Leading a team should start with following the documented processes and procedures. However, there will be times when you will need to readjust the plan based on task needs, issues with team member's other commitments, and resource changes.

Task Realignment

The task structure has been established, is well documented, and the team understands their tasks and how they fit into the team process. However, there will be incidents when a team member cannot complete a task by the assigned time. As the team lead, you will need to decide if the task can be delayed or reassigned to another team member. When making this decision, be sure to consider other tasks that are dependent on this task. Having established the team member skills when ramping up will provide the information you need to find appropriate members that can assist if you choose to reassign the task.

Team Commitments

Once the team project is underway, you will need to be responsible for tracking the time for each team member. As stated earlier, team members are often overcommitted by being part of more than one team and will need guidance from the team lead to find a way to balance their workload. It is not uncommon to revisit the percentage of time a team member can contribute to the team as work progresses. The best way to manage this is to understand each person's contribution to the team, logically evaluate if the timing of the team member's contribution will affect another task or milestone, and work with that person to document when each of their assigned tasks needs to be completed.

Resource Changes

Team resources have been documented in the Team Charter; however, most teams undergo various changes, causing a shift in resource needs. Adjusting to these changes can be challenging, as it is important to keep all members connected. Initially, budgeting for a variety of unforeseen scenarios is an important step in planning for these occurrences. However, there may be situations where you will need to involve stakeholders to make decisions about new resource needs to keep the team on track.

External to Internal Communication

The internal communication plan is documented in the Team Charter; however, there will be times when the team will need to communicate with people outside the team. The process needs to be established and shared with the team to avoid confusion about gathering and distributing the information. Often the team leader is designated as the person that will communicate with people outside the team. When this occurs, the information will be disseminated from the top down. It is best to have one team member gather information and distribute it throughout the team, which causes less confusion about where it will be coming from. However, it does not always need to be the team leader. It is common to have a designated team member connect with outside contacts.

Conflict

Keeping in mind that the benefit of having a team is that the diversity will offer a wide variety of talents to enhance the team and cover a range of expertise to extend the team's success. This also means there will be a wide range of personalities and opinions within the team that may cause conflict. Conflict occurs when there is an expression of opposing views, which may be real or perceived. Whether the opposition is real or perceived, there is a conflict if two or more members disagree. Conflict can range from a disagreement on how to proceed with a task to personality conflicts. As the team leader, you will be responsible for professionally managing the conflicts to keep the team on track.

Constructive Conflict

Constructive conflict occurs when the benefits of the outcome outweigh the cost of the issue. Constructive conflict should be supported, as the outcome is usually helpful and can produce a new process or even create a new way of resolving an issue within the team. As the team leader, you should encourage these discussions. However, you will need to make sure the disagreeing team members feel comfortable with the level of disagreement, allow all in the party to share their point of view, and keep communication flowing. The parties also need to embrace change and listen to the opposing point of view, which often leads to a mutual agreement and a shared decision. The issues should be documented, along with the outcome, for future reference.

Destructive Conflict

Destructive conflict is usually observed when team members are not focusing on the issues that need to be resolved but rather on personality attacks or hostile discussions. Destructive conflict can erupt due to a power struggle, feelings of inequality, or personal vulnerability. As the team leader, you will need to handle destructive conflict very professionally and carefully. If not handled properly, an imbalance of power or damaged relationships can result.

When a conflict becomes destructive, the following should be used to work through the situation:

1. Conversations should be halted to allow the parties involved to decompress for some time.
2. Issues should be acknowledged and you should get an agreement from everyone involved about the real issue.
3. While working with the team, demonstrate positive language and insist that all parties do the same.
4. Remind the parties involved that the issue should not become a personal attack against anyone else involved.
5. Once the situation has moved away from a destructive nature, work to make the conflict constructive, emphasizing that the outcome will benefit the team.

Conflict will inevitably occur in every team. The key is to be prepared for it. Being professional, keeping the team goals in mind, and keeping the team members focused will allow for more constructive conflict than destructive conflict.

A Successful Team

When a team is cohesive and productively working towards the same goal, this is a sign that you are managing a successful team. Happy team members, effectively and efficiently progressing through the tasks and accomplishing the goal, are ideal and should be strived for within each team. However, you can have a cohesive team that is not actively working towards the team goal. In other words, you have happy team members, but they are not productive. You can also have a productive team that is very unhappy. As the team lead, you will need to continuously evaluate your team cohesion, attitude, and productivity. If you see issues, you need to evaluate if the root cause is the unhappiness of the team members, con-

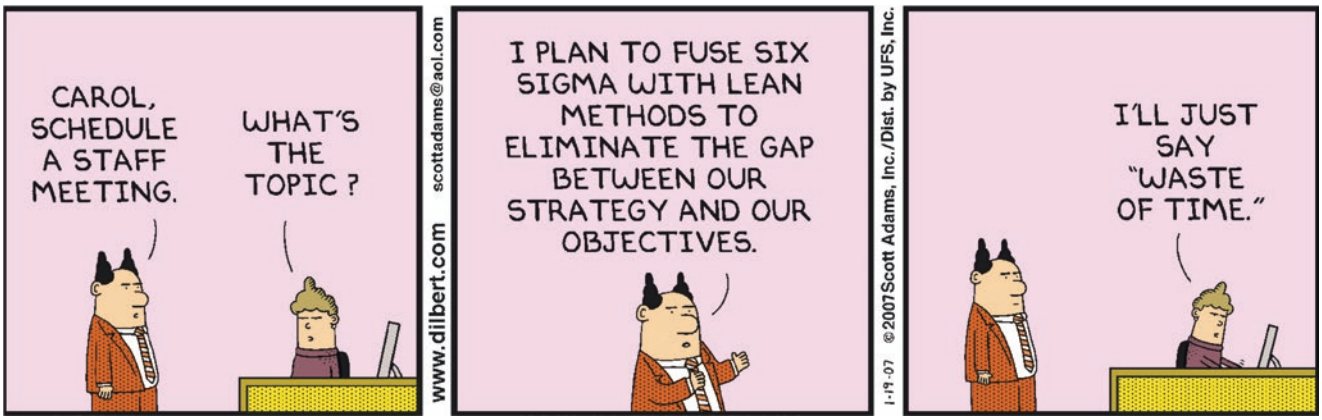

Fig. 20.2 Judging from Dilbert cartoons, meetings are among the most reviled activities in businesses (DILBERT © 2007 Scott Adams, Inc. Used By permission of ANDREWS MCMEEL SYNDICATION. All rights reserved)

flict about the tasks or goals, or one of the other core contributions to the team mentioned earlier needs to be revisited.

Things to remember:

1. Team empowerment should be developed early on, starting with the initial meeting. Every team member will need to understand the goals and processes, and know that each person will be contributing their unique expertise.
2. Relationships are extremely important. Building a strong team means having respectful relationships among the team members. Because of the variety of expertise brought to the team, there is likely to be conflict. However, constructive conflict can be good for the team. Destructive conflict can be managed to become constructive conflict.
3. More people does not always mean a better team. If there are resource issues or the team is not working towards the designated goals, adding more people can often cause conflict and decrease productivity. Often, the reallocation of tasks and responsibilities within the team is the best solution.
4. A team can fall victim to communication overload. More information and more communication are not always better, and it can often be overwhelming and decrease production. Establishing a practical way to communicate information within the team, and keeping in mind that many team members may be on more than one team, will help decrease team overload.

The techniques described here apply to all teams, whether a task force, a development team or a committee. A Team Charter will provide essential and explicit foundations for the team. The initial interactions of the team are extremely important to build relationships and encourage all members to feel empowered. Managing conflict between members is an essential part of having a successful and productive team.

Managing Meetings

Using Meetings for the Right Purpose

Holding meetings is one of the most hallowed traditions in organizations. However, judging from how often meetings star as topics in Dilbert cartoons (see Fig. 20.2), they are also among the most reviled business activities.

Meetings play a significant role in highly interdisciplinary fields such as clinical informatics. Very little of its work happens through individual and isolated effort. Rather, much of it is completed by interdisciplinary teams in highly collaborative ways. Now that you have learned about assembling and creating high-performance teams, it is time to look at how meetings can support and facilitate collaborative work processes.

Meetings are expensive, especially when all factors, such as personnel costs for participants, effort and time expended in preparation and follow-up, and meeting room and technology costs are considered. A 1-h meeting of 10 project managers and software developers, assuming a blended total salary of $150/h, has a direct cost of $1500. A similar meeting among executives will incur a multiple of that cost.

Good meetings do not just happen on their own. They result from careful planning, attention to participant needs, and follow-through [3]. At their best, meetings are important tools for getting collaborative work done in organizations. At their worst, they are time and efficiency sinks that are a drag on productivity. How you plan, run, and follow up on meetings has a lot to do with their usefulness to your project and the organization.

Activities in meetings typically fall into three categories: information-giving, information-exchanging, and information-creating. Information-giving activities include training, presenting a new concept, motivating, and delegating. Information-exchanging activities include performance

interviews, building support for a decision/approach, and exchanging ideas among various stakeholders in a project. During information-creating activities, attendees make decisions, solve problems, analyze situations, or brainstorm. Each of these activities has its rightful place in meetings, but information-creating and decision-making are the most value-added from the project and organizational perspectives. Information-giving is often more cheaply and effectively achieved with methods other than meetings, such as email. What activities a meeting is focused on determines how you prepare, what materials you provide, how you facilitate the meeting, and how you follow up.

Leading Meetings

Good leadership is essential for meetings. However, effectively leading a meeting does not mean applying the same leadership style every time. Depending on meeting purpose, attendees, topic, context, and project stage, you may use a different leadership style in different meetings or even combine two or more in the same:

- **Autocratic**: In this style, the meeting leader is always in control and organizes and follows through on all phases of the work. This leadership style works best with new employees, ill-defined topics/questions, and new teams.
- **Laissez-faire**: In this style, the meeting leader functions more like a facilitator and/or coach. He allows attendees to do what they think is best. This style works best with empowered individuals and groups.
- **Democratic**: The democratic style mixes elements of both autocratic and laissez-faire approaches. The leader encourages the group to contribute ideas and expertise but ultimately controls group decisions, even if they are often arrived at democratically.

Leading meetings effectively is challenging. Critical measurements for the success of a meeting include:

- What relevant and impactful decisions were made in the meeting?
- What action items that people can follow up on did we identify?
- How did this meeting contribute to the achievement of project objectives?

If the answers to those questions are not satisfactory, the meeting was most likely a waste of time.

During the meeting, the leader must focus on achieving the objectives of the meeting and manage the interactions among participants to maximize efficiency and effectiveness. When meetings work, they flow naturally. Everyone understands questions/problems. Comments are constructive, balanced, and promote the achievement of meeting goals. Individuals contribute maximally to the meeting. The discussion results in outcomes that single individuals or even a subset of meeting attendees could not have achieved. Finally, everyone understands what needs to be done after the meeting. Achieving this kind of flow rests, in large part, on both meeting leaders and attendees engaging in the types of beneficial behaviors listed in Table 20.3.

Table 20.3 Positive behaviors that both leaders and participants should demonstrate in meetings

Leader	Participant
be open and encouraging	decide to make the meeting worthwhile; be open to new ideas
serve as a catalyst by posing questions	attempt to answer leader's questions, especially if a long silence has ensued
maintain harmony; remind participants of shared goals and appropriate meeting behaviors	defend your ideas, but exercise appropriate meeting behavior
don't ramble	don't ramble
gather support for ideas before the meeting	review minutes of the last meeting; study agenda; assemble materials; complete tasks assigned at the last meeting
don't control or dominate the discussion	practice listening skills; don't engage in side discussions
take notes on all that occurs	take notes and ask questions
use and elicit "we" behaviors	demonstrate "we" behaviors
exercise follow-up options if consensus can't be reached	suggest closure for items that aren't resolved within the allotted time; volunteer for follow-up tasks that are assigned
concentrate on the meeting (no multi-tasking, e.g., using electronic devices)	concentrate on the meeting (no multi-tasking, e.g., using electronic devices)

Often, leaders and participants don't exhibit all or even the majority of those behaviors. For instance, as a leader, how do you handle the participant who constantly dominates the discussion? Or the fact that no one seems to show up on time? Leaders must handle many difficult situations, such as irrelevant, unworkable suggestions; attendees who don't contribute; rude, mocking comments about suggested ideas; combative attitudes towards other participants; and presenters who are not prepared. Every one of these problems can be mitigated or avoided using one or more strategies. Meeting leaders must be prepared and ready to handle these challenges if they don't want to be the subject of a Dilbert cartoon.

Participants often see themselves as passive victims of whatever transpires in a meeting. However, that viewpoint often contributes to meeting failure. Participants need to see themselves as active agents who can not only help keep a meeting from derailing but substantially contribute to its success. For instance, for meetings in which the discussion

seems to go nowhere, an attendee could ask: "Can we summarize the main points of the discussion up to now so we are clear on what question(s) we should address next?" Or, if action items have not been made explicit, the question: "What are the action items resulting from this meeting?" right before the meeting ends can work wonders.

Using Meetings for Maximum Effect

Marlene Caroselli suggests a seven-step framework for conducting successful meetings in the book "Meetings that work" [3]. This framework is an excellent way to think through meetings, starting from whether they are required to maximize the results of a meeting. Does the framework include the steps Required?; Readiness; Restraints; Record; Regulate; Review and Results, which are briefly described below.

1. **Required?** The first and most important question is whether a meeting is required at all. Most people don't even stop to think about that question but simply forge ahead with scheduling a meeting. Questions you may ask include: Are you only meeting because it has been a week/month since you met? Is it more valuable to have people work on their projects or meet for an hour? Have we made enough progress since the last meeting to justify another one? Is there an alternative to a group meeting, such as a phone conversation, one or more informal meetings, or email?
2. **Readiness**. To increase the chances that the meeting is effective, it should be well-prepared. Meeting leaders need to think about the purpose of the meeting, desired outcomes, problems to be solved, and information that attendees need to contribute fully to the meeting (e.g., materials to be reviewed before the meeting). Meeting invitations should only include the minimum number of appropriate participants. Don't invite people who are only peripherally involved with the subject or whose time would be better spent outside the meeting. A solid agenda is an important foundation for a successful meeting. Distribute the agenda at least 24 h before the meeting and other relevant items in enough time to allow attendees to review them. If you are presenting in the meeting, make sure you are ready with materials, visuals, and a well-prepared, cohesive presentation that you can deliver smoothly and concisely. You may also want to consider the day of the week or time of day for your meeting. Typically, meetings work best when participants are fresh, well-rested, and energetic.
3. **Restraints**. In the step "Restraints," think about what or who may pose a barrier to the meeting. Eliminating real or potential barriers ahead of time can significantly affect the success of your meeting. Things you can check ahead of time include room size and configuration (Is the room big enough to accommodate everyone? Is seating configured to help support the meeting objectives optimally [e.g., round table for discussion]? Is the meeting room right and well-lit, preferably by daylight?), audiovisual requirements (Is the computer for the presentation connected and ready to go?), and required materials (Do you have enough handouts?). During the meeting, try to follow your agenda. If you start running out of time, shorten discussion or defer topics until the next meeting.
4. **Record**. A good record of the meeting provides a solid basis for decisions, further discussions, and follow-up. Also, it may help you avoid revisiting issues you have already covered. Meeting minutes typically include attendees, decisions and/or action items, assignments, and a topic outline for the next meeting. Meeting minutes should be written and distributed within 24 h of the meeting. The increasing use of Web- or videoconferencing tools for meetings has opened up to other useful ways to produce a meeting record: (1) recording the meeting and (2) generating transcripts. Meeting recordings and transcripts can be very useful in generating minutes, especially for fast-paced, idea-filled meetings.
5. **Regulate**. During the meeting, the leader is expected to regulate the flow of events. Strategies to keep a meeting on target and on time include starting on time, keeping the group on target when the discussion is straying from the current topic, minimizing distractions, making sure all attendees contribute appropriately, recapping the discussion periodically, and following the agenda. Meeting participants should ask themselves: "What can I do to help the meeting leader make the meeting as efficient as possible?"
6. **Review**. Agreeing on and capturing ideas, suggestions, action items, and decisions arrived at in the meeting are very important. Whiteboards and projection screens are a good way to visualize the main points for everyone, develop lists of tasks, and diagram difficult topics. Immediately before the end of the meeting, review decisions and action items to make sure everyone leaves the meeting "on the same page" and knows what to do.
7. **Results**. Meetings are not finished when their appointed time ends. Follow-up is extremely important to translate what happened at the meeting into progress and the input for the next meeting. With good meeting minutes in hand, follow up on action items with those assigned tasks. A good idea to hone your meeting leadership or participation skills is to check with one or more participants about what went well and what could be improved.

Out-of-the-Box Ideas for Making Meetings Successful

For most people, the mental image of a meeting is a 1-h event with a defined number of participants located in a conference room, maybe accompanied by a PowerPoint presentation. However, there are many ways to adapt meetings to make them more effective, dynamic, and fun [4]. Some examples:

- **Do meetings always have to last one hour?** No. The agenda should drive the time required for a meeting. If the work of a meeting is done and it can end early, then **end it early**.
- **Why not go outside or have a "walking meeting?"** Picking an unconventional location for a meeting (e.g., in a nearby park, on lawn chairs under a tree, in a roof garden) will likely energize participants and make the meeting more interesting. A walking meeting can provide important exercise to mitigate the adverse health effects of our primarily sedentary work style and increase blood flow to the brain—potentially resulting in better ideas.
- **Are people chronically late for a meeting?** A few potential remedies: (1) Latecomers deposit a dollar into a common fund, to be periodically spent on a social gathering for the group; (2) After the meeting starts, note-taking responsibility for the meeting transitions to the person showing up late ("Pass-the-pad" approach). This has the benefit of latecomers reviewing the notes to find out what happened in the meeting so far. (3) Schedule the meeting to begin at the time when everyone usually has shown up, like at 2:12 pm.
- **Does everyone have to attend the whole meeting?** The answer is usually "no." With a well-planned meeting, you can invite specific attendees for particular segments, either in person or through videoconference. Instant messaging can deliver such invitations on demand, making sure no time is wasted.
- **Do meetings always have to run over time?** No. Bring an egg timer to the meeting, set it, and when it rings, the meeting is over. Period.
- **How can you leverage social media to accomplish the purpose of meetings?** One idea is to have a "virtual" meeting on Facebook, Twitter, or a similar venue. Post the meeting topic and question(s), and then use the platform to brainstorm or discuss, maybe over a few hours or a day. The strategy has the benefit that if your attendees have any friends or followers, a larger audience can be drawn into the discussion.
- **How can you make sure that a meeting has an agenda?** One technique is to reject the electronic invitation or not show up if the agenda is not distributed ahead of time.
- **How can you make scheduling meetings among people with busy calendars easier?** New electronic tools are emerging to make one of the most dreaded chores among administrative assistants and secretaries easier: scheduling meetings involving activities with busy calendars. Current examples of such tools are Doodle polls, NeedToMeet, Calendly, ScheduleOnce, Assistant.to and CalendarHero. These tools have a varying set of features and functions, so it is a good idea to research them thoroughly before adopting one.

In summary, group meetings are important tools for achieving organizational objectives. However, meetings work best when they are carefully considered, well-planned and –executed, and are balanced with other organizational activities.

Conclusion

Informatics sits at the unique intersection of people, process, and technology. Therefore, to get anything accomplished in clinical informatics, a leader must manage humans and navigate complex organizational structures. This chapter provided a review of strategies and best practices for managing the less fun, but important, aspects of managing people and processes, including team meetings. Hopefully with this knowledge you can more effectively, strategically lead teams to achieve organizational goals rather than feel as though you are just "herding cats" to adopt or use an information system.

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Strategic and Financial Planning

21

Natalie M. Pageler and Jonathan P. Palma

Learning Objectives

- Identify the role of the Vision statement, Mission statement, Objectives, Strategies, and Action plans (VMOSA).
- Delineate how environmental scanning, SWOT analysis, and benchmarking help organizations define their goals and objectives.
- Describe the difference between financial and managerial accounting.
- Utilize standard metrics of managerial accounting to rank investment choices and support a business case.
- Outline the revenue cycle components and explain how revenue cycle optimization can lead to enhanced clinical, financial, and patient experience outcomes.

Practice Domains: Tasks, Knowledge, and Skills

Domain 5: Leadership and Professionalism

Tasks (5.01–5.03)

- 5.01. Identify informatics trends, best practices, and new technologies and utilize governance processes to position the organization for future opportunities.
- 5.02. Establish and/or participate in Health Information Technology (HIT) governance to support strategic and financial planning, including formulation, implementation, and evaluation.
- 5.03. Participate in the development of organizational health informatics goals, strategies, and tactics in alignment with the mission and vision of the organization.

Knowledge and Skills (K 112, 114–119)

- K037. Key performance indicators
- K040. Clinical and financial benchmarking sources (e.g., Gartner, Healthcare Information and Management Systems Society Analytics, Centers for Medicare and Medicaid Services, Leapfrog)
- K045. Methods to measure and report organizational performance
- K046. Adoption metrics (e.g., Electronic Medical Records Adoption Model, Adoption Model for Analytics Maturity)
- K097. Issues related to integrating emerging data sources into business and clinical decision making
- K112. Environmental scanning and assessment methods and techniques
- K114. Business plan development for informatics projects and activities (e.g., return on investment, business case analysis, pro forma projections)
- K115. Basic revenue cycle
- K116. Basic managerial/cost accounting principles and concepts
- K117. Capital and operating budgeting
- K118. Strategy formulation and evaluation
- K119. Approaches to establishing Health Information Technology (HIT) mission and objectives

Case Vignette

Lisa is an experienced CIO and was recently hired to lead the Information Services (IS) department at an academic medical center. As part of the interview process, she inquired about the university and the hospital's mission and vision to ensure they aligned with her goals. She also learned that the IS department's budget represented 25% of its capital budget and 4.5% of its annual operating budget. Because this budget is competitive with peer organizations, Lisa felt her department would be adequately resourced.

Nevertheless, resources are not infinite, so decisions about project prioritization must be made. For this reason,

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one of her first decisions as CIO was to establish a new, IS Strategic Planning process to help align hospital priorities with available resources. Knowing her approximate capital budget for the following fiscal year, she gathered hospital clinical and administrative stakeholders to contribute to the prioritization process. Before the meeting, she solicited project requests and made rough estimates for their capital and ongoing operational expenses.

In the first Strategic Planning session, she shared the approximate capital budget for the following fiscal year and in-flight initiatives the department and organization were already committed to. She then outlined how new requests would be presented, evaluated, and prioritized during the strategic planning process. Subcommittees including Clinical, Financial, and Infrastructure were formed to discuss and prioritize new requests pertinent to each area. Based on the preliminary prioritization in the first session, a more detailed evaluation of the projects' financial costs and required departmental resources was performed.

In the final Strategic Planning session, each subcommittee returned with prioritized lists of new capital projects presented in detail to the entire group. Following the presentation, an anonymous voting process was used to prioritize new capital requests across all subcommittees. To represent the organization's limited resources, voting stakeholders are asked to rank each capital request as high, medium, or low priority, with a limit on how many high and medium priority votes can be exercised.

After the process, Lisa and the IS Leadership team prioritized new capital requests and estimated their impacts on the budget and internal IS resources. This list was subsequently presented to the IS Executive Committee for approval before being presented to the Hospital Board of Directors. Because the proposed capital projects were aligned with the organization's priorities, within budget, and supported by various stakeholders throughout the hospital. They were approved as part of the IS Strategic Plan for the following fiscal year.

Introduction

Information systems can comprise up to 30% of a healthcare institution's capital budget and 3% or more of its yearly operating expenses [1]. As the size of an organization grows, this expenditure can easily reach the tens of millions of dollars. For this reason, clinical information systems require robust strategic and financial planning.

When we plan our lives, we ask ourselves several fundamental questions, including:

- What do I want to accomplish?
- What skills do I have?
- What tools do I possess to help me?
- What opportunities exist?
- What specific steps do I need to take?
- What can I afford?

These are the very questions involved in strategic planning for information technology. This chapter presents a formalized framework of how to ask and answer these questions.

Mission & Vision

Whether for a project, department, or entire organization, strategic planning begins with developing a *strategy*: a set of rules and priorities to help guide decisions. These ideas are often encapsulated into mission and vision statements designed to keep teams focused and motivated.

Before crafting these statements, the goal of the project or department must be defined. In project management, the document stating a project's goals is commonly called a Project Charter (see Chap. 23 for more information). Example project goals include implementing a new Electronic Health Record (EHR) and establishing an enterprise data warehouse. The goal for an IT department is likely broader, e.g., to support and extend existing information infrastructure.

The next step is to clarify the goal by defining performance indicators and expected milestones. For example, "to implement a new EHR across all inpatient areas on budget within 12 months, and to achieve efficiency gains in radiology and surgery as measured by radiology result turnaround times and OR block schedule utilization, respectively." A departmental goal may be "to maintain current applications and hardware and prevent unscheduled downtime (uptime >99.9%), and to respond to customer support tickets in less than 24 hours."

A valuable construct for defining appropriate goals is to create SMART goals [2]:

- Specific—clear; answers the 5 W's (what, why, who, where, which);
- Measurable—to track progress, ask "how much" or "how many";
- Achievable—realistic and attainable;
- Relevant—aligns with other relevant (e.g., organizational) goals; and
- Time-bound—by target milestones and deadline dates.

A *mission statement* combines these ideas into a brief yet clear statement of purpose. The most effective mission statements are inspiring but straightforward; technical jargon should be avoided. An example mission statement is "to implement the best available certified Electronic Health Record to improve patient safety and maximize provider

efficiency." A departmental mission statement would be broader (e.g., "to provide world-class support with best-of-breed software, reliable hardware, and responsive technicians").

The *vision statement* is more aspirational. When composing a vision statement, consider the mission statement and extract the human value in that mission. How does the organization change people's lives? How does it make the world a better place? Consolidate these ideas into the values (or desired values) of the organization. A vision statement should describe the organization in a perfect world—hyperbole is expected. The statement should motivate those within the organization and entice people to become patients, customers, partners, or team members. For example, "to improve the care of the sick and injured by giving providers reliable and powerful tools to efficiently diagnose and safely treat our fellow humans." In this case, the vision statement might apply both to an IT department and an EHR implementation. It is important to note that though the mission may change, the vision typically remains the same.

The *objectives* of an organization or project encapsulate "how much" and "when". A statement of objectives lists concrete goals, including appropriate timelines and expectations. This section is more specific and includes definitions of success and failure for each phase of a project.

Environmental Scan

With the mission and vision in mind, the next step is to perform an **environmental scan**. This is the process by which organizations continuously monitor the surrounding environment, looking for early signs of change that could affect current or future plans.

The goals of scanning are:

- To **detect** scientific, economic, social, political, regulatory, or technological trends relevant to the organization.
- To **predict** how these trends may impact areas in which the organization is lagging and identifying which business units may be endangered.
- To **alert** management to trends that are emerging, developing, and waning.

Environmental scanning is usually broken down into **internal scanning**, which looks for issues within the organization, and **external scanning** looks at broader trends in the marketplace and among competitors.

In some cases, environmental scanning is mandated by law. For example, the Affordable Care Act of 2010 requires nonprofit hospitals to perform a Community Health Needs Assessment (CHNA) every three years. This specialized form of external scanning encourages hospitals to identify ways to improve their surrounding communities.

Information collected from an environmental scan can be summarized and presented using a SWOT analysis method, which delineates Strengths, Weaknesses, Opportunities, and Threats in a 2 × 2 table. Strengths and weaknesses describe the organization and are therefore derived from internal scans; opportunities and threats refer to the surrounding marketplace and competitors and result from external scans. Box 21.1 shows an example SWOT analysis.

Box 21.1 Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis

Summary of environmental scan:

- The clinic does not earn as much money as it did two years ago. Possible reasons include decreased volume of patients and a charge master that has not been updated in five years. Staff training budget has nearly doubled.
- The clinic has a happy and engaged medical staff with modern equipment but often complains that the clinic "looks old and decrepit"
- A patient satisfaction survey showed that most patients like their doctors, but a large proportion is on public assistance and goes to the local hospital for emergency and routine care because they lack personal transportation.
- Certain services are difficult to obtain in this region, such as psychotherapy and addiction treatment. Wait times for advanced diagnostic studies, such as nuclear medicine and CT scan are very long.

Strengths (internal)	Weaknesses (internal)
• State-of-the-art diagnostic equipment • Energetic workforce • Well-trained support staff	• Aging facility • Far from public transportation • Lower-than-average charge master
Opportunities (external)	**Threats (external)**
• Department of Health softened requirements for addiction treatment facilities • Prices for used CT scanner are at historical lows • RFP out for shuttle bus between clinic and train station	• The local hospital is developing a telepsychiatry program • Local factory closure results in joblessness

SWOT Analysis for clinic

When the analysis is complete, **strategic formulation** begins. The organization reviews each of its threats and develops programs to prevent or mitigate them. Opportunities are enumerated, and decisions are made regarding which ones to pursue. A variety of factors are important in selecting projects. In general, projects that satisfy governmental regulations and maintenance of commonly used equipment are prerequisites to new ventures.

A helpful mnemonic for strategic planning is VMOSA, which stands for Vision, Mission, Objectives, Strategy, and Actions. These activities progress from the most abstract to more concrete (see Fig. 21.1).

- **Vision**—the *dream*; meant to be uplifting and hopeful about the future.
- **Mission**—*what* and *why*; briefly describes what the organization is trying to achieve and why it is important.
- **Objectives**—*how much* and *when*; a list of concrete goals with appropriate timelines and expectations. This section is more specific and includes definitions of success and failure for each phase of a project.
- **Strategies**—*how*; the various methods and procedures that need to be done to achieve the objectives.
- **Action plan**—the complete *roadmap*; the cookbook that gives managers and team members clear instructions on how to complete tasks. The action plan divides objectives into individual actionable steps. Each step includes a responsible entity, an expected timeline, the resources needed for implementation, anticipated barriers, and potential collaborators and remedies. An example action plan for a portion of an EHR implementation is shown in Table 21.1.

Fig. 21.1 The Vision, Mission, Objectives, Strategy and Action (VMOSA) Pyramid

Whether setting goals for a project or a department, it is vital to ensure that the goals of the smaller units align with the organization's broader goals. Put simply; a CIO is much more likely to have her projects funded when her mission and vision statements support those of the organization.

Organizational Benchmarking

The process of external environmental scanning may include conducting **organizational benchmarking**—comparing key metrics for your organization against industry peers and standards. Several sources exist for organizational benchmarking in healthcare and health information systems. Some key examples of benchmarking resources include:

- **Gartner** is an example of a private research and advisory company that can provide organizations with industry trends and insights to support their mission [3].
- **Health Information and Management Systems Society (HIMSS) Analytics** publishes several adoption models that demonstrate an organization's level of technological maturity in areas such as EHR implementation (EMRAM, Electronic Medical Record Adoption Model) and analytics capability (AMAM, Adoption Model for Analytics Maturity [4].
- **The Centers for Medicare and Medicaid Services (CMS) Core Measures** are tools designed to help "quantify healthcare processes, outcomes, patient perceptions, and organizational structure...associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include effective, safe, efficient, patient-centered, equitable, and timely care" [5].
- **The Leapfrog Group** is a national nonprofit organization that conducts a yearly hospital survey that "assesses hospital safety, quality, and efficiency based on national performance measures that are of specific interest to health

Table 21.1 Example of an action plan

Action step	Person or team responsible	Due date	Resources required	Potential barriers	Collaborators and remedies
1. Train Physician Staff	Juarez and team	Jan 25	Lecture Hall from 6AM to noon, January 2–24; 2 lecturers	Doctors with difficult schedules	Medical staff office may help coordinate
2. Purchase new Scanners	CIO	Jan 3	$25,000	Shipment delays	Alternative suppliers
3. Deploy new scanners	Marra and team	Feb 2	Scanners from item 2 above; 4 technicians	Interruption of radiology procedures	Dr. Barco to arrange gaps in schedule to permit installation

care purchasers and consumers" and allows for comparison of organizations through competitive benchmarking reports. Several of the included measures reflect the same goals of national agencies, including CMS, the Centers for Disease Control (CDC), National Healthcare Safety Network (NHSN), and The Joint Commission [6].

Key Performance Indicators

At the level of a project or an individual, **Key Performance Indicators (KPIs)** are defined as the critical indicators of progress toward an intended result [7]. KPIs focus on operational improvement by defining **targets** and measures and establishing an analytic basis for decision-making.

Leading and lagging indicators are important concepts to managing KPIs. **Leading indicators** look forward to predicting future success and tend to be input-oriented (e.g., number of open ambulatory encounters). **Lagging indicators** look back to evaluate past success and are therefore more output-oriented (e.g., billing revenue collected) [8].

IT Planning Approach

The process by which an organization plans, implements, and evaluates an information system is called the **systems development lifecycle (SDLC)**. Chapter 12 describes this concept in detail, but a brief synopsis is presented here.

The SDLC includes four phases: (1) planning and analysis; (2) design; (3) implementation; and (4) support and evaluation [9]. The cycle begins when an organization identifies the need for a new system and continues until that need resolves or the costs of maintaining the system become prohibitive. At that point, a new cycle pertinent to organizational need begins.

Planning

The SDLC begins with planning. During this phase, operational needs are defined. What functions or tasks is the system supposed to accomplish? What is the business need of the organization? What set of tools best meets this need?

For small projects, the entire planning phase may be a brief meeting in the CIO's office. For large purchases, a more formal approach is required. An IT **steering committee** or **governance council** is formed to make these decisions, consisting of the organization's major stakeholders and knowledge experts. In many cases, an outside consultant is brought in to assist. The steering committee is responsible for establishing the **project goals** and timelines. This might include a literature review for best practices and a survey of the vendor landscape to identify which products are appropriate for the organization's needs. It also can involve the evaluation of current vendor installations at other institutions. When the options have been identified, the top vendors in contention are invited to demonstrate to the committee. After a cost-benefit analysis, a system is selected. An example timeline is shown in Fig. 21.2.

When estimating system cost, it is vital to include all costs incident to the system. This is often referred to as the **total cost of ownership**, which must consist of the additional annual operating cost of the software and predictable future upgrades. In some cases, training and/or hiring new staff with expertise in a new operating system is necessary. Construction of a new facility to house the information system may be required. Because infrastructure costs can be so high, some organizations will outsource applications to another vendor. This enables the organization to focus on its core missions while allowing the vendor's experts to maintain the system. One downside to outsourcing is that the organization loses control over its technology and is considerably less agile in the face of changes. Also, since the application is supported remotely, the vendor's staff will not be as

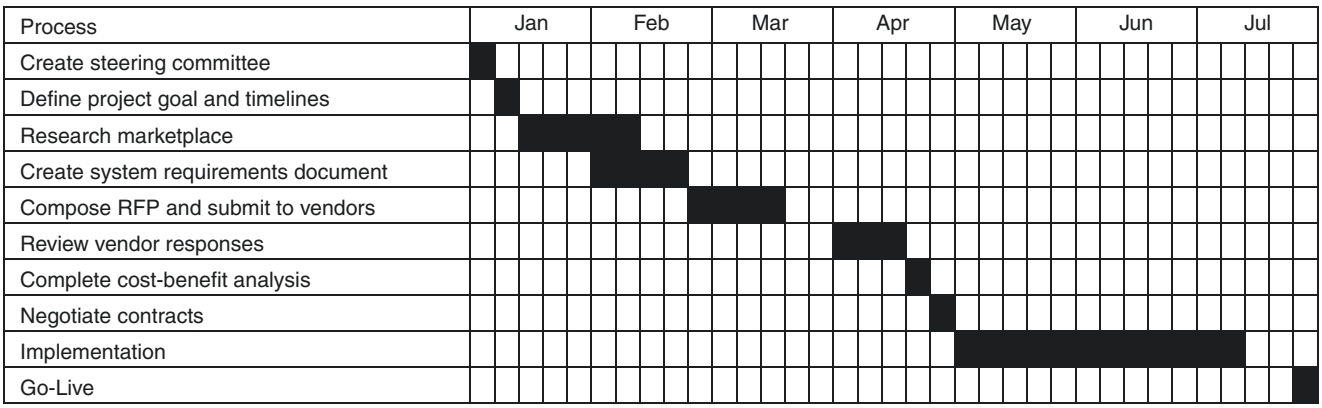

Fig. 21.2 Example of project management timeline (Gantt chart)

familiar with the organization's operational peculiarities as local IT support staff.

There are two standard models for outsourced software. The older, more traditional model is called **Application Service Provider (ASP)**. In this model, the vendor provides remote computing power and maintains the application for the customer in exchange for a subscription fee. In general, the ASP does not write the software itself but provides access to already existing packages. When a customer logs into the vendor's system, he is provided with an individual *software program instance*.

In most cases, each user is provided with a *virtual machine* or share storage space and processor time on the server. In some cases, an application cannot be virtualized and requires its own dedicated server. This approach does not scale well; if a vendor has 1000 customers, he may have to provide 1000 physical computers for them to use.

In the late 1990s, a shift was made to provide **Software as a Service** (SaaS). In this model, the vendor develops entirely new software, which is provided as a web-based application. This web app communicates with the vendor's central database via an **Application Program Interface** (API) to generate the user experience. Instead of running 1000 instances of the application, the vendor now must run only one instance with a dramatically lower computational cost. In some cases, a vendor may opt to provide individual application instances to different customers to guarantee isolation of sensitive data. For example, XYZ hospital may run one instance of the software while ABC hospital runs another. *Multitenancy* is the term used when multiple users (i.e., tenants) share the same software instance.

See Table 21.2 for a comparison of traditional Client/Server applications with ASP and SaaS.

Table 21.2 Comparison of client server, Application Service Provider (ASP) and Software as a Service (SaaS)

Model	Client-server	ASP	SaaS
What is it?	Application is developed by vendor and licensed to customer; customer buys and maintains hardware.	Application is developed by third party, vendor buys hardware and software and provides remote access	Application is developed and maintained by the vendor
Who maintains software?	Customer's technical team applies upgrades and modifications	Vendor	Vendor
Where is the main database server?	The server is maintained by the host organization, usually on-site.	Server is maintained by the vendor, off-site	Server is maintained by the vendor, off-site
How do users access the application?	Users access the server through a dedicated client application which runs on a desktop computer. If the user wants to use another device, a new client application must be developed	Remote access to a virtual or physical computer.	Web browser.
Security Features	Application data stays on-site.	Application data is encrypted but travels on public networks and could be intercepted	Application data is encrypted but travels on public networks and could be intercepted
Customer hardware Investment	Significant. Server hardware must be purchased.	Low. Customer can usually use a commodity PC	Very low. Customer can usually use any internet device
Continuing costs	Lower. Customer IT staff provides maintenance and backup	Highest.	Moderate. Fees tend to be lower than ASP because of improved efficiency.
Other Benefits	Local IT staff is more intimately familiar with institutional operations and can provide more responsive support to users	Ability to use established products without purchasing expensive hardware	Application can be used in virtually any place with internet access.

Design

The design phase can be fairly complicated. It involves analyzing an organization's current (or ideal) workflows and modeling them into data processes. This information can be gathered in several ways, including management decisions, open forums, user surveys, and/or appointed spokespersons for the various functional groups or departments.

When purchasing software from a vendor, much of the design has already been completed; customization can be quite expensive or even impossible. Therefore, the design phase may be limited to configuration decisions, small modifications, or selecting various add-in modules to meet business needs. On the other end of the spectrum, an organization may opt to develop an entirely new application. This option is considerably more expensive but allows the organization to customize the system precisely to its needs.

Once system requirements are defined, an organization creates a **request for proposal** (RFP), a document submitted to various vendors to determine if their products meet the organization's needs. When vendors return the RFPs, the committee can make realistic comparisons between the dif-

Table 21.3 Example of a Request for Proposal (RFP) for an Electronic Health Record

Questions	Met	Not met
Name of System & version		
Is the system CCHIT certified?	x	
Please list all products necessary for our facility to meet meaningful use Stage 1, 2, 3.	x	
If we signed on 1/1/2016, what is the expected timeline to go live?	x	
What resources (type and amount) would the hospital be expected to provide during implementation?	x	
What resources will vendor provide during implementation?	x	
Is the product positioned so that the system will be able to interact with Health Information Exchanges (HIEs)?		x
Are there any other third-party vendors that the hospital will need to partner with to ensure a successful install? Please list and explain use.	x	
Is the product PDA, smartphone, and tablet compatible? If yes, for what functions? What type of devices are supported?		x
What is the code change request process?	x	

ferent systems. A small section of an RFP is shown in Table 21.3.

Implementation

Implementation involves installing the system, training staff, and preparing the organization for the **go-live** date. This phase requires data conversion or transferring information from the old system to the new in many cases. When data cannot be brought over, they are often kept in an archive that can be accessed if needed.

There are two standard methods of implementation. In the **big bang approach**, the entire organization is converted to the new system at once. In the **staged approach**, the latest technology is brought in on a planned schedule. The benefit to the staged approach is that it tends to cause less disruption for day-to-day processes. It also allows more time for minor "bugs" to be recognized and resolved before a major service interruption occurs. However, the benefits of whole-system connectivity and efficiencies cannot be realized until the conversion is complete.

For an implementation to be successful, it is important to create an implementation team. This team is usually composed of many members as the project steering committee from the planning phase. A critical member of this team is the **champion**, a person who is well respected in the organization and can encourage other users to embrace the new system. A typical scenario is enlisting a physician champion to implement Computerized Provider Order Entry (CPOE) to train and inspire other physicians to use the system [10]. For a new system to be adopted, users must believe that it is (or will be) an improvement over the legacy system. Physician champions must understand provider concerns and demonstrate the potential value in the new system to be effective in change management.

Training is another key component of successful implementation. High-quality initial training helps mitigate the need for support following implementation. Training involves many logistical challenges, including navigating clinical schedules and ensuring the correct knowledge experts are available. Matching the clinical skill set of the instructor to the students is crucially important. For example, a pharmacist would be better suited to teaching providers about medication ordering than clinical documentation.

Support and Evaluation

Even well-designed systems eventually have unscheduled downtime when unanticipated problems arise, and the IT department is often called upon to optimize and enhance the system. Invariably, as the environment changes, there will be bug fixes, minor and major upgrades, new modules, and significant overhauls. Up to 80% of the IT budget can be spent on support, which is the longest of the four phases.

Continuous analysis (sometimes called the **ongoing process of planning**) is important to evaluate the constant business need for the system. The system will have diminishing value at some point, and it will be time to begin the SDLC again.

Financial Planning

Accounting is defined as recording, synthesizing, and reporting financial and operational data. There are multiple branches of accounting, but we will focus on financial accounting and managerial accounting for this chapter. **Financial Accounting** is how companies report financial information to external parties, such as regulators, stockholders, creditors, and the public. Financial accounting must adhere to specific standards and usually reports information for the company as a whole. Financial accounting takes a more formal approach because it must comply with accounting standards issued by national governing bodies. In the United States, the **U. S. Generally Accepted Accounting Principles (GAAP)** are governed by the Financial Accounting Standards Board (FASB). Much of the rest of the world, including most European nations, use the International Financial Reporting Standards (IFRS) [11]. There have been efforts to align US GAAP and IFRS, but this has not yet been achieved.

Managerial Accounting provides actionable information to managers within the organization and can be represented

in any format useful to the manager. Managerial accounting usually focuses on a specific segment of the company for which the manager is responsible [12]. See Table 21.4 for a comparison between the two types of accounting.

One specific type of managerial accounting is **cost accounting**. In this form of managerial accounting, the goal is to assess all the variable and fixed costs to capture the total cost of production. Because cost accounting is a type of managerial accounting (i.e., as opposed to more formal financial accounting), the approach can be flexible to meet the needs of management. There are several specific types of cost accounting, including standard costing, activity-based costing, and marginal costing.

In **standard costing**, the cost of goods sold (COGS) is calculated based on labor and materials to produce a good or service when these resources are used *efficiently* under standard operating conditions. These calculated costs would be used to create the budget. The variance between these calculated and actual costs indicate whether the organization is performing favorably or unfavorably from a resource utilization perspective.

Activity-based costing (ABC) allocates portions of an organization's overhead costs to specific activities required to produce a good or service (e.g., A healthcare example could be attributing a portion of operating room expenses to a particular procedure). Because costs are allocated to specific activities, this method can be much more helpful in determining the true costs and gains of specific health care procedures and services.

Table 21.4 Comparison between financial and managerial accounting

	Financial accounting	Managerial accounting
Audience	Stockholders, regulators, community	Managers inside the organization
Describes	Financial impact of past decisions	Plans for future
Emphasizes	Reliability, objectivity, precision	Relevance and utility
Pertains to	Whole organization	Specific to manager's needs
Requirements	Must follow generally accepted accounting principles (GAAP) and can be mandated by law	Can be in any format and can be customized according to need

Marginal accounting (AKA cost-volume-profit analysis) assesses the impact on the cost of a good or service by adding one additional unit (e.g., seeing an additional patient per day in a clinic). The **break-even point** is the production level where total revenue equals total expense:

$$\text{Break-even point} = \text{total fixed costs} / \text{contribution margin, where contribution margin} = \text{revenue} - \text{variable costs}$$

This cost accounting method can be useful in determining charges for specific procedures or services and determining the impact of marketing campaigns to increase patient volumes for specific services.

Capital Expenses (Capex) vs Operating Expenses (Opex)

Since budgeting and planning are internal processes, they fall under the scope of managerial accounting. In budgeting, expenses are divided into **Capital Expenses** (Capex) and **Operating Expenses** (Opex). Capital expenses are purchases that can be recorded as an asset, and the expense for that asset can be recognized over the asset's life. Capital expenses are usually very expensive, multi-year plans, such as building a new facility or acquiring another line of business. The order of priority for funding capital budgets is dependent on both the cost and risk of the project. In general, the following categories are listed in *decreasing* order of desirability.

- legal or regulatory requirements
- requirements to maintain the financial integrity
- completion of previously started projects
- replacement of commonly used equipment
- cosmetic improvements and marketing campaigns
- new ventures

Operating expenses are the day-to-day expenses of running an organization, such as maintenance, insurance, space rental, and payroll. In healthcare, the IT budget comprises a large portion of both capital and operating expenses.

The funds for Opex and Capex may come from different sources. Operating expenses typically come out of the organization's daily cash flow and budgeting process. Capital expenses may come from retained earnings but more frequently come from other sources. In many nonprofit hospitals, fundraising and government grants are the largest sources of capital. For example, between May 2011 and January 2018, the Center for Medicare and Medicaid Services (CMS) paid over $24 billion to doctors and hospitals who attested to Meaningful Use of certified electronic health records [13].

Capital budgeting is often called **investment appraisal** because it guides the organization in investing or borrowing money. There are many ways to calculate the value of an investment.

Table 21.5 Illustration of yearly profit and loss

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Revenue	$450,000	$400,000	$350,000	$300,000	$250,000	$1,750,000
Opex	($100,000)	($100,000)	($100,000)	($100,000)	($100,000)	($500,000)
Capex	($1,000,000)	$0	$0	$0	$200,000	($800,000)
Total Expenses	($1,100,000)	($100,000)	($100,000)	($100,000)	$100,000	($1,300,000)
Return	($650,000)	$300,000	$250,000	$200,000	$350,000	$450,000

Table 21.6 Illustration of the payback period for a CT scanner purchased by a hospital

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	450,000	400,000	350,000	300,000	250,000
Expenses	(1,100,000)	(100,000)	(100,000)	(100,000)	100,000
Profits since inception	(650,000)	(350,000)	(100,000)	100,000	450,000

Consider the following example:

A hospital purchases a CT scanner for $1,000,000. After five years, the technology becomes outdated, and the scanner is sold for $200,000. The yearly operating expense (i.e., electricity, supplies, maintenance, and salary for the CT technician) is $100,000. During the first year of implementation, the revenue for the scanner is $450,000. Unfortunately, declining reimbursement decreases that value by $50,000 each year.

Table 21.5 below summarizes the yearly profit and loss. Negative numbers are written in parenthesis.

Was it a good investment? There are several managerial accounting methods used to determine if an investment is worthwhile.

The **Accounting Rate of Return** (ARR) is the yearly **return on investment (ROI)**, expressed as a percentage. Since the total return (i.e., profit) is $450,000 over five years, the annual return is $90,000. The **total cost of ownership** of the scanner (i.e., the sum of capital and all operating expenses) is $1,300,000. Dividing the annual return by the total expenses gives us an ARR of 6.92%. Practically, this means that the hospital collects about 7 cents for each dollar invested in the CT scanner.

Many organizations have a Required Rate of Return (RRR), the minimum amount of return needed for investment. If the ARR is greater than the RRR, the investment should be accepted. If not, it is rejected.

Another metric of investment is the **payback period** or the time it takes to completely recoup the costs of the investment. This measure answers the question, "how long does it take for the investment to pay for itself?" In general, the shorter the payback period, the better the investment. In our example above, the CT scanner becomes profitable sometime during year 4. This is illustrated in Table 21.6.

While the payback period and ARR are the most common means of investment appraisal, there are some drawbacks, chiefly that they do not account for the **time value of money**, which reflects the fact that money dedicated to one investment cannot be used for other purposes. For example, instead of buying a CT scanner, that money could have been put into a stock portfolio, used to pay off debt, or invest in another project.

One method to correct this decreasing value is to calculate the **present value** (PV) of all future returns at investment time. To do this, we look at the average interest rate that the organization pays for capital, called the **Weighted Average Cost of Capital** (WACC). Each organization has a different WACC, depending on the source of its capitalization and the quality of its credit rating. In general, a company with a good credit rating can borrow money cheaply. A company with a poor credit rating has to pay more interest to borrow the same amount of money and therefore has a higher WACC [14].

Using a hypothetical WACC of 5%, $100 invested today would be worth about $121 in five years, so the PV of $121 at five years is $100.

Using this methodology, we can re-create our table (Table 21.7) for the CT example as follows:

As time goes on, the difference between the revenue and the PV of that revenue becomes greater and greater. The **net present value** (NPV) is the difference between the total costs and the PV of the revenue. In this case, the NPV is $313,240. A positive NPV is generally considered a good investment.

Another way to express this value is the **profitability index** (PI), which reflects the PV of the Revenue to the initial investment. In this case, a PI> 1 would be considered a good investment. Like the NPV, this metric can be useful to rank various projects under consideration.

These two measures complement each other but can be misleading when applied to projects of different scales. Consider the two fictitious projects in Table 21.8.

The PI for the CT scanner is almost double the PI for the new building, which makes it seem a better investment. However, the new building will reward the investor with almost three times as much return when the investment has matured. While these financial metrics are important to fuel decision-making, knowing their strengths and limitations is important.

Table 21.7 Illustration of present value (PV) for a CT scanner purchased by a hospital

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Revenue	450,000	400,000	350,000	300,000	250,000	1,750,000
PV of Revenue	450,000	380,952	317,460	259,151	205,676	1,613,240

Table 21.8 Illustration of present value (PV), net present value (NPV), and profitability index (PI)

Project Name	PV of Revenue	Investment Cost	NPV	PI
New Building	15,000,000	12,000,000	3,000,000	1.25
CT Scanner	1,700,000	800,000	900,000	2.125

Enterprise Resource Planning Systems

Enterprise Resource Planning (ERP) systems are integrated software systems designed to provide a central planning and control system around business processes [15]. The functionalities incorporated into an ERP system include financial and managerial accounting, human resources management, supply chain management, project management, customer relationship management, etc. Healthcare organizations are increasingly turning to integrated ERP systems to improve communication, increase efficiency and productivity, and enhance the patient experience. ERP systems can be located on-premises, but more and more are being moved to cloud-based services for the promised benefits of better system reliability, enhanced security, improved efficiency, and decreased capital expenses [16].

Business Plans and Business Cases

A **business plan** is a document that describes a business's goals and the roadmap for achieving those goals. A business plan is usually designed for external investors. There is some variability in guidance around how to write an ideal business plan. Still, the core pieces of a business plan generally include (1) executive summary, (2) description of products and services, (3) market analysis (see the section on external scanning above), (4) marketing strategy, (5) financial plan, and (6) a budget.

A formal financial plan typically includes three key **pro forma financial statements**: the **income statement** (revenue minus expenses and losses), the **balance sheet** (snapshot of all asset, liabilities, and equity), and the **cash flow statement** (description of cash on hand at a specific time point) [17]. Pro forma financial statements incorporate forecasts or estimates to provide a picture of the venture's possible profits. See methods detailed above for calculating return on investment to be included in financial projections.

In the context of a large health system, a smaller **business case** may be created for a specific program or project within the health system. A business case may contain many of the same elements as a business plan but generally is much shorter to guide strategic prioritization and internal budget approval. For example, it is likely not necessary to include basics about the organization's structure and business model in a business case. However, the business case should flow from the organizational strategic planning and then focus on the description, market analysis, marketing plan, and financial projections for the new program that is being proposed.

Revenue Cycle

Finally, this chapter will close with a description of how healthcare systems generate their revenue, which significantly affects all financial planning. **The revenue cycle** is a healthcare-specific term that describes the "series of activities that connect the services rendered by a healthcare provider with the methods by which the provider receives compensation for those services" [18]. There are multiple phases of the revenue cycle, including patient intake, clinical services, charge capture, billing, and collections. Revenue cycle management is a complex process that involves a wide range of stakeholders from hospital administration, finance, patient access, health information management, patient accounting, clinical services, and information services.

Because the revenue cycle is so complex, there is a wide range of opportunities for performance improvement to increase efficiency and revenue capture. Specific targets for revenue cycle performance improvement include financial clearance (the process of validating payor coverage and authorization for the clinical services), streamlined check-in and check-out processes, charge capture, proper claims management, automated claims, and patient statements, payments and denial posting, insurance follow-up, denial management, and payor management. Revenue cycle optimization is critical for ensuring efficient patient healthcare access and optimizing total revenue capture and cash flow, significantly impacting a health system's operating budget and financial viability. Furthermore, an optimized revenue cycle can enhance the financial aspects of patient experience and reduce sources of patient stress during care delivery.

There are multiple accepted metrics for measuring revenue cycle performance and establishing benchmarks to identify areas of opportunity for improvement. Metrics loosely fit into three categories: optimizing revenue, speeding billing, and increasing collections [18]. It is important to benchmark against peer healthcare providers of a similar size and type of healthcare service. A few key metrics are described in Table 21.9 below:

Table 21.9 Metrics for measuring the revenue cycle performance

Category	Metric	Description	Calculation
Optimizing Revenue	Cash Collection as a Percentage of Net Patient Revenue (AKA Yield)	Total patient service cash collected as a percentage of gross billed charges by discharge month	(Total Cash Collected) / (Avg Monthly Charges)
Speeding Billing	Discharged, No Final Bill (DNFB) Days	Days between patient discharge and billing department submitting the claim for payment	(Gross Dollars in DNFB) / Avg Daily Revenue
Increasing Collections	Days in Accounts Receivable (AR)	How long it takes the organization to collect its accounts receivable on average	(Total Accounts Receivable) / Avg Daily Charges
Increasing Collections	Point of Service Collections	Percent of patient-pay balances collected before completion of service	(Patient Payment Collected Prior to Service) / Total Patient Payment Opportunity
Increasing Collections	Denial Rate Upon First Submission	Percent of claims denied the first time they are submitted, a marker of how "clean" (devoid of errors or omissions) claims are	(# Claims Denied) / (Total # Claims Submitted)

Role of Clinical Information Systems in the Revenue Cycle

Clinical information systems play a major role in optimizing revenue. Information technology components of revenue cycle management include registration systems, scheduling systems, insurance eligibility software, case management/utilization review software, compliance software, charge capture software, scanning equipment, contract management software, centralized denial management database, etc. [19] Interoperability or integration of clinical information systems across the enterprise (see Chap. 14) can enhance efficiency and decrease errors. The revenue cycle functionalities of large enterprise EHR vendors include more and more of these functionalities in a single system.

Emerging Trends

One of the major emerging trends in financial planning and revenue cycle management is implementing automation technologies to make back-office processes more efficient and cost-effective. These technologies include robotic process automation (RPA), low-code software, artificial intelligence/machine learning (AI/ML), document ingestion, etc.

RPA may have particular benefits in healthcare rev cycle management and financial planning but has been slow to enter healthcare [20]. As stated simply, RPA is software that carries out repetitive, mundane tasks previously handled by humans to make them more efficient and reliable. Processes that may be particularly amenable to RPA technologies are repetitive, independent, and involve purely mental work [21]. In healthcare, these processes are found throughout the rev cycle, including extraction of patient registration data, appointment requests management, and claims processing.

Similarly, AI/ML technologies may significantly increase the efficiency and accuracy of medical back-office processes. The concept of AI/ML in medicine usually brings to mind the more compelling concepts of predictive algorithms to guide diagnosis and treatment, automated medical image interpretation, and deep-learning algorithms that empower the general public to monitor and manage their own health. Still, the many limitations and obstacles have significantly hindered the implementation in patient care [22]. However, there is significant potential for AI/ML technologies to assist in administrative jobs such as coding and billing, patient scheduling, staffing, and supply chain management in the near term.

Summary

Mission and vision statements help define an organization's culture and shape the objectives, strategies, and action plans. Environmental scanning defines the strengths, weaknesses, opportunities, and threats relevant to an organization.

Evaluating and acquiring new systems is called the system development lifecycle and involves planning, designing, implementing, and supporting. When a system is no longer useful, it is removed, and the cycle begins anew.

Accounting is the process by which financial data are reviewed, recorded, organized, and displayed. Financial accounting prepares reports for use outside the organization, while managerial accounting provides information for managers to assist in planning, budgeting, and decision making. Cost accounting is a specific type of managerial accounting that focuses on capturing all production costs, including variable and fixed costs, on informing business decisions.

An organization with a limited budget must decide which opportunities it wants to pursue. In organizational budgeting, there are two major categories of expenses to consider: operational and capital. There are a variety of financial metrics which can be used to appraise different kinds of investments. The ARR describes the annual percentage of profit expected from an investment. The payback period explains how long it will take for an investment to pay for itself. Neither of these metrics considers the time value of money. The NPV reflects the future value of an investment in terms of what it is worth today. ERP

software is a major IT investment that can help healthcare organizations manage much of their financial systems.

The healthcare revenue cycle is complex and has significant clinical, financial, and patient experience implications. Health information technology plays a major role in improving the efficiency of patient intake, scheduling, and financial approvals to facilitate the delivery of care and then tracking the claim throughout the entire lifecycle to improve revenue capture and ensure the organization's financial viability.

Questions for Discussion

1. Most healthcare organizations have similarities in their mission and vision statements. Why is it important to spell out the mission and vision statement for each healthcare organization? How are your organization's mission and vision reflected in the organization's objectives, strategies, and action plans?
2. Organizations like to keep their application portfolio as lean as possible. How do you think IT managers know when an application is no longer needed? What would happen if the manager removed an application that was still in use?
3. If you were a new CIO trying to plan the annual budget for your department, would you want to work with a financial accountant or a managerial accountant? What types of information might you ask for from that person?
4. If you wanted to persuade a budgeting committee to purchase new smart infusion pumps with EHR integration, which financial metric would you use to quantify their benefit? Would your opinion change if you were trying to convince them to buy a new building?
5. Why is it important for a Chief Medical Information Officer to understand the revenue cycle components? Which aspects of the revenue cycle would you expect a Chief Medical Information Officer or clinical informaticist to influence the most?

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Effective Implementation of a Clinical Information System

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Learning Objectives

- Describe the process to assess organizational culture and behavior.
- Apply strategies for promoting effective use of clinical information systems.
- Leverage key success factors that need to be included in an implementation strategy.
- Describe the role of diffusion in an organization to adopt a new system—technical and non-technical.

Practice Domains: Tasks, Knowledge, and Skills

- K125. Change management principles, models, and methods
- K126. Assessment of organizational culture and behavior change theories
- K127. Theory and methods for promoting the adoption and effective use of clinical information systems

Introduction

Health information technology (IT) failures are multifactorial. An often-underappreciated aspect in the implementation of clinical informatics systems includes the human behavioral changes required to impact clinical outcomes. The behaviors of the end-users, who use a clinical IT system, are the ultimate test of the functionality of a system. Creating a product and "throwing it over the wall" without a plan to engage the users "on the other side of the wall" predisposes that system to fail and creates a culture among users of anticipation of future technological failures and resistance to change in general [1]. As organizations decide about an information system, implementation failure with high costs (on finances, morale, employee satisfaction, patient care) is not an option. This chapter describes an interconnected and continuous process that will produce successful adoption of clinical information systems.

Grasping the importance of managing personal and institutional change in a clinical information system project cannot be achieved by simply reviewing the literature. Foremost, there appears to be a publication bias towards successful implementations, and thus there is little peer-reviewed evidence of failures and pitfalls in implementation [2]. Additionally, most studies describing new systems do not include the implementation plans, and the implementation process itself is rarely evaluated. Those that do describe the implementation seldom contain more than a project timeline [3]. As a result, the case-report literature creates difficulty in ascertaining the important dynamics among people, organizations, infrastructures, processes, and software and factors of a successful adoption.

Imagine that you are involved or responsible for one of the following three actual cases.

Case Vignette

chemoSABE: Designing for Success

Oncology Hematology Specialists (OHS) is a medical care provider for patients with cancer and blood disorders with 50 physicians and 15 practice sites across three states. In the early 2000s, OHS implemented a computerized chemotherapy ordering system called chemoSABE (chemotherapy Safety, Administration, Benefit, and Evaluation).

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Before the implementation, the leadership of OHS searched for available commercial systems and concluded that none met its needs. Failing to find a suitable commercial system, a design firm was hired to develop and deploy chemoSABE. Physician champions and non-physician leadership aligned to produce a common set of goals for the new system. Goals for the project included that chemoSABE had to be scalable across all practice sites, should not increase physician workload, provide means for clinical decision support, and aggregate chemotherapy data for quality and practice management metrics.

Armed with these goals, the software designers created prototype programs. OHS physicians were brought repeatedly into the design studio for system evaluation and feedback over one year. ChemoSABE went through three major iterations to ensure that it met the stated goals. During the development phase, progress was communicated to OHS physicians through quarterly meetings. Iterative testing and design changes improved chemoSABE to the extent that designers and physician leadership concluded that formal training on the software would not be necessary.

There was an initial "soft launch" of chemoSABE, with the system being available for a month for early adopters, optional staff use, and debugging. Following this month, chemoSABE was implemented across all sites simultaneously without formal user training; however, physician champions and technicians were available during ordering hours for questions. The OHS leadership mandated the use of chemoSABE, with all physicians using the system for chemotherapy orders by the rollout date. Paper backup forms were available for chemoSABE downtime. Following a recent successful practice management implementation, the staff and physicians were willing to alter their workflows to gain the potential benefit of chemoSABE.

Technical issues that arose during early implementation were addressed quickly. Sufficient redevelopment support was provided during the implementation to perform multiple rounds of rapid cycle improvements to chemoSABE within the first weeks of deployment.

Evaluation of the chemoSABE system demonstrated nearly 100% utilization for all chemotherapy orders, a reduction in errors, and no reduction in physician satisfaction. Lessons from this successful implementation include that key factors included consistent leadership, an iterative design strategy utilizing end users' input, and sufficient technical staffing to implement modifications following the mandatory rollout.

Lag Time between Reported Lab Values and Actions

At a large tertiary academic institution, in a 45 bed Newborn Intensive Care Unit (NICU), concerns were expressed by attending physicians about the lag time between reported laboratory values and subsequent actions by the house staff to correct abnormal values such as hypernatremia.

Without consulting with the house staff, one of the faculty designed and implemented an automatic laboratory result pager using a ColdFusion server with a connection to the institution's EHR. An automatic task would scan the EHR for all new laboratory results for NICU infants every five minutes. If a result was abnormal, a page was initiated to a pager carried by one of the senior residents on duty.

The first iteration of this alerting system was deemed a complete failure. The residents quickly pointed out several design flaws:

1. Each abnormal result was paged individually. Since laboratory tests are often sent as bundles (i.e., a complete blood count may contain a white blood cell count, a red blood cell count, platelet count, and a hematocrit), a patient may have multiple abnormal results reported at the same time. The system as designed translated them into multiple pages, which residents perceived as disruptive.
2. The decision, which results were considered abnormal, was driven by the normal values reported by the laboratory system. As a result, age and disease-specific normal values for the NICU were ignored, and residents were paged with values that would be considered normal in the NICU.
3. Often residents were already aware that the patient had abnormal results. An example was a page for abnormally high sodium for a patient at 150. The resident reported that the previous value had been 152 and that there was no need for this page since the information that the patient had hypernatremia was already known.

A week after the pager system was introduced, its use was suspended, and the system was redesigned based on the residents' feedback. The redesign included batching of pages for individual patients, defining new "normal" ranges for the laboratory results based on NICU norms and diseases, an extensive algorithm that compared new values with prior values, and paged only when the new abnormal value was more than 10 percent or worse than previous results. The modified system was reintroduced with some moderate effect on provider behavior [4].

Lessons drawn from the failure to introduce the initial paging system included that the inclusion of end-users in the design process is critical; workflow and information needs of end-users must be studied and analyzed. The effect of the new intervention must be modeled on workflow, new work demands, interruption of other tasks, and local culture and conditions.

Parenteral Nutrition

Parenteral nutrition is difficult to order. There are many complex rules of glucose, lipids, and protein ratios, precipitation concerns, and individual doses for supplements such as vitamins and trace elements. In pediatrics, this is further complicated by the need to provide weight-based dosing. At a large academic center Newborn Intensive Care Unit (NICU), a web-based tool was developed that allowed trainees to use a form to create a parenteral nutrition order. The tool would perform all calculations and provide alerts and suggestions if the order violated any of the 68 different rules. The tool was introduced to trainees in the NICU and used successfully with a reduction of errors by 89%. One month after the tool had been rolled out, the developers noticed that it was being used outside the NICU in the Children's Center and an affiliated hospital shortly after [5].

When questioning the trainees why they were using this tool outside the NICU, the developers received the following feedback:

1. Because the tool was reducing the total effort by the trainee from 10 minutes per order to 2 min, the trainees felt the use of the tool was beneficial.
2. Trainees stated that the look and feel of the form resembled the paper form and did not require any adjustments or learning.
3. The number of subsequent phone calls from the pharmacy was reduced by 90% due to the tool saving trainees additional time.
4. Because the tool retained the prior day order, it was simple to make slight corrections based on electrolyte of nutritional status, adding to the usefulness.

Every software developer hopes that his product one day goes viral where the software used is learned from other users and adopted spontaneously without training, advertisement, or clinical mandate [6]. Software that will reduce errors and will save time for busy providers has the potential for viral distribution. Positive user experiences are shared with others who try the software and add to the viral marketing.

Lessons drawn from this case include the fact that a system with tangible benefits to users will be quickly adopted and further disseminated throughout the organization. Furthermore, users will adopt a tool designed for one hospital area for another if it functions well and saves time. Finally, not all tools have to be a complete "system." Well-designed functions or apps appended to the electronic health record system can also win for users and organizations.

Overview

Implementing a new information technology system is as complicated as developing a new system or adapting a system to the clinical decisions and technical needs of an organization. In development, there are system requirements, such as ensuring software delivers the core functionality that most users need, the tools and support that specialty providers require, and that the system is usable. There is an equally long list for implementation. Since implementation involves both people and organizational needs, the list is complicated and requires attention to more than just technical details, but also consideration of how people work and the barriers to implementing new technology.

There is no magic solution or checklist that will make every implementation successful. Successful implementation is a continuous effort, ongoing assessment, and incremental modification from before a system is purchased or developed until long after it is installed. Implementation leaders must understand and manage four areas, the complexities of each area, and the interconnections of the areas. The areas are:

1. ***Organization*** culture, the distinct culture in different organizational areas, and how to prepare the organization for the pending changes.
2. ***People*** in the organization and how to prepare people to more rapidly adopting the pending new technology.
3. The process of ***implementation*** of the new technology, system, or component.
4. Understanding the ***technology*** well enough to be the change leader.

Table 22.1 illustrates the connectedness of the four areas. To be successful, there must be an alignment of culture, organizational processes/procedures, people, and process when implementing a new technology.

Table 22.1 Areas requiring management during information technology implementation

Culture of the Organization	
Prepare Organization for Change	Prepare People for Adoption
Process of Implementation	
The Technology Product/System	

Many non-technical factors influence the adoption of clinical informatics systems [7]. Organizational culture and behavior can be misaligned, failing system implementation. Social impediments to use can prevent adoption. End-user psychological variables can influence how a system is used or if it is used at all. Compounding these variables are time pressures and a perception that information systems can be life-threatening [8]. These non-technical factors occur not only during the initial implementation period but also continue over the system's life cycle, with the result that different factors can dominate different stages of technological diffusion. Challenges at initial adoption might not be why a project cannot cross the implementation chasm to achieve full adoption. Successful change management includes initial awareness of these various factors and accounts for them throughout the life cycle of an informatics intervention.

The value of clinical information systems makes successful adoptions critically important. Successful implementation relies not only on the design of the product [9] but also on the workflow, the organization itself, the implementation plan, and personal dynamics. Anticipating and overcoming resistance and negative perceptions requires planning. Success is measured in improved care, return on investment, and user satisfaction.

Toward Adoption: The Product/System

Successful implementation of health IT involves multiple factors [10]. Still, the foundations for success involve the quality of the technology, its usefulness for its intended purpose [9], and the preparation to implement the technology. First, the technology itself must work as intended, with a high degree of reliability and stability [11]. Frequent downtime events and major ongoing changes to user interface design and functionality pose significant challenges and risks to achieving successful implementation. Software failures in the initial or early implementation phases create a lasting reputation for poor performance that is difficult, if not impossible, to overcome later and creates risks to patient safety [12]. Setting the stage for success is crucial.

In preparing for implementation, the implementation team must analyze the potential benefits of the technology and clearly explain these benefits across multiple levels of responsibility. It is important to provide a coherent and comprehensive analysis of potential benefits to management and those in charge of making software purchase or development decisions. While increasing the number of individuals involved increases the time to make a decision [13], the analysis and explanation of benefits need to extend across organizational levels, including the intended end-users of the technology [14]. Too often, technology design or purchase decisions are made without the substantial involvement of end-users in the process and without clearly defining the specific benefits the technology will have to different roles in the organization.

Furthermore, to be adopted, novel technology must deliver tangible benefits to the intended end-users [15–17]. While benefits such as "improving care" or "reducing disparities" are laudable [18], end users need a clearer understanding of how the new technology will benefit them or benefit their patients in a more direct and specific fashion. For example, defining a benefit such as "improving efficiency" provides little detail for end-users and may create job insecurity. A more tangible benefit would be "decreasing the time it takes to complete documentation." The end-users of technology are sometimes not the main beneficiaries of the new technology but frequently carry some of the added burdens [19]. Finding ways to deliver at least some tangible benefits to the users in this situation is a requirement.

Finally, concerning the role of the product in implementation success, the software itself must allow some degree of customization to address specific organizational and user constraints and preferences [20]. Healthcare is not a monolithic enterprise; practice environments and requirements vary significantly, even within a single organization. A "one size fits all" approach to technology has a poor success rate in healthcare contexts. Balancing customization and standardization is an important success factor for implementing health IT.

Culture of the Organization

It is often easy to forget about the organization as a whole when contemplating the implementation or modification of an information system. With 'organization,' we are not talking about the organizational chart and reporting structures, but rather the community of people who work in the organization and who can drive success or failure together.

Frequently, leadership becomes focused on the product or the implementation schedule, and people are somewhat forgotten or ignored in their needs. People function within a culture with their own "vital signs". People have memories of past experiences of both successes and failures. Ask people to tell a story of what they were told when they started working at your organization. Some of the stories will be about events that happened two, five, or ten years earlier and expose failures, disappointments, and poor management that will color expectations of any future change. For example, the introduction of health information exchange (HIE) within the U.S. Department of Veterans Affairs (VA) met resistance from employees who reported "we've been through this before" about new health IT components which "won't work until five years from now." [21] These sentiments resulted in low adoption and usage of the new VA system, despite any potential benefits in using the HIE system for improving care.

This section focuses on the organization and the steps that are critical to gain adoption throughout the organization, from the senior leaders to the person on the front line, from full-time employees to trainees, and from all new hires to life-long employees.

The Organization's Culture

There are multiple techniques for assessing and becoming knowledgeable about the current organization and its culture. The following are a sampling of the techniques. While all these techniques provide benefits, it will take the experience to identify which technique is needed or most appropriate at any given time.

General Assessment

Comparable to "taking" a history and physical of the organization, ideally, this effort to develop a model begins even before the planning for the technological implementation of the new system. There are two parts to the assessment phase. The first is to inform all potentially affected people, in writing, of the impending change. This written information need not be lengthy or elaborate, but it will alert everyone to the changes in the process. The second part involves collecting information from those involved in the change through surveys and interviews. The survey instrument could be sent to randomly selected members of the affected group(s). During the personal face-to-face interviews with randomly selected people at all levels throughout the affected portions of the organization, it is important to listen to the stories told and assessed their people's positive and negative feelings about the current organization and the proposed technology changes. An alternative or supplement to the one-on-one interviews is the conducting of focus-group sessions. Focus groups allow anywhere from five to seven people from across the organization to share their feelings and ideas about the current system and proposed changes [22].

Organizational Climate Assessment

Assess the general organizational climate by observing and talking with people from multiple organizational areas. If the general organizational climate is relatively negative, address this problem directly through organizational development techniques independent of technological change. No matter how good it may be, installing an information technology system will not solve a negative organizational climate. A negative climate may doom the new system before its implementation begins.

Assess the Workflow

The current workflow, especially in the early implementation areas, will need to be assessed, and if needed, a redesign team can be established. This team could be an internal multi-disciplinary team with people from the various parts of the organization, for example, clinic operations, the quality office, the informatics department, etc. This team could analyze the operations and recommended process improvements before implementation.

Current and Emerging Political Trends

Power Assessment

Regardless of organization type, there are sources of power. Some power is easy to detect through the organizational chart, but other forms of power can be more subtle. Understanding power is important because power can aid or derail any change process. Thus, understanding power structures can aid in the prediction of impediments and the design of anticipatory interventions.

There are several types of power [23, 24]:

- *Interpersonal power* is the ability of one individual to influence the actions of other individuals, independent of other variables. There are many components in organizational life, such as negotiating, influencing, selling, persuading, etc. Also, variables such as perceived bravery, integrity, fairness, and morality can affect interpersonal power.
- *Knowledge-expertise (or expert) power* derives from one's abilities in a recognized skill area—typically a technical one. The skilled nurse, physician, or systems analyst has definite power, especially among their professional peers.
- *Knowledge-information (or informational) power* stems from, "I know something you don't; therefore …" The information has to be perceived to be of some value for power to accrue. Again, the danger is obvious; hoarding knowledge can be seen as a source of power even if it may be negative for the organization.
- *Positional (or legitimate) power* derives from the organizational role or position and is often thought of as "formal" power. The organization confers the authority to lead, make decisions on behalf of the organization, and set a course including the ability to approve, disapprove, delegate, assign tasks, etc.
- *Coercive power* is derived from a person's ability to influence others via threats, punishments, sanctions, and withholding of resources. Coercive power includes the ability to punish, fire, or reprimand another employee. This form of power is important to assure adherence to the organization's policies and norms but is easy to overrate.
- *Reward power* is the opposite of coercive power as it uses rewards, allocation of resources, promotion, and tenure to influence others.
- *Derived power* is a form of second-hand power that arises when one person appears to have the ear of a powerful person

or even the right to speak for. The executive secretary often has high derived power in the eyes of the organization.
- *Referent power* is akin to interpersonal power but operates at more of a distance. This is the "monkey see; monkey does" form of power. Referent power is created when people model their behaviors on the behaviors of someone they admire.

Prepare Organizations for Change

Organizations usually have statements emphasizing the importance of their employees and their value to the organization, but then often act and treat their employees in completely contrary ways that do not reflect those values. As health care organizations strive for higher productivity in a very competitive market, it will be the health care systems that most effectively manage their human resources, including providing more than lip service to their employees' value that will be able to make the needed changes to redesign their systems to meet current demands.

No matter how good the new information system is, it will not solve every problem in the organization, and it cannot be marketed as the "penultimate" solution. Overselling people on what the new system will do will result in the system being regarded as a partial failure. "Technological mysticism" is a term applied to the belief that technology will magically fix everything. In contrast, "technological nihilism" believes that it will fix nothing or make things worse—striking a balance between these when setting expectations. Setting realistic expectations for the impact on *initial productivity* during the early implementation stages is critical. It is almost inevitable that productivity will initially decline, no matter how good the system or the preparations made for its implementation.

To deal effectively with the competitive reality, it is important to involve employees in any change processes that an organization undertakes. Today's workforce is changing demographically. It is becoming older and more diverse. Training and education vary. To remain competitive, healthcare organizations must develop and retain better trained and more highly valued workers. Part of retention includes involving employees in change management. Organizational leadership needs to directly include workers in the change process and train them to handle the new technology and embrace basic core values. Peter Drucker said, "The single greatest challenge facing managers in the developed countries of the world is to raise the productivity of knowledge and service workers. This challenge, which will dominate the management agenda for the next several decades, will ultimately determine the competitive performance of companies. Even more important, it will determine the very fabric of society and the quality of life in every industrialized nation." [25]

Strong Organizational Commitment

One of the key factors to success is a strong organizational commitment reflected in the behaviors and messages from organizational and local leaders. A health system constitutes a micro-cosmos with many smaller organizations contained within the whole with different cultures, needs, desires, interests, and conflicts. Committing to a change requires that all levels of organizational leaders commit to the process. When a multi-center system wanted to implement a new integrated cancer system, although administrative leadership was fully committed to the new vision, local hospital leaders had "competing perspectives, including a strong emotional loyalty to their host institution with its embedded processes and culture," which failed [26] Unless organizational commitment has permeated through all levels from leadership to clinicians, any implementation initiatives are likely to fail [27]. Organizational commitment or buy-in from individuals may change over time. Factors influencing the commitment include experienced outcomes such as changes in workload and revenue, competition with other efforts, changes or lack thereof in outcomes, relationship to existing workflows, and opinion of peers [28]

Leadership & Champions

As discussed elsewhere in this chapter, organizational leadership is a critical key factor to success. Unless end-users know that the leadership at the highest level and the local level are committed, they feel less inclined to contribute to the success. Champions, who promote the change to their peers, support the planning and design, serve as content and domain experts, and lead the implementation and rollout, are key factors to success. Selecting champions should focus on individuals respected by their peers, perceived as thought leaders with great communication skills, and the ability to rally others to achieve the best results.

Prepare People for Adoption

The Organizational section reviewed the macro approach for preparing the organization for new technology. This section reviews the individual side of adoption. Several studies investigated the role of new or replacement electronic health record (EHR) systems [29]. Since EHRs vary significantly in design and functionality, the results of these studies are mixed without a conclusive effect of

technology on efficiency [30–33]. The experienced efficiency tradeoff for many providers creates a perception of low personal benefit to their work. Additionally, the change in roles or workflow by implementing a new clinical information system can create new demands on healthcare personnel that can provoke resistance to the system.

Build Ownership

Experience tells us that motivated, involved people can make bad systems work. After all, they have done it for years. In the same way, people can bring the best system to its knees, unmotivated—or even worse, negatively motivated. Which situation will you have? How well you carry out the steps outlined above will often answer that question. Profound change initiatives come in many shapes and sizes. They can be as focused on meeting a crucial business objective or as complex as a corporate-wide "transformation."

Ownership in the new system is created in several different ways. The following are the most visible and tested methods.

Champions—as stated previously, an informatics system needs champions. The optimal approach is to identify several *clinically-respected* physicians or nurses to fulfill this champion role. These people should be integrated into the planning process from the beginning with their advice sought on virtually all aspects of the development and implementation process. [34]

General ownership—developing respected champions is only the first step in building ownership in the system. The primary twin tools for ownership are involvement and communication. The single best tool in building ownership is participation in the overall process—planning, design, selection, implementation, etc.—by those that the new system will affect. However, an important issue arises in medical areas: in systems of any size, the participation often has to be representative based rather than everyone participating.

Increasing ownership—the danger is that the participation process often attracts the "amateur techies" in the organization, either by self-selection or appointment. However, these people may not be high-clout nor persuasive people in the organization. Key organizational leaders must participate in the process. This includes administrative and clinical leaders.

Protecting professional egos—although it is costly, skilled one-on-one or very small-group training may be an effective strategy for those physicians and other professionals most likely to be affected by "computer-phobia". This is especially important if these professionals are also highly respected medically by their peers within the organization. Professionals have an understandable need for respect. Therefore, the dialogues present in informatics systems should be carefully reviewed for usefulness, clarity, and a *respectful tone*. For example, alerts should be programmed as respectful questions rather than as terse declarative statements. Error messages must give useful instructions for correcting the situation. While these suggestions may sound simple, they are often violated by informatics personnel, which are used to functioning under another paradigm of human/computer interface.

Feedback processes—any change management strategy needs to contain multiple mechanisms for actively soliciting feedback at all stages of the change process. The alternative is to have rumors, half-truths, and even untruths flooding the grapevine. When feedback is solicited and obtained, it must be processed promptly, and responses must be provided as soon as possible. This includes responses when the answer is still unknown. Not every issue can be resolved to everyone's satisfaction. However, people must feel that both they and their concerns are heard and regarded as important.

Senior Leaders

Senior leaders must be *committed* to the change process, not merely involved [35]. They must ensure that their visibility is broad and constant. They must "stay" with the process and ensure that all their decisions and actions are consistent with the organization's values and the change process. A senior leader can negatively impact a change process is to make decisions, not in accord with the overall vision. The person or team responsible for leading the technology change effort must have an option to address issues before the strategy is in serious trouble.

The senior leadership must ensure the planning for the new system is fully integrated into the overall organizational planning and decisions rather than occasionally review and solving problems out of context with the total organization. Since major systems are not implemented overnight, there needs to be a pre-determined process or strategy to address complex problems [36].

System Users

The system or end users are key stakeholders in the implementation of any health informatics system. Five key areas must be addressed:

1. End-users must know and comprehend what the system will be realistically capable of doing.
2. End-users must be included in the communications and information regarding changes being considered and/or developed.
3. End-users must believe that key people are committed to the success of the system.

4. End-users who are gatekeepers and opinion leaders need additional information and attention as they will be critical for adoption. There are times when the support of the system pushes or pulls others toward either success or failure. The gatekeepers or opinion leaders do not need to have formal organizational roles.
5. End-users need feedback on their issues and inputs as rapidly as possible.

Incentives

Building perceived benefits for the user into health information technology reduces efforts required in the training of users since novices will seek out experienced users on their own to be trained. The ability to identify the salient features that will satisfy the user and reduce required efforts or time, improved quality and safety, or elimination of extraneous tasks are important. If the benefits for the user significantly outweigh the costs associated with adopting new technology (learning process, initial inefficiencies, adjustment to change), then health IT implementation may go 'viral'. This means users will tout the application's benefits so effectively that they will recruit additional users. For example, when an online parenteral nutrition calculator was introduced in a NICU, users quickly realized that it resulted in fewer ordering errors and reduced the time required from 10 minutes to two. Without a formal push to roll out this tool in other units, the calculator was quickly picked up and used throughout the institution as word of its utility spread through the residents rotating through the NICU [37].

Training

Implementation of large-scale systems such a provider order entry or electronic health records pose significant logistical challenges regarding user training. For an effective roll-out, users must be trained and familiar with the system, and this knowledge should be fresh in their minds [38]. Training users too early will result in poor retention at go-life. Training too late may result in users remaining untrained due to shortages in training facilities and trainers. When large workforces have to be trained, the earliest trainees may be offered 'refreshers' immediately preceding go-live. A key success factor is to engage the users in training and gain their attention and interest. This is best achieved by tailoring the training to the individual user's anticipated role and task and avoiding training on aspects of the system rarely or never used by the user.

Process of Implementation

Preparing for implementing a new health IT system must begin well in advance of the actual implementation date. The implementation team needs to assess the organization's current state, understand readiness for implementation of new technology across the organizational landscape, and formulate plans. This assessment should include understanding current aspects of workflow across different parts of the organization, as mismatches between technology and workflow can cause significant challenges and difficulty in implementation and long-term use. Based on the assessment of the organization's current state, the team should develop implementation plans, strategies, and options specific to the local context [39].

Potential implementation strategies can include concepts such as identifying clinical champions and setting realistic expectations. Clinical champions are individuals who are part of the environment where the technology is to be implemented [40]. A clinical champion for a health IT project need not be a technology-oriented clinician; in fact, someone perceived by their peers as not being overly oriented towards technology solutions might serve as a better partner for implementation. In this way, the clinical champion can be seen as an honest-broker intermediary between the technology and the other end users. The purpose of partnering with a clinical champion is to access someone with local, contextual knowledge who has connections to and influence with peers. While the implementation team can be viewed as "outsiders", the clinical champion is an "insider" who can assist with building trust and confidence with the intended users of technology.

Setting realistic expectations is another strategy that can assist with achieving successful implementation [41]. An initial loss of productivity after the installation of new technology is a well-known phenomenon [42, 43]. Implementation teams need to be aware of this potential for productivity loss and assist with accommodating this initial, and hopefully temporary, change. For example, in a clinic implementing a new electronic health record system, the number of patients scheduled for appointments should be decreased for a few weeks after implementation to allow the clinic staff to become proficient with the new technology and adapt its use to their needs. Setting realistic expectations also includes being aware of and planning for some degree of failure. No large-scale health IT implementation is without some minor or even major failures during implementation. Planning for how the implementation team will adjust to failure is critical, i.e., rapid-cycle problem resolution to address problems as they occur and are reported.

As the implementation moves forward through different parts of the organization, the team should move through an iterative assessment and reassessment process [44, 45]. This iterative process will allow the team to adjust the implementation based on earlier implementation phases and locations knowledge. Implementation should be viewed as a continuous learning cycle, where success and failure of implementation strategies in one area should be incorporated into continuing implementation activities in other areas [46]. This reassessment and evaluation should continue well past the "go live" date for new technology, to ensure problems that emerge over days and weeks of use can be addressed.

Good Communication

A critical tool to improve organizational commitment is effective communication of a project's anticipated goals and benefits. Various types of messages will motivate. Using messages that help the recipient to think in "terms of emotions and personal experiences" (also known as experiential information processing) especially using mixed emotions, more likely motivates individual and social behaviors critical to user commitment [47, 48].

For the success of the implementation, messages must reach all users and staff. Repeating each message will ensure that the message reaches all shifts, locations, organizational positions, and providers are important. Besides, creating messages using various channels and modalities targeted at how and when individuals want to receive news. Channels may include mass emails, print and web publications, letters, hospital television pieces, social media (Twitter, Facebook, etc.) messages, fliers, informational events, and posters [49].

Implementation Planning

Change requires careful and deliberate planning to assure the success of an implementation and to avoid undesired consequences. Current processes and workflows need to be identified and analyzed. Future processes need to be proposed and evaluated for risks. The workflow chapter (see Chap. 8) in this book provides additional guidance. Collaboration between end-users, stakeholders, IT staff, leadership, and the implementation team is critical to define and prioritize vulnerabilities and propose and develop new workflows and interfaces. The planning group will develop an implementation plan containing required resources and staff, redundancies for the implementation period to assure processes are minimally interrupted, and the design of an evaluation to determine the effectiveness of the implemented change [50].

Local Change Agents

Change leaders might want to establish a change agent group. The Vanderbilt University Medical Center established a change management group with people representing each hospital unit, ambulatory clinic, and ancillary organization. Members of this group were selected about a year before the actual implementation. They experienced early training on change management as well as other general and technical topics. As time moved closer to implementation, they were critical to walk-through workflow efforts, preparing the staff in their areas, etc., for change. Most of the change agents also became super-users and were instrumental in facilitating implementation.

Implementation Support

During implementation, access to knowledgeable trainers, super-users, vendor consultants, and others is critical to success. Frustration often develops in response to a task that cannot be completed or executed as desired and quickly leads to disenchantment, resentment, and user dissatisfaction. Implementation support must be available at all hours the new system is operated. Users should be able, without significant barriers, to engage in support (this usually translates to support being available where the users conduct their work). Support must be knowledgeable, patient and must avoid minimizing the user's concern. Empathizing with the user's frustrations over lost time or added efforts is critical. Implementation support must record and analyze issues brought to them to detect systemic problems requiring software design or implementation changes.

Addressing Problems in a Rapid Cycle approach

An implementation may generate hundreds or thousands of problems reported by users [51]. Addressing these issues during the implementation period followed by reports about the progress is a key factor to success. It validates the users and their concerns, improves satisfaction, and builds ownership. Allowing problems to persist will result in user disillusion with the product, create frustration, and result in users harboring resentment towards the product and leadership, resulting in a productivity drop-off.

Technology: The Interplay of Usability, Context, and Implementation

Reliable and bug-free software are critical for implementing any software system, particularly ensuring that a wide variety of use-case scenarios and maximum loads are tested. However, reliability goes deeper than load testing and use

cases and ensures that the system meets fundamental usability criteria, including efficiency, effectiveness, user satisfaction, and error tolerance. The technology will be useful for end-users [52]. We refer the reader to Chap. 9, which focuses on human factors, including usability, for a further in-depth discussion of the dimensions of usability.

For this chapter, we focus on the steps needed to move from foundational assessments of software usability, which should be evaluated by vendors, to the importance of identifying and addressing potential context-based usability concerns, which are crucial for healthcare organizations to evaluate for any potential technology. As healthcare organizations select technology systems to purchase from vendors, organizations must ensure that vendors have conducted thorough usability evaluations of the technology [53] to ensure compliance with fundamental usability principles. As organizations implement specific features that work with a vendor-based system, such as clinical decision support, they must also evaluate the usability of these features [54].

Approaches such as contextual inquiry [55], organizational assessments [56], and workflow process mapping [57] can assist with proactively identifying potential technology-process mismatches, errors that may emerge only in the context of use, patient safety concerns, and the unique technology requirements of a specific clinical setting (e.g., pharmacy [58], high-acuity emergency department [59]). Another important aspect to consider is patient-centered perspectives on the role of technology in healthcare delivery. Connecting knowledge about technology usability with insights about the unique characteristics of a specific healthcare organization and clinical context is crucial to successful technology implementation and change management.

Other Key Vendor Considerations: Culture and Service

Beyond the functionality and usability of software, due to the complex structure of healthcare technology purchases, it is often also crucial to assess potential long-term considerations for the relationship between the healthcare organization and the software vendor. Before any purchase decisions are made, a careful assessment should be made of the vendor's culture and whether it is a good match for the organization's needs and expectations. Additionally, service agreements during implementation and long-term maintenance and software update agreements must also be considered [60]. In particular, although the technology may have a defined "Go Live" date when the system is turned on, these agreements should consider that issues can often be uncovered weeks, months, and even years after this initial date. Additionally, ongoing analyses of system performance should be considered for the long term after implementation begins [61]. These considerations are crucial regardless of the size of the healthcare organization, with specific needs of specialty care providers as an area that should also be carefully considered during technology selection and contract negotiation [62].

Summary

This chapter discussed the critical macro building blocks of a comprehensive implementation process. All too often, people want to only focus on the "actual implementation" with the training component and neglect the other components for the most part.

Implementation is expensive, and most organizations avoid discussion of costs. However, every organization must decide not if they will pay but when they want to pay for proper implementation. A past television commercial featured an auto mechanic holding up a dirty-corrosive-looking automobile that says, "You can pay me now or pay me later. Pay me you will". Just as money and time spent on the maintenance of a car will prevent downstream costs, proper approaches to implementation will have similar effects. The recommendations and proposed best actions in this chapter take time, and if organizations do not follow the process, they will spend their time in a greatly expanded "Recovery" component. Not to mention that people in the organization will be telling "horror" stories about the implementation for years to come.

Implementation of health information technology cannot occur in a vacuum. It requires extensive assessment of organizational culture and readiness, user requirements/needs, and workflow to guide the selection or design of the information technology solution. In preparation for implementations, users must be informed through various channels and repeatedly about the pending changes, the tangible benefits of the new technology, realistic expectations, and support of organizational leadership for the effort. Champions and developing general ownership of the new system and assuring that user feedback is heard and acknowledged are critical, as well as implementation support and rapid cycle response to system problems.

Questions for Discussion

1. You become responsible for implementing a major clinical informatics change in your hospital system. What are the first two "to-do list" tasks?
2. What types of resistance might you encounter?
3. What are the most successful strategies for successful adoption?
4. How much time do you think needs to be spent on adopting the clinical informatics system's cultural/behavioral issues?
5. What would be your response if people say that everything related to implementation planning sounds like common sense or generalities?

6. What are the three characteristics of a clinical champion? Why are they important?
7. What do you need to plan for to perform rapid cycle improvement during implementation?
8. What are your options if you think that support from the organization's overall leader is beginning to decrease?
9. Given that something unforeseen might occur even with the best of plans, what are your thoughts about a "recovery" strategy?
10. You are alerted to a problem of interactions between one of your implementation team members and a number of the end-users. What would you do first and why?

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Project Management

23

Lisa M. Masson, Carole A. Klove, and Noelle Provenzano

Learning Objectives

- Describe the basic principles of project management.
- List the phases of project management.
- Discuss how to determine resource needs.
- Analyze three challenges in project management.

Core Competencies

- K129. Basic principles and practices of project management
- K130. Project management tools and techniques

Clinical Vignette

Your large healthcare system plans to move its urgent care to a new site, a mile up the road from the current site. At the same time, there will be "workflow transformation" for the healthcare system. Thus, this is a project with two arms. There will be a physical move that includes new hardware. There will also be a careful analysis of their workflows with optimization, which will utilize new enterprise-wide software. The urgent care has a separate module within this software with features not found in the primary care realm. One goal is to allow appointments to flow from the urgent care to the primary care offices and the primary care offices to the urgent care if available and appropriate. This will require consideration of the physical location of the patient and provider and the software functionality to be used. There is a redesign of how patients receive care, optimizing workflows between the urgent care and internal medicine departments. Your project is to ensure integration of the new software to allow for effective and efficient communication of information between the two practice areas and relocation of the urgent care practice.

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Introduction

Project management is not new. Innovations and technology are omnipresent in healthcare. Implementing change is not easy. Over time, healthcare projects have failed and failed magnificently at high rates. Noting the project failure is too often the norm rather than the exception, this chapter describes how projects can benefit from well-defined project management processes and the details of those processes.

As a clinical informaticist, you have likely encountered many project managers and attended meetings with charts, outlines, and deadlines. You probably are familiar with many of the tools but may not have yet recognized the science of project management as a stylized and well-honed methodology.

As the field of clinical informatics matures, informaticists find themselves leading various projects, including but not limited to software implementations. This chapter highlights the basics of project management to aid and abet the informaticist as you dive into project leadership.

Definitions

What Is a *Project*?

This seemingly simple question often becomes relevant when asking for a change or optimization in an electronic

J. T. Finnell, B. E. Dixon (eds.), *Clinical Informatics Study Guide*, https://doi.org/10.1007/978-3-030-93765-2_23

health record (EHR) system. A request may seem trivial to the end-user, but a request often has downstream repercussions or impacts other users, departments, or services. One of the analysts may push back, noting that the amount of work involved is at a project level. A project is then prioritized and resourced along with the set of guidelines and governance of your organization.

So, what is a project? "*A project is a temporary endeavor with an endpoint in the form of a product, a service or a result*." [1] Projects may be large and complex or small and relatively simple. Regardless, a project is defined by its purpose. Every project encounters constraints. Examples of a project may be organizing a closet, furnishing a home, or designing a new hospital. The Urgent Care move in the vignette fits the definition of a project.

Business operations should not be confused with projects. Standard business operations are repetitive. Business operations are not demarcated by a distinct start and end date. In contrast, a project has a defined timeline, an end date, and a unique deliverable.

What Is *Project Management*?

Project management is defined as applying knowledge, skills, tools, and techniques to project activities to meet the project requirements [2]. Put another way; it is the process of leading the project through defined phases to achieve all project goals within the given constraints. Project management focuses on specific goals, resources, and timelines. Once a project is defined, the Project Manager (PM) is responsible for ensuring the goals and requirements outlined in the project are met within the allotted time frame.

A project manager must work to achieve these specific goals, manage the stakeholders' expectations with excellent communication skills, keep to the budget, and facilitate the process by both managing and leading. A *stakeholder* is any person who will be affected by or has an interest in the project. A PM works within a defined time frame. The PM understands the need to balance trade-offs and create equilibrium. The PM is a negotiator and a problem solver.

Why Does a Project Need Management?

A rule of thumb is that it is more likely than not that a project will fail. This is an alarming statistic, but over half of all projects fail. Why do they fail? There are three typical lapses (Fig. 23.1). First is the failure to plan the project's requirements or scope. The second is failing to complete the work according to the timeline. Finally, projects fail to deliver something worthwhile [3].

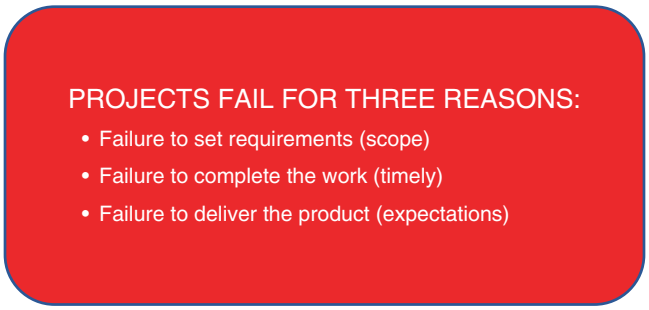

Fig. 23.1 Why Projects Fail

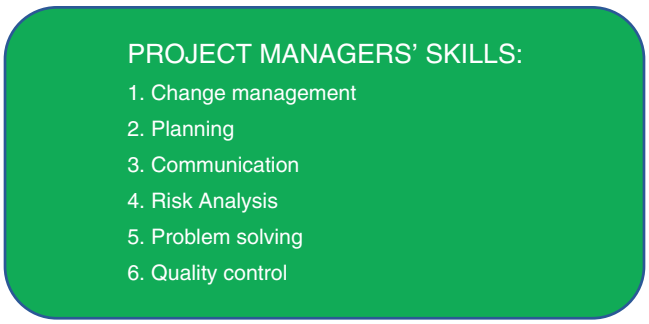

Fig. 23.2 Project Manager's Skills

With this frequency of failures, it becomes evident that projects can benefit from project management such that they are complete on time, on budget, and meeting expectations.

How does a PM create this magic? A PM must-have skills. The trick is to manage change, plan, communicate, analyze risk, solve problems, and control quality (Fig. 23.2).

The Swing Cartoon

There are many versions of "The Swing Cartoon" (Fig. 23.3). The cartoon highlights that without clear communication, projects will fail. There are various captions, but commonly the captions are:

1. As proposed by the project sponsor
2. As specified in the project request
3. As designed by the senior systems analyst
4. As produced by the programmers
5. As installed at the user's site
6. What the user wanted

The swing cartoon emphasizes that communication between the project sponsors, requestors, analysts, programmers, builders, and the user is often imperfect.

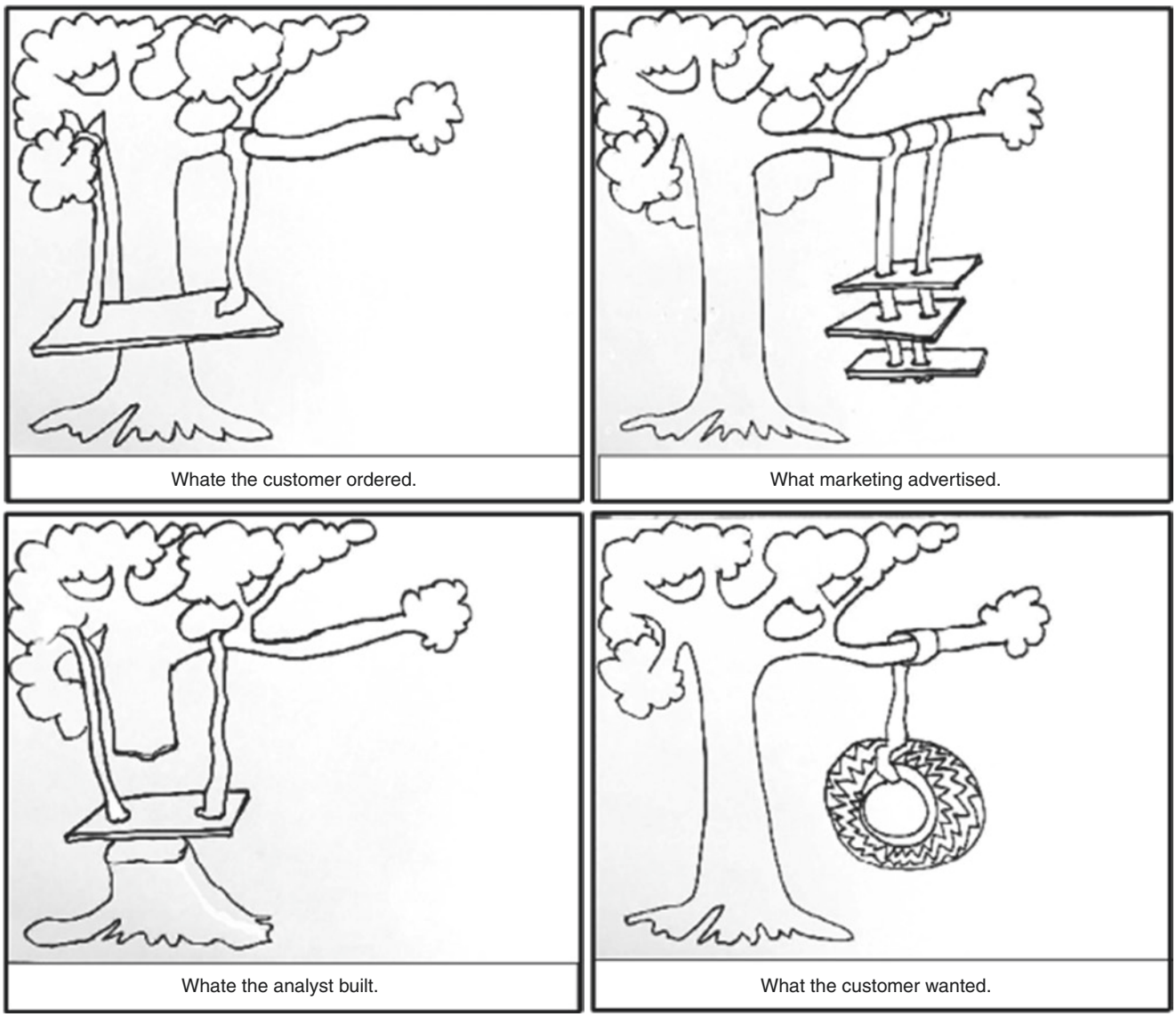

Fig. 23.3 The Swing Cartoon (Reproduced with permission from Angela Masson)

Project Constraints

A project manager, even with exemplary skills, must still overcome formidable obstacles. Every project, large or small, is bound by "the triple constraint" [4]. *Constraints* bind or restrict. The urgent care move and all projects share these triple, common constraints: Cost, Time, and Scope. Cost includes the price tag and the use of all resources. The timeline refers to the project's schedule. *Scope* defines the depth and breadth of the project, and it refers to the combined objectives and requirements.

While these are the three big constraints referred to during the history of project management, there are always more considerations. Some refer to the quadruple constraints, which add quality to scope, cost and time. More comprehensive is the six-pointed star (Fig. 23.4), which adds quality, risk, and resources.

Why Does a Clinical Informaticist Need to know about Project Management?

Clinical informaticists are often called upon to lead health care projects such as implementing and upgrading EHR systems, preparing to meet new legislation and government mandates, and developing analytics projects to improve care. The lead to a new Urgent Care with the merging of EHR systems and workflows would benefit from a PM.

Projects can benefit from project management to bring them in on time and budget while meeting stakeholder expectations. Clinicians often make good project managers as they already have many traits that make a good PM, such as the ability to plan and well-honed communication skills.

While talented, clinicians do not necessarily know how to manage projects. Basic project management training helps hone the skills PMs need to keep projects on track. This includes the ability to: manage change, plan, communicate, analyze risk, solve problems, and control quality. As you read through this chapter, you will recognize many tools you have seen used in your training or have already used yourself. Project management formalizes the process, ensuring that critical pieces are not inadvertently omitted in the planning and execution of the work.

Often clinicians are leaders and looked up to by staff and project members. When the PM and physician leads are synced in the project requirements, it is easier for everyone else to follow suit and embrace the vision.

Clinical Informaticists function in the healthcare industry, which is embracing new technology and new standards of care. Legislation evolves with new mandates. The population is increasingly involved in their care, and the population is aging. Accommodation of these changes efficiently can only occur with the use of good project management principles. The skill-set for a PM in healthcare has mirrored the skill set for a typical PM. These skills must adapt to the ongoing challenges.

The move of a practice or department is an example of a healthcare-related project. Other examples of healthcare projects that benefit from project management: the implementation of a barcode medication administration tool, implementation of a patient portal, integrating infusion pumps with the EHR, converting to an EHR or changing vendors, and so forth. Each of these projects has different costs, timelines, resources, levels of difficulty, and complexity, but they all have common qualities. They all create a unique product or service. They are all temporary and will have a completion when the objectives are met. They require specific resources, including people, technology, or physical assets. They each have a primary customer. Each could benefit from being managed with a defined methodology.

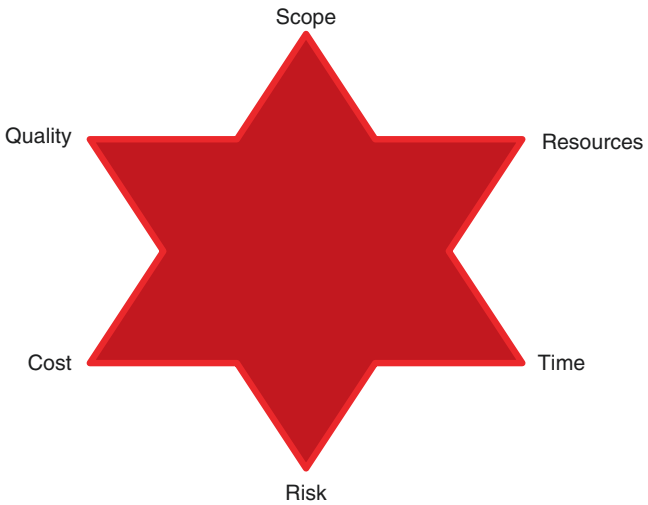

Fig. 23.4 Project Constraints, the six-pointed star

History of Project Management

Project management has been around for centuries, and its history is summarized in Fig. 23.5. Pause for a moment to consider that the Great Pyramid of Giza was built in 2570 BC. The pyramid is composed of 2,300,000 blocks of stone, each weighing an average of two and a half tons. It is four hundred and fifty feet high and is oriented to the points of the compass. It stands yet today [5, 6]. Many ponder just how the pyramid was built. Ponder also how the workers who built the pyramid were organized to pull off this amazing, enduring, engineering feat. The magnitude of the creation implies that the Egyptians employed disciplined project management.

Evidence of more recent project management is evident in the 208 BC construction of the Great Wall of China. Some historical evidence implies that the builders for this large project were organized into groups. Three of the groups were soldiers, common people, and criminals. Millions were ordered to complete the project. Imagine orchestrating those groups to work together! [7]

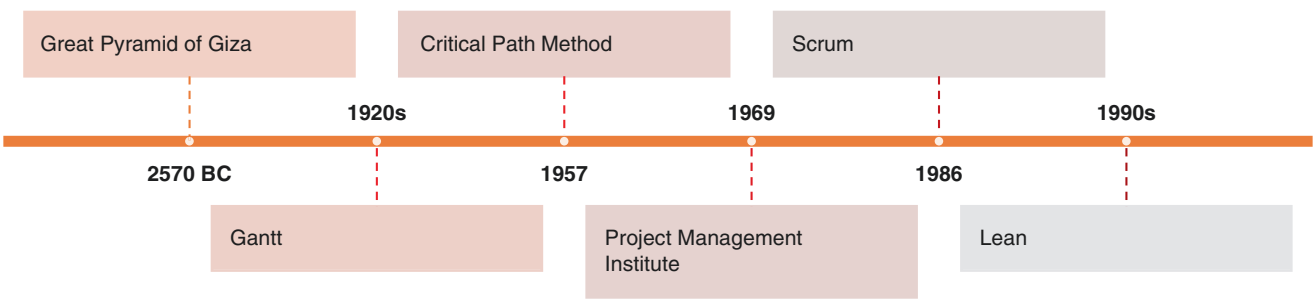

Fig. 23.5 Project Management has a long history

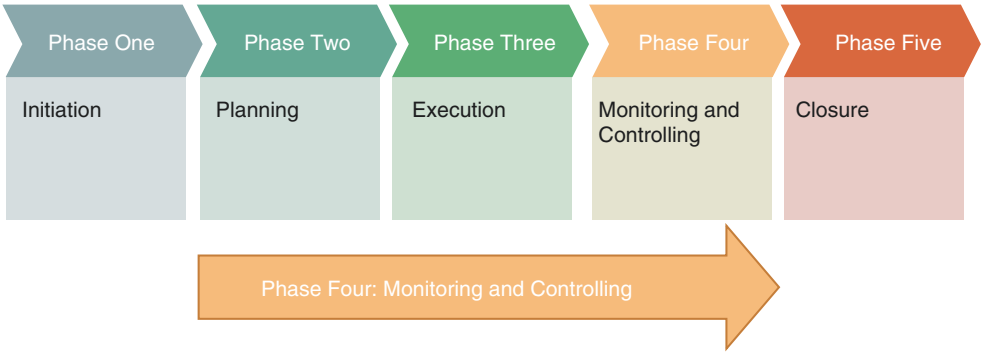

Fig. 23.6 The Phases of a Project

The forefather of project management was Henry Gantt. The Gantt chart was a radical idea and an innovation of worldwide importance in the 1920s. One of its first uses was on the Hoover Dam project started in 1931. Gantt charts remain a ubiquitous tool.

In the 1950s, the U.S. Navy developed a methodology to manage the Polaris submarine missile program. This methodology was named Program Evaluation Review Technique (PERT). Shortly after that, Dupont created another similar tool known as the Critical Path Method (CPM). The Critical Path Method is an algorithm for scheduling a project's activities [8].

In 1969, a group of project managers founded the Project Management Institute (PMI).

The PMI is the world's leading association for those who consider a project, program, or portfolio management their profession. Several other organizations have also defined standard practices in the area of project management, including the Australian Institute of Project Management (AIPM), the United Kingdom's Association for Project Management (APM), and the International Project Management Association (IPMA).

Scrum was described in 1986. Scrum is an agile framework. The intent is to help people, teams, and organizations create value through adaptive solutions for complex problems. If you have watched or played rugby, you know that a scrum is a formation of players. The authors chose "scrum" as the moniker as it emphasizes teamwork [9].

Lean management was named such in the 1990s, although the philosophy was derived from the success of Toyota in the 1950s and 60s [10]. Lean describes the elimination of waste, *Muda*. Muda is directly translated from Japanese to mean waste, uselessness, or futility. Lean also describes waste due to overburden, *muri*, and waste created through uneven workloads *mura*.

Five Phases of a Project

A project is defined as having an identified beginning and end. During the project's lifespan, there are five recognized phases, summarized in Fig. 23.6. The phases occur in a natural linear fashion from beginning to end. Not surprisingly, projects start at the beginning with phase one, the initiation phase. Phase two is the planning phase. Phase three is the execution phase. Phase four, the only phase which may be out of sequence and may occur concurrently with other phases, is the monitoring and controlling phase.

Phase One: Initiating

The initiation phase begins with a *business case*, which justifies a proposed undertaking defining the expected benefit [11]. During initiation, the proposed project is evaluated against a business need and technical feasibility. There must be ample justification for a decision to move forward. If feasibility testing needs to occur, it will occur during this stage. The research will be done to determine if the project is achievable and reasonable to pursue. The goal during initiation is to articulate the project at a broad level. The important stakeholders should perform their due diligence to provide their input. If the project is given the green light, the project manager must create a project charter or a project initiation document (PID) that will outline the purpose and requirements of the project. This document will include the business needs, the stakeholders, and the business case. (The technical details will be outlined in Phase 2.)

The *project charter* is a document comprised of various components. These components may vary with the complexity of the project. At a bare minimum, the charter will include the project's name, the name of the project manager, the description of the unique product or service being proposed, justification for the project, anticipated milestones, risks, and the expected cost and timeline. The risks can be broadly classified as anything that will prevent the project from moving to its completion. A project sponsor, serving as the champion of the project, is also identified at this point. The project sponsor links the project manager and the decision-making bodies, such as the board and C-suite. The project charter will identify the stakeholders and clarify what is in-scope and what is out-of-scope. Clear boundaries are crucial.

Regardless of the components or intricacy of the charter, the charter's approval validates the authorization of the project and the project manager.

In short, the project initiation phase is the first phase within the project management life cycle. The business problem or opportunity is identified within the initiation phase, a project is formed, and a project team is chosen to deliver the solution. A business case is crafted to delineate the problem or opportunity in detail with the identified solution for implementation. Crucial to this phase is clarity and communication. (Remember the swing)

Phase Two: Planning

Next, a project management plan is designed. The PM will leverage the project charter to begin to outline the project plan. The plan is the heart of the project life cycle. Planning represents a significant amount of time and often the bulk of the work effort. Aspects of the project are carefully defined in the plan, including integration, scope, schedule, cost/budget, quality, human resources, non-human resources, communication plans, risk, procurements, and the stakeholders.

The PM ensures that the right people have reviewed and signed off on the plan. The project scope must be well delineated to avoid confusion or backtracking. Without a defined budget and or approval, the project will not be able to proceed.

Once the project plan is finalized and approved, create a formal project baseline. The baseline is important as it is a reference point during the monitoring and controlling phase. The baseline helps understand what was accomplished at the end of the project. No changes should be made to the project plan without adhering to a strict change control process. The maxim for understanding the value of an established baseline is that "it is hard to remember that your objective is to drain the swamp when you are up to your neck in alligators."

Planning is all about getting back to the basics. What problem needs solving? Who will be involved, and what will be done? Document the problem being addressed. Identify the stakeholders. Define the objectives. Delineate scope. Identify needed resources. Record necessary tasks to be completed. The PM is always prepared to balance trade-offs between time, cost, and quality.

By the end of the planning phase, a roadmap that everyone can follow will be completed. Planning is about defining and setting goals. A common method for setting goals is the SMART rule: [12]

- **S**pecific: The plan should dive into the weeds, including concise and clear details.
- **M**easurable: It should be clear when the project is completed.
- **A**cceptable: The plan must be palatable to the stakeholders.
- **R**ealistic: The objectives should be within reach and based on reality.
- **Time-based**: The plan should have labeled deadlines.

Another acronym useful in setting goals is CLEAR.

- **C**ollaborative: Involve all the stakeholders in planning.
- **L**imited: Delineate the scope of the project and the time, money to be expended.
- **E**motional: Embrace the passion of those involved.
- **A**ppreciable: Dissect the large goals into measurable steps.
- **R**efinable: As new situations arise, be flexible and refine as necessary.

Phase Three: Execution

Once the plan is complete and approved, it is time for action! The execution process may begin. The PM's responsibilities during this phase will be dependent on the details of the project. This is the phase where the majority of the work is done. Now the deliverables are developed and completed. Throughout this phase, status reports, meetings, development updates, and performance reports are shared. At the onset of the execution phase, there is most often a "kick-off" meeting. Here all the teams involved are aligned and informed of their duties and tasks [13].

Tasks fulfilled during execution include the team's development, assignation of resources, the performance of the project management plans, tracking of the systems, status meetings, updates, and any necessary modifications. Although the project monitoring phase has different requirements, these two phases frequently transpire simultaneously.

At the end of the execution phase, the PM signs off that key milestones are completed and have documented performance reports.

Phase Four: Monitor and Controlling

A PM is responsible for ensuring that the project is kept on track and the progress is appropriately communicated to the stakeholders. The project monitoring and control phase happens in tandem with the planning and executing phases.

This phase involves actively reviewing the project's status, evaluating potential obstacles, and implementing necessary changes. The PM must ensure that everything happening aligns with the project management plan. The PM juggles

her multiple responsibilities, including keeping to the schedule, staying within budget, avoiding scope creep, and managing risk. The project manager compares projected performance with actual performance and takes necessary corrective actions to accomplish the desired outcomes.

As implied by the name "monitor and controlling", this phase includes measurements of the project's progression and performance. *Key performance indicators (KPIs)* are used to determine if the project is progressing appropriately. The PM identifies quantifiable KPIs. Usually, two to five KPIs are used to measure the headway being made. Examples of KPIs include keeping to the project schedule, the labor costs, the resource allocation, the specific task deliverables, and the log of changes and issues.

Phase Five: Closing

After the product or service has been successfully delivered, the PM needs to archive the work and step away from the project in a process known as closing. The PM will review all deliverables against the project plan and charter to ensure they have been completed.

The PM will conduct a lessons learned process to highlight project areas that went well or could be improved in the future, so later similar efforts can perform even better. These lessons could be incorporated into a completion or closure document, which can be accepted by the project sponsor or other decision-making body.

The PM's responsibilities for this effort are complete, and the PM will no longer serve as the point of contact for the product or service. The product or service should have been transitioned to an ongoing support team. Outstanding issues or action items will be documented and assigned to an individual or group for ongoing follow-up so all project activities can be closed.

Simply stated, the closing phase includes the postmortem, completion of paperwork, archiving and release of documents, and the celebration of success.

Tools of Project Management

Projects are managed successfully by implementing appropriate tools. The tools used in project management help focus the members of the project team and the stakeholders on the outcomes throughout the project. This focus is needed to complete the project on time and within budget. The principal tools for project management include the business case, project charter, stakeholder analysis, timelines, communication plans, risk management plans, and a follow-up tracker. Via these tools, information is managed clarifying why the project needed to be done, what needed to be done, who needed to be involved, when the project needed to be done, how the project would be explained and communicated, and how risks would be handled.

There are fundamental tools that should be utilized in every project, regardless of the magnitude or complexity. For large projects involving multiple departments or areas, these tools need to include extensive detail around the project and the stakeholders.

In smaller projects, the tools can be tailored and used as guidelines to move the project forward. Examples of basic tools include Microsoft Project, Skype for Business, Trello, Evernote, Microsoft Visio, etc.

Tools: Charts and Graphs

Numerous charts and graphics can assist with the project. These are most often used during the planning phase. Examples of charts and graphs include the Ishikawa (fishbone) diagram, the Mind Map, the Program Evaluation Review Technique (PERT) Chart, and the Gantt Chart.

An Ishikawa or fishbone diagram (Fig. 23.7) is a graphic tool used to explore and display opinions about sources of variation in a process. The concept is that the main problem is entered at the right of the diagram, and the "bones" represent the main categories that affect the main problem.

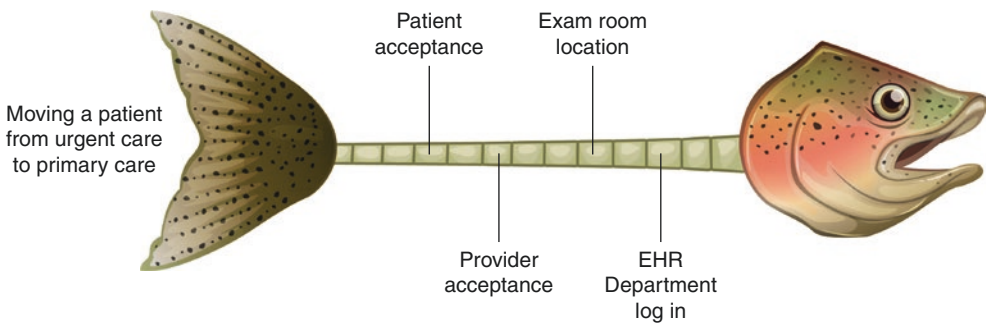

Fig. 23.7 Example of a Fishbone Diagram

The idea is to have three to six main categories that encompass all influences. This technique is best accomplished by a group where brainstorming adds all possible causes to the "bone."

When complete, the team usually has a good idea of the root cause for the problem. This is a good way for the project manager to include the team and stakeholders in the project planning.

A mind map (Fig. 23.8) is a planning tool that supports team brainstorming activities. It is an easy way to brainstorm thoughts without worrying about order and structure. It allows a visual structure of ideas to help with analysis and recall. A mind map is a diagram for representing tasks, words, concepts, or items linked to and arranged around a central concept or subject using a non-linear graphical layout that allows the user to build an intuitive framework around a central concept. A mind map can turn a long list of monotonous information into a colorful, memorable, and highly organized diagram that aligns with your brain's natural way of doing things. A mind map can be used as a simplified content management system (CMS). It allows you to store all your data in a centralized location to stay organized. With the various mind mapping software programs today, you can attach files to different branches for even more flexibility. You can also change to various views to find one that suits you best

Another oft-used and useful tool is the Program Evaluation Review Technique (PERT). A PERT chart (Fig. 23.9) is used to schedule, organize, and coordinate tasks within a project. The PERT chart may be used instead of the Gantt chart because it clearly illustrates task dependencies. On the other hand, the PERT chart can be more difficult to interpret, especially on complex projects. Both techniques are frequently employed.

A Gantt chart (Fig. 23.10) provides a graphical illustration of a schedule that helps plan, coordinate, and track specific tasks in a project. Gantt charts may be simple versions created with a spreadsheet or more complex created using project management applications.

Another way to look at the relationship of the tasks is the GANTT chart. While the PERT shows the various sequential tasks, the GANTT clearly shows the concurrent tasks. It is the same information in both graphs, with the GANTT displaying a linear timeline.

Business Case

Most organizations will require a business case before considering funding a project. A business case should include a

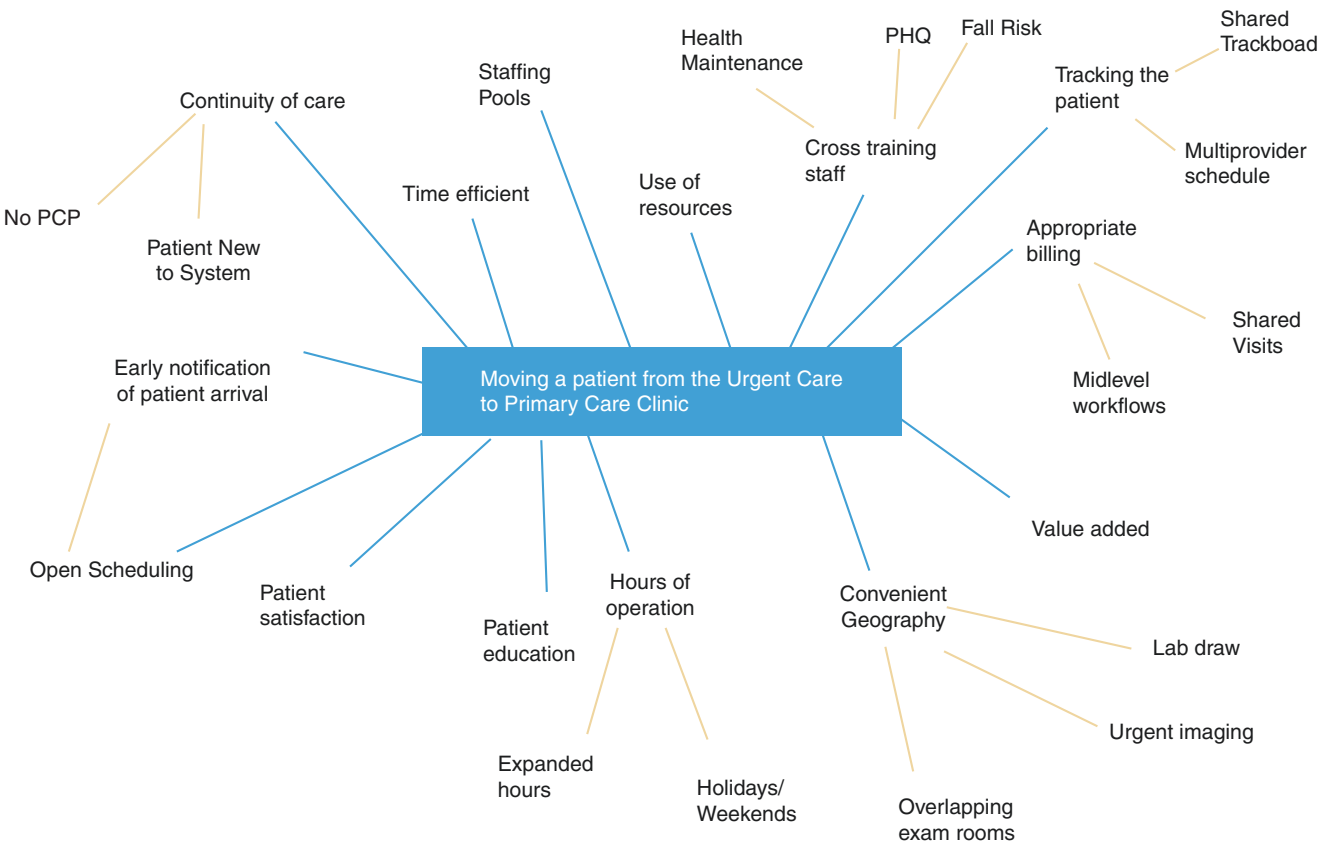

Fig. 23.8 Example of a Mind Map

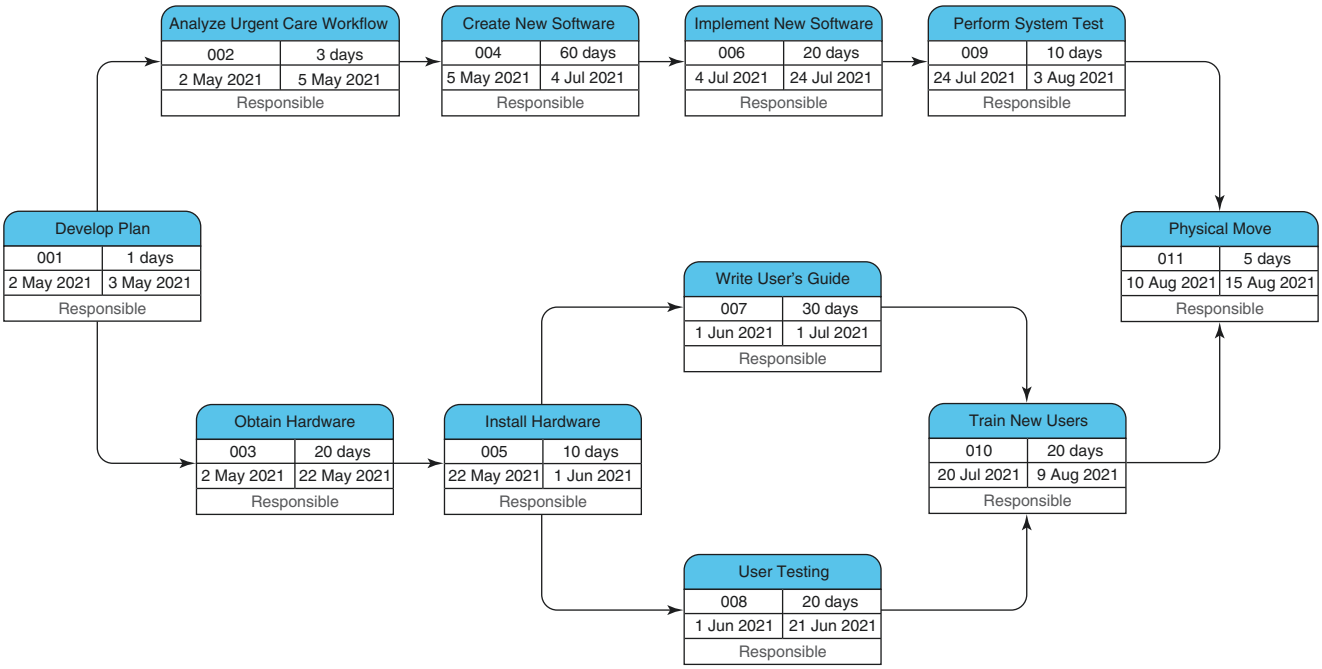

Fig. 23.9 PERT example

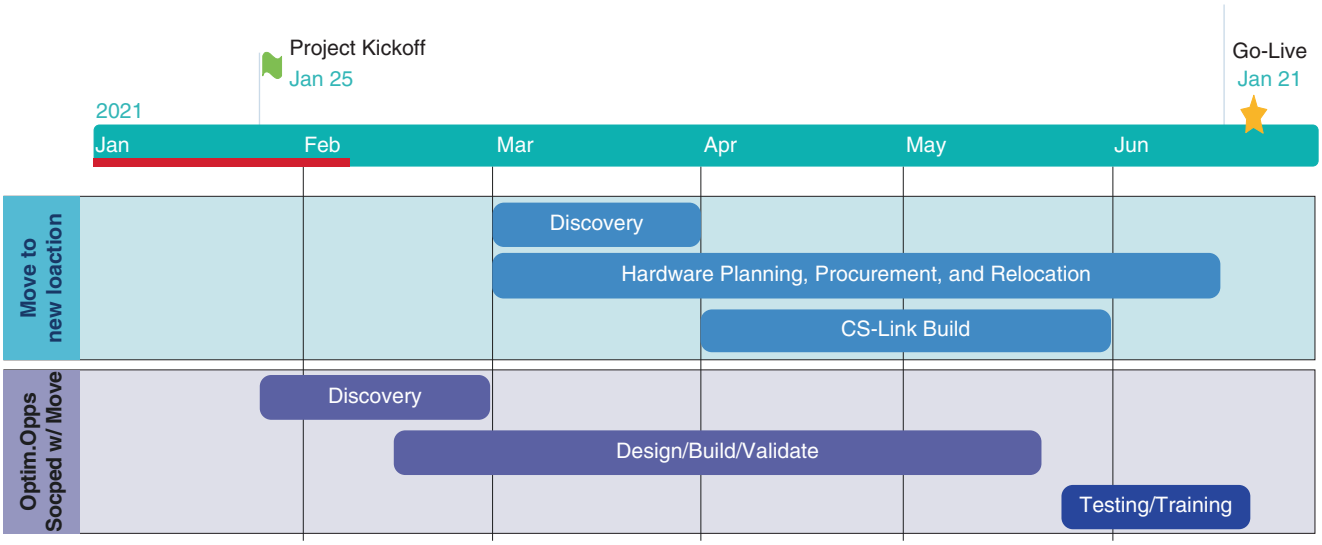

Fig. 23.10 Gantt Example

"plain language statement of the problem to be solved, with key data to illustrate its significance, as well as its severity and complexity." [14]

The business case should identify stakeholders. The impact on the stakeholders if the project is done should be described and the impact on them if the project is not completed.

Within the business case, assumptions are delineated. The estimated costs and resource needs are described. Options should be reviewed comparing the current state with the potential future states with and without the project completion.

Care should be taken in crafting the business case. A well-written business case increases the project's chance of approval. This document should make the value of the project apparent to the funding committee. The funding committee invariably has many projects competing against each other. Obtaining monies and resources will require that committee members have a clear concept of the project's potential benefit.

Part of the business case will be an executive summary. This allows the decision-makers to focus on the most salient points. Key elements in the executive summary include the problem statement, the project's scope, the business impact, and the financial impact.

Project Charter

Once the project is approved, the next step is the project charter. This document formally authorizes the existence of a project and provides the project manager with authority to apply organizational resources to project activities." [15] With the charter, the project manager obtains the agreement and sign-off from the stakeholders. The charter should be tightly worded. The goal is to have concise statements of the plan, the resources, the roles of participants, the milestones that will be tracked, and identify the project management team. This document is not simply signed and forgotten, but rather it is used as a guide for the team members and stakeholders for the project's duration. It is a living document, which should be appropriately updated throughout the project. Invariably some team membership changes occur as well as project specifications being modified. These changes must follow a recognized change management process. "If project content is allowed to change freely, the rate of change will exceed the rate of progress." [16]

The project charter is not simply a formality. This is an important record with a distinct purpose. The agreement between the organization, the project team, the project sponsor, and the stakeholders are documented. Still, there is also a clear statement of the project's purpose and what the team is committed to delivering. The team members' roles and responsibilities are detailed. The charter provides a baseline for the scope and expectations.

Contents of the project charter should include:

- Project description,
- Purpose,
- Goals,
- Scope,
- Assumptions,
- Approach,
- Reporting structure,
- Timeline and budget, and
- Signatures.

Project Description The charter's section on project description should include a paragraph or two expressing what the project is expected to accomplish. In addition to the project purpose, record the specific goals and outcomes that are expected.

Project Scope The discussion of the project scope should be clear. Scope defines what is and what is not part of the project. Each department that is included or excluded should be listed. Referring back to this section of the charter will benefit the team in avoiding scope creep, which could fail.

Project Assumptions No endeavor is without assumptions. Acknowledging those assumptions may be critical to the project's success. Assumptions guide decisions throughout the project. These expectations guide the team's effort. Recognizing the common ground helps to standardize the decision-making processes. Frequently there are assumptions around duration, prerequisites, software functionality, and building codes. The project manager should be alert to understand these and suppositions.

Project Risk No action is ever without some risk. Risks may include financial burdens and time burdens for staff. Additional detrimental outcomes may occur in terms of staff or customer well-being. These risks should be addressed.

Project Approach A complete project charter explains the approach to the project. In this section, details around how the project will be implemented and high-level milestones to be identified. These milestones will likely include planning, analysis, build, testing, training, and go-live activities. The approach should describe how risks and costs will be managed.

Project Reporting Structure Also, the project charter should clarify the reporting structure. Reporting structures are crucial in any endeavor. Not infrequently, many of the project team members do not report to the project manager. Everyone must understand the hierarchy of responsibility. The project organization structure is necessary. This section will also include a list of the project participants, including the project team, the stakeholders, the leader,s and any third-party vendors.

Timeline and Budget The project manager will grasp the expected timeline and should define this in the charter. The budget will also be explained, including cost, resources human and non-human.

Signatures The charter is not complete without the stakeholders' signatures. As the charter will be a point of reference during the project, this obvious step ensures that everyone agrees.

Stakeholder Analysis

The project manager's tool chest includes stakeholder analysis. A stakeholder is anyone who is touched by the project.

This includes those who are involved in the actual work of the project. The stakeholders influence the project deliverables and outcomes. The PMI defines a project stakeholder as "an individual, group, or organization who may affect, be affected by, or perceive itself to be affected by the decision, activity, or outcome of a project." [17, 18] The savvy PM will evaluate the political climate and local culture enveloping the project.

The project sponsor, once identified, should be able to assist with stakeholder identification. Referring to documented lessons learned from similar projects can be a great asset in recognizing who was impacted and who might be impacted with the current undertaking. Anyone who will be needed to assist or support the PM or team should be included on the stakeholder list. Reaching out to the team members, the decision-making commit, te,e, and even vendors can be beneficial in possible stakeholder recognition.

The list of potential stakeholders can be extensive. Potential stakeholders include organizational leadership, the sponsors, the end-users, the vendors, the project manager, the project team, the resource managers, marketing, sales, quality assurance, legal, finance, contracting, patients, visitors, customers, business partners, consultants, payors, and members of the care team, including physicians, mid-levels, nurses, and support staff.

Once the roster of stakeholders is created, the PM can work to understand what each person's stake is in the project. What does each stand to gain or lose if the project succeeds or fails? Stakeholder analysis appraises each person's expectations, needs, perspective,e and objectives for the project. The analysis will not be static. The outcome will require ongoing review as the results will change as people adapt their views and priorities for the project.

Various tools exist for stakeholder analysis. A simple spreadsheet can be used to parse out the stakeholder's role and involvement in the project (Fig. 23.11). The stakeholder analysis will include the stakeholder's name, along with the role and that person's involvement. For example, they may be active participants in providing requirements and testing or inactive but touched by the project's reach. Also, the analysis might include the stakeholder's interest and influence within the organization.

Similarly, the power or authority that an individual wields at the organization may be explained. The degree of impact of the project on the stakeholder is part of the analysis. That person's expectations for deliverables should be identified how the stakeholder would like to be appraised of the progress, including channel, frequency, and form. The support the stakeholder can provide is important information as well.

With the stakeholders identified and information obtained around their involvement and attitudes, the PM can evaluate the best method for managing each individual or group. Different columns may be added as needed for the project and management of expectations.

Another project management tool in stakeholder analysis is to graph with two rows and two columns to plot the stakeholders. Multiple versions (Fig. 23.12) can be used as appropriate for the situation; the variations depend on the criteria deemed important to the project. The main criteria include influence/power and importance/interest. Anyone high for

Stakeholder Analysis								
Stakeholder Analysis	Role	Involvement	Interest	Power	Impact	Expectation	Communication	Support
	Urgent Care Manager	Large	Large	Medium	Large	Positive	Frequent (daily)	Large
	Team Member A	Large	Low	Low	Low	Positive	As needed (weekly)	Large
	CEO	Low	Low	High	Low	Neutral	Major Milestones	Neutral
	Project Sponsor	Low	Medium	High	Low	Positive	Major Milestones	Large
	Physicion A	Medium	Large	Medium	Large	Negative	Weekly	Negative

Fig. 23.11 An example of a spreadsheet for stakeholder analysis

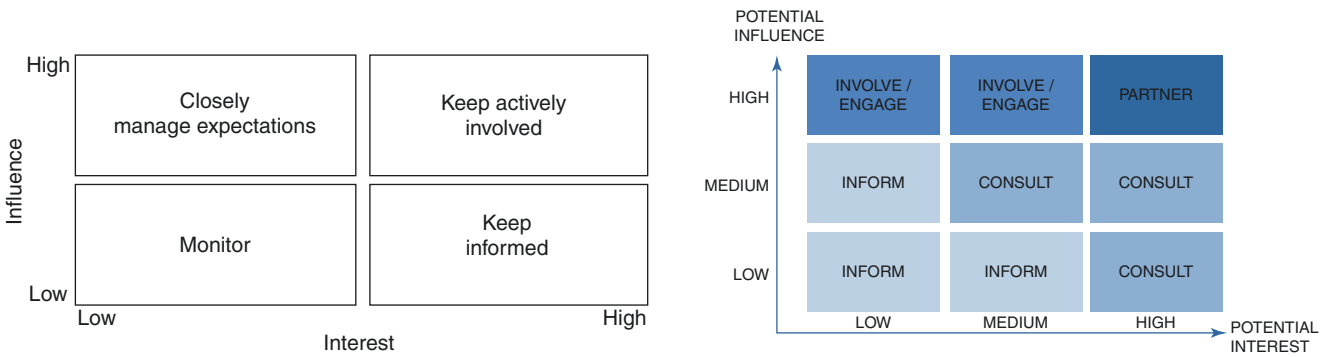

Fig. 23.12 Examples of graphs to plot stakeholders

both of these criteria is key and should be actively involved. Stakeholders high for one criterion should be closely managed to meet specific needs. One with high interest and low influence should be kept informed of the project's progress. Those who are low for both criteria should still be monitored but will require the PM's least effort.

The PM may find themselves in a crossfire between the multiple stakeholders. Stakeholders will not have the same perception, enthusiasm, goals, or expectations. Different opinions come from leadership versus clinicians or external factors such as government regulations, consultants, and vendors. One of the goals of stakeholder analysis is for the PM to recognize the different perspectives, anticipate potential conflicts, and mitigate potential detrimental effects on the project.

Conflicts do not infrequently arise due to cognitive differences. These differences stem from variances in judgment about data or facts. Optimally, these differences can be used constructively when recognized and discussed transparently.

Other conflicts which are more dysfunctional and unlikely to be constructive are due to personalities and animosity. Conflicts may be open, and everyone is aware, hidden where only some people know or latent. Latent conflicts only surface if the normal mode changes [19].

The conflicts may be apparent over objectives, needs, interests, or processes. The project manager and all team members should aim to build and maintain positive relationships between all stakeholders.

In summary, the stakeholder analysis includes:

1. Identifying the stakeholders,
2. Identifying the stakeholder needs and interests,
3. Classifying groups of interest (stakeholder mapping),
4. Identifying potential areas of conflict,
5. Prioritizing and balancing stakeholders and
6. Aligning the stakeholder needs with the organizational strategies. This work will need ongoing review throughout the project.

Work Breakdown Structure (WBS)

The next tool in the armamentarium of the PM is the *Work Breakdown Structure (WBS)*, which is a dissection of the project into deliverable tasks. The runner must break it down into individual miles and then into individual strides to complete a marathon. The WBS is the decomposition of the total scope of work to be carried out to accomplish the objectives and deliverables. WBS is the process of subdividing project deliverables and project work into smaller, manageable components. The process takes expansive complex projects and breaks them into bites that can be chewed and digested.

WBS helps with scope, cost, and schedule baselines. It ensures that the project plan accounts for each of these important factors. The purpose of the WBS is to create a scaffolding for the work that will be delivered. Some consider WBS the most valuable of all the project manager's tools, as this ties the entire project together.

The WBS allows the PM to organize individual tasks that, combined, will complete all the work required. The first step in creating a WBS is to identify the major tasks needed to complete the project's scope. The purpose of the first step is simply identifying the major tasks, not organizing them. Identifying the steps first allows the PM to better organize and schedule the steps.

Once the first step is completed, the PM begins breaking the major tasks down into further details. The major task of moving equipment in urgent care might, for example, be further defined as measuring the new space, determining where each item being moved will reside, moving exam tables, moving electronics, disposing of outdated furniture, purchasing new furniture, etc. The PM does not complete the WBS in isolation. Discussing the breakdown of tasks and listing subtasks with the team members and appropriate stakeholders can help understand different views and aspects of the work.

The PM continues to identify subtasks until confident the work is well delineated.

Once the subtasks are clarified, each subtask can be appropriated resources—the estimated time needed to complete subtasks created. The PM can make projections on cost and timing by reviewing the timelines and budgets of prior similar projects. Almost every health IT project will need certain human resources, including a leader, a sponsor, an analyst, and a trainer.

Up to this point, the subtasks are identified but not yet organized. The PM can now determine which tasks are dependent on other tasks and which can occur in parallel. Knowing the estimated time to complete a task and understanding dependencies, the critical path is clear. The critical path is the longest set of sequential tasks and represents the shortest possible estimated time to complete the project. A critical path is the longest path or set of tasks through the project. This path or set of tasks drives the project duration; that is, the project cannot be completed any sooner than the last task in the critical path.

Even small projects can benefit from WBS. The WBS defines all the work to be done and allows for a graphical representation of the work. The WBS provides the basis for resource assignments. The WBS allows the project manager to estimate each task's time and calculate the resources needed.

The Project Management Office

A *project management office (PMO)* is a group, person, or place that maintains and ensures standards for project management within that organization. The concept of a PMO has existed in other industries and is becoming more common in healthcare [20]. The principal purpose of a PMO is the standardization of project-related governance processes. By having one place to look for project management, it becomes easier to share resources and resources and techniques. A project manager can turn to the PMO to obtain past lessons learned and gather information about potential stakeholders. Having seasoned project managers who know the institution can set the point of reference for future expectations. The new project manager can have confidence in the PMOs standards. A PO is a corporate entity with one job: to ensure projects are completed on time, on budget, according to specifications while maintaining quality and customer satisfaction.

Communication Plan

If one principle of project management stands out as the most vital, it would be the communication plan. The objective should be that no stakeholder experiences a surprise. The PM should be skillful at getting the right information to the right people at the right time and in a useful format. The communication may be continued selling and reselling of the project throughout the project lifecycle. As snags in the plan invariable occur, there will be new dissenters expressing dissatisfaction. The project manager must be aware of the under stirrings. The PM must determine who needs what information to maintain the project and complete the required tasks. Not everyone needs to be alerted to every detail of the project; however, they need to know about issues and risks that will have to affect them.

Good communication can be the key to the project's success. Poor communication can cause even a good project to fail. The communication channels should flow from the PM to the team, the team to the PM, the PM to the sponsor, and other stakeholders. The team members should have an open line of communication with the PM, who can consolidate the information into a status update for all.

The length of the project guides the decision around the frequency of communication. In any project, short or prolonged, the communication should be scheduled and consistent. The team should be able to anticipate the communiqués. The basic status reports should follow a template and answer such questions as What was accomplished since the last report? What activities are currently planned? Are there issues or risks that need to be emphasized? The stakeholders will want information on the progress toward milestones, overall status, key issues, mitigation plans as necessary, and anticipated milestones.

Commonly, the status report will use red, yellow, and green highlights. Project tracking is ideally transparent.

Risk Management

There is no way to eliminate all risks, whether managing projects or walking across the street. However, risk can be identified, anticipated, and managed. The time-honored solutions entail less risk than innovative solutions. The new software has yet undiscovered idiosyncrasies compared to established software. Inexperienced staff, new hires, and new consultants involve more risk than known personnel. These may be excellent people and excellent software and risks well worth taking. Identifying the unknown can alleviate some of the possible perils. For example, mitigating the risk with new technology may involve allowing a longer timeline as a buffer for testing. Pairing the new consultant with a seasoned employee may create an amazing synergy.

During the planning phase, the project manager should identify hazards and ask questions. What could go wrong? What threats exist? What other initiatives may negatively impact this project. During the implementation phase, the PM should continue to review the project's progress, the issues that have developed, and continue to identify potential risks. A hazard is something that may cause harm. A risk is a hazard combined with exposure. For example, a shark in the ocean is a hazard. A risk would be swimming in that ocean.

The PM should analyze the risks. They will make sure stakeholders are aware of the risks going into the project. They will define milestones to measure the at-risk areas to recognize the second they become off track. Once the risks are acknowledged, each risk is assigned a probability and a severity score. This will allow for the prioritization and development of a strategy to avoid the risk. The ranking can be simple. For probability, is it likely to occur or not likely? A score of one to five is generally adequate and allows for a ranking of the risks. The severity score anticipates impact to the project should the risk occur. Thus, a severity score of five would describe a risk that would derail the schedule, budge,t, or deliverables. Combining the scores determines where the greatest potential for disaster lies. Risks with the highest scores (over seven) require a careful review and mitigation plan. The serious risks should be included in the status reports, so all decision-makers are familiar with the risks and possible consequences throughout the project's duration.

Resource Allocation

Human Resources

No project can begin without resources. The resources were enumerated in the business case. Often, human resources are the most difficult to secure, manage and afford. The team may be assembled with people from different departments and with different skills and skill levels. Rarely is a person completely devoted to one project. Thus competing priorities may have a bearing on the meeting schedule, the effectiveness of the meeting (if missing key decision-makers), and the estimated time to finish specific tasks. In a perfect world, the PM is aware of the individual's availability and manages this.

One of the chores completed during the planning phase is the estimation of time to complete each task. To make a realistic estimation, one must understand the complexity of the task, the skill of the team member assigned the task, and the attitude of that person. This can only be done by making rational assumptions about the availability and skillsets of the team members. These assumptions can positively or negatively influence the project's progress and success. The time estimates need not be done by the project manager alone. The opinion of people with the appropriate skills or knowledge, the subject matter experts, should be leveraged in making time estimates. These may or may not be the people completing the task.

Essentially, a project is a group of people completing tasks. To be a successful project, these people must function as a team with a common goal. Teams that work together are more likely to finish on time and budget, while dysfunctional teams are assured to fail. Katzenbach & Smith investigated what made some teams high performing and discovered that teams are not just groups working together but are grouped with individual and mutual accountability and discipline [21]. To achieve mutual accountability and discipline requires that the team help shape a common goal. The common goal or purpose should be tied to the organization's strategic objective.

The PM, to complete the project, is capable of managing and allocating resources. This presumes the PM has a working familiarity with the team member's skill set, availability, work ethics. The PM must also understand the culture of the organization. The expectation is that each individual completes their tasks on time and with superb quality.

This considers the competing priorities and the possibility that other activities will usurp this project's tasks. This is even more likely when the team member does not directly report to the project manager. Furthermore, the team member who is not well managed may have incomplete knowledge of the urgency of the job at hand and not prioritize your project. The PM will remind the team of their contribution to the overall project and be sure they are aware of the dependencies on their tasks and the urgency with which they must work.

Not uncommonly, projects are planned with specific participants in mind. However, these participants may not be available in sync with the project timing. A better approach is to characterize the skill set necessary for the project, not an individual.

The team must function as a team. Workstyle matters. For some tasks, analytic skills and attention to data might be necessary. For other tasks, clinical experience may be paramount. Yet other tasks may require respect and informal authority over others. Not all the required skills may be present at the project's outset, but some skills can be learned.

The human resource requirements may need modification. People may leave the organization, or become ill, or be pulled in another direction. More work may be identified, or the project may fall behind, necessitating the addition of new team members. However, a principle called "Brook's Law" states, "adding people to an already late project may only make it later" [22] Clearly, careful consideration is necessary before adding personnel. We have all experienced instances where having two people allows us to get something done twice as fast, and other cases where the additional person simply hinders progress. The Project Manager will weigh the potential benefit versus risk of expanding the team.

There are tools to help define the need for human resources. For example, project management tools such as Microsoft Project can help to define the amount of time an individual is working on a task (i.e., full time, 20 %, etc.). One method to estimate is to assume that a full-time resource will only dedicate thirty to thirty-five hours to a project, not a full forty hours, as they will still have other responsibilities. In addition, identifying holidays and time off at the beginning of a project can help correctly estimate resource time commitment to a project.

Non-human Resources

People alone will not complete the project. Also needed are resources-both financial and physical. There will be software needs, possibly construction needs, or hardware or devices. Workspace for the team members may be required. Virtual tools may also be needed. Team members may need to be granted access to new software, including project management tools or collaboration tools, such as Microsoft SharePoint, Teams, Dropbox, or Box. Before the project, the PM will have categorized and pinpointed these needs. Also, the PM will have made reasonable assumptions and estimates on the availability of these resources as part of the planning phase and identified in the business case.

Standard questions will help identify these non-human resources. Where will the teamwork be? How will the team share documents? How will the team share knowledge? Is the software currently available, or does it need to be purchased? Does the hardware to support the software already exist? What will the end-users need to utilize these tools (laptops, tablets, training)? Is the bandwidth adequate for storage and access? Is construction necessary for the new technology or staff? What other services might be required to support the project (contractors, training, technical writers)?

Not all of this information may be known during the business case planning. Adding time and tasks to identify the details and estimates on costs is necessary. Specific details can be added during the planning phase.

Financial Resources

Budgets are estimates of the costs and will need to be managed throughout the project duration. Labor costs, also known as the budgeted cost of work or planned value, are often the most difficult to manage and can quickly take a project beyond budget. The PM will be following resource hours and the time reported to the project. Most often, the ask is to track both consultant hours and also employee hours. While the PM is not usually responsible for actually contracting the consultants, they manage them as valuable assets. Owned resources should be expected to give the PM their reported work hours for the status reports. Consultants will report their billable hours, and the PM will need to review these and crosswalk with their budgeted hours and the progress toward milestones. Any actual or expected overages should be included in the project manager's status report to the sponsor and stakeholders. Any additions to the budget, human or non-human resources or durations, should follow the standard change management process and approval.

Informatics Project Challenges

Challenges exist. There will be issues, risks, and resources. There will be organizational attributes. External factors will impede progress. Scope creep must be restricted. Expectations must be managed. Competing priorities must be balanced.

The number of challenges an informatics project may face is countless; project managers must be prepared to handle any given situation and any given time by using standard methodology, status reports, and change control processes.

Unclear Requirements

Project managers confess that a top challenge is for a project is unclear requirements [23]. Communication is key, yet it may be tough for the stakeholder to unambiguously describe what they need. (Remember the swing.) The PM's skill set includes the ability to elicit clear requirements. This challenge can be diminished with clear documentation and communication. The assumptions, constraints, risks s, and goals should all be apparent to the stakeholders. The entire project team should provide their input to ensure a complete and comprehensive analysis of the requirements. Even with these precautions, it is possible to miss critical requirements. Every requirement absorbs some time, effort, and money. The stakeholders ought to be certain that only documented things will be done. If it is not documented, it will not happen. Pursuing work that is not part of the approved plan adds unnecessary time and cost and potentially introduces legal and contractual violations.

Even with specific and precise requirements, other challenges around work effort may still cause problems. Examples include as incorrect and insufficient work assignments or inaccurate cost and schedule estimations.

Obtaining the correct human resources on a project is crucial to success. These are the people that will be performing the majority of the work against the project scope and requirements.

Just as with any organization, however, challenges with individuals can cause problems on projects. This may include personality conflicts between team members, health issues, and general morale and motivation to get the job done. A good PM should monitor resources for issues in these areas and take appropriate action, including escalation to the individual's supervisor or removal from the project team.

Resource Allocation

Even with a careful selection of team members, they must have the right skills to accomplish their work. IT projects often involve the implementation of new software and hardware that may be unfamiliar to project staff. Thus, the PM should review skill sets during project planning and determine if training or subcontracting is necessary. If a project requires support from external resources (human or non-human) via a contract, this will introduce other challenges around procurement, communication, and conceivably legal matters.

Organizational Attributes

When analyzing potential risks and issues beyond the project itself, a project manager should be aware of organizational attributes that could impact the project. A seemingly simple change or upgrade to a single system may impact several others, and a project manager needs to consider those dependencies when planning a project. Dominoes are not just a game.

The PM will likely need to collaborate with other managers and system owners to define dependencies. Organizational attributes that impact a project include lack of support from upper management, conflicting business objectives and agendas, quality of available non-human resources, poor stakeholder management, and an insufficient infrastructure or working conditions.

External Challenges

The least predictable challenges are those which are external. These may include natural disasters, power outages, or pandemics. The project manager will identify backup plans or alternative plans. External challenges may stem from the local, state, or federal legislature. Legal and regulatory constraints often govern health IT solutions. Permits or registrations may be needed. The product itself may be subject to public policies. Regulations such as the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted as part of the American Recovery and Reinvestment Act of 2009, Centers for Medicare & Medicaid Services (CMS) regulations, and the twenty-first Century Cures Act may affect the project. While the software vendors are responsible for keeping their software compliant with government requirements, project managers must understand them.

Scope Creep

A very real and seemingly omnipresent challenge is that of scope creep. *Scope creep* refers to increasing work that was not defined in the original plan. Specifically, scope creep is the unauthorized addition of tasks, objectives, or requirements to a project plan [24]. Scope creep should be avoided and meticulously managed. However, it is a universal tendency to add to the initial project requirements, resulting in missing project timelines, going over budget, and not completing the initial project.

Once the project management plan has been finalized, the PM should not allow other work. In the, hopefully rare, occurrence where something must be added, it should occur only with careful consideration and escalation through the identified change control process.

Scope creep frequently occurs in small tweaks and alterations to the requirements. Again, the requirements must be crystal clear at the outset. A PM may consider allowing the work to proceed as a gesture of goodwill. However, the requests may increase in number and complexity. As the PM tries to stem the flow of unauthorized changes, it may be difficult. The stakeholder may have come to anticipate the work to continue without comprehending the negative impact of even small changes to the project as a whole.

Thus, good change control processes must be followed from the beginning of the project. This does not mean that absolutely no changes can be made; it does mean that changes require evaluation and approval. The initial communications include a description and understanding of the change control process.

Change control means that processes are developed and maintained to define each step required to perform an activity before that activity occurs. The primary purpose of change control is to gather data, define the need for a change, identify all impacted resources, timelines, systems, and other projects. The change should be proposed to the stakeholders, validated, and authorized. These items should all be documented in a change request form presented to an authorizing body for approval [25].

Managing Expectations

One of the best ways a project manager can manage expectations appropriately is by having frequent, clear, concise, and honest conversations with stakeholders. Any policies that the project manager will follow, particularly around change management, should be discussed early during the planning phase. Conversations around project assumptions, constraints, risks, and issues should be ongoing, with status reports to demonstrate that the PM is working on completing the objectives of the originally defined project.

Project managers need to be cautious in these communications. It may not be necessary for stakeholders to be aware of every issue on a project. Some stakeholders could become frustrated by a long list of problems. Some could lose confidence and withdraw support.

While it is important to convey the project's status, a PM should be judicial in determining the positive and negative items that are most likely going to impact the stakeholder.

Although the PM will make every effort to meet the needs of stakeholders, there is still a possibility that expectations will not be met. A PM must have appropriate soft skills to deal with these circumstances. It is quite possible that a project was completed successfully, meeting all objectives and requirements. However, stakeholders still feel that the project was a failure because the end product or service does not perform as well as expected, or user interfaces may not be as intuitive as hoped [26].

Not unlike parenting, it may be easy to become defensive. After all, the project was completed and met the stated requirements. However, being defensive is not going to appease an unhappy stakeholder. Here, the import of the decision tracker is evident. One can look back without revi-

sionist history. The reasons for decisions leading to the outcomes are documented and can be referenced.

The PM invokes compassion. A well-honed technique is using reflective listening skills—paraphrase issues back to the stakeholder, providing evidence that the situation was understood. Additional responses may include the offer to escalate the issue through his or her chain of command or providing alternative options. Potentially, the PM can point the stakeholder to a request for a separate project or changes to the existing system through the organization's configuration management practices. Many times, a simple apology without accepting blame is sufficient. The PM should assure the stakeholder that the issue will be documented as part of lessons learned to help reduce the possibility of future occurrences.

Balancing Competing Priorities

No project occurs in isolation. Every PM needs to balance competing priorities. The first step is to recognize the priorities and then strategize an approach to manage them—appreciating where the competition lies assists in developing a strategy. For example, if a key team member is overbooked, the PM should determine what timelines could or should be altered without disrupting the entire project timeline. Perhaps the task can be completed asynchronously. Alternatively, the task may be reassigned. If the conflict is unavoidable, the decision must be made on which priority goes first.

Determining priorities can be determined by assigning a matrix across projects and by communicating with other project teams. The projects and operational work may be divided into categories such as urgent and important, not urgent but important, important but not urgent, and neither urgent nor important. These categories shed light on where the different projects fall.

Emerging Trends

The healthcare environment, already complex, continues to evolve in challenges and convolutions. Organizations, by necessity, are implementing more innovations and stretching their geographic reach.

Ongoing trends include compressed project work cycles and cloud-based collaboration tools. The emphasis on remote work has increased. With remote work, the challenge of keeping everyone engaged increases. Additionally, tweaks to meeting schedules may be essential as people reside and work from different time zones. Different collaboration tools are continuously being developed, each with benefits and each with disadvantages [27].

Communication tools have multiplied. The varied communication tools must be folded into the communication plan, including texting apps, email, and shared document repositories. There should be guidelines for what is appropriate and when each method of communication will be used. Regardless of which platform is used, ensure the basics. Namely, each team member has access to the tools they need to effectively communicate with the team and that the team has access to documents generated for and by the team.

Project Management Skills

As mentioned previously, the clinical informaticist may have many of the skills inherent in a PM. As project management changes, the skill set will evolve as well. The PM must have a good knowledge of the tools available to them. They must be detailed oriented and compulsive in their documentation. They must have soft skills, which may become even more crucial with the emerging complexity of work done and the social impact of working remotely. Their communication styles must be modified to fit the communication tools employed. They will find themselves as coaches, mentors, and motivators. The leadership skills necessary to manage a project are paramount.

Summary

Nothing remains static. This is even more true in the healthcare arena. Project management may seem simple when dissected down to the basics. Indeed, excellent project management necessitates breaking complex matters into smaller matters. Put together, like a beautiful mosaic; individual tasks coalesce into a successful masterpiece. However, recognizing individual tasks without skipping the mundane is a talent that can be practiced and refined. The capacity to recognize real and potential risks is crucial to avoiding project catastrophes.

The PM is patient. They are competent at defining the work to be done and documentation. Moreover, they understand people, work habits, personalities, and time constraints.

In project management, each step has express activities and deliverables. These can be learned and followed to optimize the change the project succeeds.

Clinical informaticists can expect to be tagged with many roles during a project. They may be a team member, a sponsor, a subject matter expert, or an end-user. Some, even those who do not yet have experience, may find themselves asked to be a project managers. They certainly will be involved with communicating with clinicians. Each of these roles

within a project has characteristics and functions that the informaticist should understand.

Questions for Discussion

1. Have you been involved in a project that ultimately failed? Can you articulate reasons for the failure?
2. What are characteristics of a project manager that you found effective?
3. How many current projects can you name at your organization? What challenges do these projects face?
4. What are common external challenges to projects in your organization?
5. Can you outline the salient features of an excellent project charter?
6. How does your organization communicate with project team members? With stakeholders?
7. What common project management tools have you used? Did you find them effective?
8. Can you site examples of a project that struggled with scope creep?
9. Can you articulate the benefits of systematic, stylized project management?
10. How do you foresee the future of project management?

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Part V

Beyond Clinical Informatics

Consumer Health Informatics: Engaging and Empowering Patients and Families

24

Deepti Pandita

Learning Objectives
At the end of this chapter, the reader should be able to:

- Identify how patient empowerment via Consumer Health Informatics solutions drives healthcare outcomes
- Identify strategies for adoption and implementation of solutions that engage consumers in Healthcare and methods to measure success
- Guide design, process, implement solutions that maximize the effectiveness of Electronic Health Information for Consumers
- Examine emerging trends and strategies that are driving the rapid adoption of Consumer Health Informatics

Practice Domains: Tasks, Knowledge, & Skills
The following domains and core competencies are covered in this chapter:

Domain 2: Improving Care Delivery and Outcomes

- K048. Use of Patient-Generated Data

Domain 3: Enterprise Information Systems

- K069. Consumer-facing health informatics applications (e.g., patient portals, mobile health apps, and devices, disease management, patient education, behavior modification)
- K084. Non-regulated medical devices (e.g., consumer devices)

Key Terms Explained
Blue Button: The Blue Button represents a national movement that enables consumers to have easy access to their own health information in a format that they can use. The Blue Button logo signifies that a consumer can download a single electronic file that contains their available health data.

Computer Literacy (also called **Digital Literacy**): the range of skills and level of familiarity and comfort that a person has with using computers and computer applications.

Consumer Engagement: motivating and activating consumers to increase their knowledge, skills, and confidence to manage their health and health care.

Consumer Empowerment: empowering consumers to manage their health care and advocate for themselves using healthcare services.

eHealth: a field of research and practice focused on using information and communication technologies to improve health care.

Health Information Technology (HIT): the area of Information Technology involving the design, development, creation, use, and maintenance of information systems for the healthcare industry.

Health literacy is the degree to which individuals can obtain, process, and understand basic health information needed to make appropriate health decisions and services to prevent or treat illness.

Information and Communication Technologies (ICT): an overarching term used to refer to technology that supports communication and/or the gathering, sharing, and using information.

Open Notes: a national initiative in the United States to give patients easier access to the clinical notes written by their healthcare providers and other healthcare professionals.

Patient-Centered Care: an approach to healthcare where the locus of control and decision-making is centered upon the patient and aligned with their individual needs and preferences.

Patient-Generated Data: health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern, including health history, treatment history, biometric data, patient entered questionnaires via the EHR patient portals,

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symptoms, lifestyle choices, patient owned device-generated health data, etc.

Patient Portal: a secure online website or web application that gives patients convenient 24-h access to personal health information from anywhere with an Internet connection to enable them to interact with their medical information via the Internet, usually connected to their Healthcare systems EHR.

Personal Health Information Management: the activities that support individuals' access, organization, and use of the information pertaining to their own health.

Personal Health Record (PHR): a private, secure application through which an individual may access, manage, and share their health information, including information entered by the consumer and/or data from other sources such as pharmacies, labs, and healthcare providers.

Secure Electronic Messaging: the ability for patients to send and receive asynchronous, secure electronic messages with their healthcare providers (i.e., secure email, secure messaging).

Sociotechnical Perspective: To fully understand information and communication technologies, it is necessary to examine the interrelation between technology and its social environment.

Information blocking: Information blocking is a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI).

Case Vignette

Mary Smith is a 72-year-old widow who lives independently with help from her daughter who lives nearby and her son, who resides far away. She typically sees her primary care doctor about three times per year to monitor her high blood pressure, osteoarthritis, and history of skin cancer. She has a basic cell phone and uses her laptop to email and see photos from her family. Her son helps to manage her care as a delegate user of her clinic's patient portal. He can view information from her medical record, including visit notes, test results, and medications.

After Mary confided in her son about having several weeks of fatigue, he logged into her health system's portal using his proxy (delegate) access to view available appointments. He saw via the portal that the care system offered in-person and virtual visit options for patients; he chose the in-person option. Unable to see her usual doctor for two weeks, he scheduled an appointment to see another doctor in the clinic the next day. Still concerned, that night, he logged into the portal and read over the visit notes and test results for the past few years. Upon noticing an abnormal hemoglobin result from one year ago, he searched the portal's education library to learn about low hemoglobin and fatigue. He sent a secure electronic message to his mother's healthcare team through the portal, asking about the low hemoglobin test results and possible causes of her low iron. Could this be causing her fatigue? He then called his sister, who was planning to drive their mom to the clinic for her appointment, letting her know about the information. The following morning, the triage nurse at the clinic read the secure message from Mrs. Smith's son, who also mentioned that she had an appointment but would not be seeing her usual doctor. The nurse confirmed the prior test result and alerted the healthcare team taking care of Mary, and she messaged her usual primary care doctor. The care team pre-ordered some labs that they could review at the visit. When Mary arrived, the doctor already knew about her issues and her son's concerns. Additional history, exam, and testing that day revealed iron deficiency in the context of a change in bowel habits. Mary was referred to a specialist and scheduled for a colonoscopy the following week.

Introduction

Several powerful forces are transforming the role of the contemporary healthcare consumer and creating new opportunities to improve patient care. Technological advances, coupled with a shift toward patient-centered care and unprecedented consumer access to information [1], have created a new era of consumer engagement, empowerment, and activation. This transformation has striking implications and opportunities for all those engaged in delivering and receiving health care—patients, providers, purchasers, payers, and public health institutions. It is also directly shaping the work of clinical informaticians, including the emergence and evolution of the interdisciplinary field of Consumer Health Informatics. Coupled with this is the consumer expectation of getting care where they want it and in a manner they deem appropriate, which is increasingly evident given the rapid adoption of both synchronous and asynchronous telehealth [2].

Consumer Health Informatics is a critical biomedical informatics domain, focusing on informatics from consumer or patient perspectives [3]. Drawing on multiple disciplines, Consumer Health Informatics emphasizes information structures and processes that augment the capacity of consumers to manage their health and enable them to collaborate with healthcare professionals for their care, according to their needs and preferences. Clinical informaticians must apply knowledge in the field of personal health as well as procedural knowledge and skills to effectively design, develop, and evaluate systems approaches to improve consumer health and management of their conditions [4, 5]. Recognizing

that patients are consumers of healthcare services and that consumers will inevitably assume the role of "patient" in some form and degree across the course of their lives, we use the terms "consumer" and "patient" interchangeably. We also emphasize that family members and informal caregivers are crucial resources for patients and are often integrally involved in their support and care.

Historically, the social context of medicine was characterized by professional dominance and authority [6]. By the 1970s, American healthcare's economic and moral problems were drawing public attention, including an increased focus on the imbalance of power in the structuring of medicine, the dynamics of the physician-patient relationship, and patient rights [7]. With the emergence of managed care in the 1980s, the notion of patients as "consumers" of healthcare services emphasized the importance of patients engaging in shared decision-making [8]. The paradigmatic shift towards more "patient-centered" care [9, 10] also set the stage for the emergence of a new era of consumer empowerment [11, 12]. This is now further strengthened with the emergence of Value-Based Care and Accountable Care organizations. The total cost of care can be lowered by engaging the Patients to meet their needs rather than the traditional face-to-face clinic visit constraint [13].

As these developments in health care continued to unfold, the evolution of the Internet and other advances in information technology in the late 1990s enabled unprecedented consumer access to information and new forms of communication. Information technology was seen to play a central role in improving healthcare delivery, and clinicians and scholars began to refer to a new field of "eHealth," which was focused on the use of information and communication technologies (ICTs) to improve health care [14–16]. Eysenbach defined the emerging field of health care informatics as 'the branch of medical informatics that analyses consumers' needs for information; studies and implements methods of making information accessible to consumers; and models and integrates consumers' preferences into medical information systems (17, p. 1713). Noting the shifting focus of traditional medical informatics, consumer informatics 'stands at the crossroads of other disciplines, such as nursing informatics, public health, health promotion, health education, library science, and communication science' (17, p. 1715), paving the way for 'health care in the information age.'

In its landmark report *Crossing the Quality Chasm*, the Institute of Medicine proposed six guiding aims to redesign health care for the twenty-first century: providing safe, effective, patient-centered, timely, efficient, and equitable health care [18]. Inherent in these aims was a new approach to health care design, including fostering continuous healing relationships between patients and providers and providing tools to help patients become more active participants in their care. A decade later, significant progress has been made, yet much is still to be accomplished. ICTs have an instrumental role to play in advancing this transformation. The use of web-enabled electronic health information systems such as personal health records (PHRs), patient portals, and other technology-supported tools offers promising potential, yet realizing anticipated benefits will require strong collaboration between the science of informatics and the art of medicine.

This chapter examines the fundamentals of Consumer Health Informatics from a sociotechnical perspective, emphasizing that the field pivots on the information structures and communication pathways that arise from the interactions between people, processes, and technology. Next, we describe the major drivers of Consumer Health Informatics, along with factors that influence consumer adoption and use of ICTs, and key elements and strategies associated with implementation. Finally, we provide an overview of the evidence in the literature and methods for assessing impact, concluding with a brief discussion of emerging trends.

A Sociotechnical Perspective of Consumer Health Informatics

Similar to the broader field of clinical informatics, Consumer Health Informatics has come to embrace that a wide range of factors at different ecological levels (e.g., the individual, interpersonal, organizational, and community) can influence the adoption and use of ICTs. Perspectives that once focused narrowly on technology alone have given way to more encompassing approaches to understanding how consumers and technology interact and the kinds of impacts they can have on one another. The term "sociotechnical" is commonly used to express that to understand ICTs fully; it is necessary to examine the interrelation between technology and the social environment [19]. Applied to Consumer Health Informatics, a sociotechnical perspective emphasizes that consumers, as well as ICTs designed for use by consumers, are products of the social, organizational, and cultural contexts in which they are situated; and that efforts to study the relationships between consumers and ICTs must foreground these contextual forces.

Proponents of the sociotechnical perspective have argued that healthcare delivery settings are high-pressure, fast-paced, distributed, and uncertain; and, as such, are best characterized as complex, adaptive systems [20]. Table 24.1 presents a series of eight dimensions that proponents argue are critical to understanding the design, implementation, and evaluation of ICTs in health care [20]. As suggested by Table 24.1, in such complex contexts, interactions among people, processes, and technologies create powerful forces that affect consumer adoption and the use of ICTs. This sec-

Table 24.1 Sociotechnical Dimensions for Understanding ICTs in Healthcare Settings [19]

Dimension	Description
Hardware and Software Computing Infrastructure	Technical dimension composed of physical devices and software
Clinical Content	All data, information, and knowledge stored in a system
Human Computer Interface	Aspects of a system that support interaction
People	Those individuals involved in the design, development, implementation, and use of the technology
Workflow and Communication	Tasks necessary to ensure that patients receive the appropriate care and services
Internal Organizational Policies, Procedures, and Culture	Structures, policies, and procedures of an organization that influence all other dimensions
External Rules, Regulations, and Pressures	Forces outside an organization that facilitate or impede efforts to design, implement, use, and evaluate technology
System Measurement and Monitoring	Includes system availability, its use by stakeholders, its effectiveness, and associated unintended consequences

tion examines the people, processes, and technologies that focus on much of the contemporary work in Consumer Health Informatics.

Patient-Focused Informatics Solutions

Managing health using information has long been understood as an important resource for individuals confronted with a health condition. Social scientists argue that information can lessen a person's fears and misunderstandings, help them develop practical coping strategies, and effectively manage treatments [21]. Just as important, clinicians should appreciate that the many health-related processes consumers engage in involve interaction with and use or exchange of information. We briefly describe the most salient of these processes below.

Seeking and Managing Personal Health Information

There is substantial literature spanning psychology, sociology, and the information and communication sciences regarding consumer health information-seeking behavior. Much of this research follows the premise that individuals respond by gathering and using information when confronted with information needs about their health. In the process, they may consult preferred information sources, avoid unwanted information, and negotiate various factors that can facilitate or impede their efforts. While a certain amount of consumer health information seeking is accurately characterized in this manner, some scholars have commented on the limitations that accompany such an individualistic view [21]. Overlooked is the considerable evidence that health information seeking is also often collaborative.

In many cases, individuals seek health information for themselves and others—an activity sometimes referred to as surrogate seeking [22]. Balancing both an individualistic and more socially-oriented view of health information seeking is important as the field of Consumer Health Informatics advances. Similarly, personal health information management refers to the activities that support individuals' access, organization, and use of the information pertaining to their own health [23, 24]. Sharing or "exchanging" information to support health-related tasks is an important aspect of personal health information management that commonly involves an individual's informal caregivers and their healthcare providers. Research has shown that health information is often gathered and organized with sharing in mind. That information sharing is performed through various means, including both paper-based and electronic systems [25]. As indicated elsewhere in this section, seeking and sharing health information are also important to consumer education initiatives and realizing shared-decision making in practice.

Self-Management

As chronic conditions have become more prevalent in the population, there has been increasing recognition of the shortcomings associated with models of care. Healthcare providers take responsibility for treatment decisions based on their clinical expertise, and patients are expected to adhere to designated management plans [26, 27]. While perhaps fitting for acute conditions where treatment is mostly confined to medical settings, such models do not accurately represent consumers' experiences faced with conditions where the majority of management happens in daily life. As expressed in the trajectory concept, the onset of chronic health conditions can introduce complex treatment plans, emotional turmoil, and social repercussions for patients and their informal caregivers.

In the most fundamental sense, self-management refers to a patient's participation in managing their own health and has been framed as an alternative to more established, provider-driven models of care [27, 28]. It foregrounds a patient's expertise, circumstances, and responsibility. The concept of self-management also accounts for the point that to effectively manage their health; patients require a repertoire of skills and accompanying resources, including problem-solving, decision-making, help-seeking, action-taking, and establishing supportive relationships with healthcare providers and other stakeholders [29]. Consumer Health Informatics applications can facilitate consumer education

regarding self-management skills and resources and enable effective communication between patients and providers. As part of a personal health maintenance model, ICTs can also augment the ability of patients to perform common self-management tasks by enabling access to high-quality information, providing decision support tools, offering accessible and convenient options for interactions with the healthcare system, and creating a comprehensive longitudinal Electronic Health Record (EHR) that also includes patient-supplied information through multiple means including patient managed device interfacing to the EHR.

Changing Health Behavior

The everyday behaviors in which consumers engage have direct implications for their health. Regardless of whether they are healthy or living with a health condition, it is often possible for consumers to improve their well-being through health promotion behaviors or more effective condition management activities. Health behavior change refers to the processes and intervening factors involved in reducing or eliminating unhealthy behaviors and adopting and maintaining healthy ones. The importance of health behavior change as a field has grown in conjunction with alternative models of care, including self-management and patient-centered care. Changing any behavior can be challenging, and there are various behavior change principles and theories available to inform the design, implementation, and evaluation of behavior change interventions [30]. As described below, ICTs, including PHRs, secure electronic messaging systems, and other networked tools, can be used as platforms on which to deliver behavior change interventions to consumers and to help them integrate changes into their daily lives.

Communicating with Others

Communication processes have been called "a link between personal, social, cultural, and institutional factors and various facets of health and illness" [31]. Health communication refers to the study and use of communication strategies to inform and influence individual and community decisions that enhance health [32, 33]. As described in the landmark *Healthy People 2010* report [34], effective communication is critical across healthcare contexts and can support all aspects of disease prevention and health promotion.

Clinical informaticians must appreciate that consumers are members of communities and social networks comprised of family members, friends, peers, and others. Beliefs about health are shared, and information is exchanged. Communication about health also transpires through many channels, and regardless of the channel, ICTs are changing the consumer's experience of that communication. More so than ever before, consumers have access to information from sources representing different perspectives and content that reflects individual situations and preferences. The emerging patient-centered care paradigm has also focused attention on patient-centered communication. Patient-centered communication is a crucial component of the delivery of patient-centered care. It aims to strengthen patient-provider partnerships by focusing on patients' perspectives, needs, and values, providing patients with the information needed to participate in care to the extent that they desire, and building a shared understanding of health conditions and treatments [35, 36]. Patient-centered communication is continually influenced by overlapping factors about the patient, the health system, relationships among stakeholders, and the availability of resources—including ICTs—to support its realization in practice.

Coordinating Care

The Institute of Medicine [18] described coordination across patient conditions, services, and settings as one of the most formidable challenges facing our nation's healthcare system. It included care coordination as one of 20 national priorities to improve healthcare quality [37]. The growing prevalence of multi-morbid, chronic conditions among consumers, coupled with increasing clinical specialization and fragmentation of services across settings and time, has only exacerbated this issue in recent years. Care coordination has been defined as the deliberate organization of patient care activities among stakeholders to facilitate the appropriate delivery and receipt of healthcare services [38]. Integral to this organization of activities is effective sharing of health information across settings (e.g., clinic to clinic; home to the clinic) and stakeholders (e.g., patients, informal caregivers, primary care providers, subspecialist providers, etc.).

Patients and their informal caregivers have long had a recognized role to play in the process of coordinating care, for example, updating a primary care provider on events that have transpired since a previous visit or delivering test results to specialist consultation. Still, effective sharing of information among patients, informal caregivers, and their various healthcare providers is often limited at best, increasing the potential for adverse outcomes and increased costs [39, 40]. What has changed in recent years is the range of ICTs and other tools available to support patients and informal caregivers in their efforts to access information about their care, capture that information in formats that are readily usable (and reusable), and share it conveniently with others. As we describe further in the Emerging Trends section of this chapter, some of the most influential developments in consumer-mediated information exchange include tools like Blue

Button and the OpenNotes movement [41]. As argued by the IOM [18], when thoughtfully and effectively implemented, such tools can reduce the need to develop laborious, case-by-case strategies for coordinating patient care.

Technologies: A Rapidly Changing Landscape

The design, implementation, and use of ICTs to improve consumer health and support the kinds of health-related processes just described is a defining feature of Consumer Health Informatics, the eHealth movement, and related efforts to engage patients and informal caregivers in their own care. Functional groupings of consumer ICTs intended to conceptualize the kinds of services that will become increasingly available to patients in the future have been articulated in the literature and emphasize the ability to conduct healthcare system transactions, access expert care, and support self-care and community [42]. This section briefly describes some of the major representative technologies at the core of such functional groupings, with the caveat that the technologies themselves continue to evolve rapidly.

Personal Health Records (PHRs)

The joint PHR Task Force of the Medical Library Association and the National Library of Medicine [43] offered a thorough definition of the electronic PHR, stating that it is:

> A private, secure application through which an individual may access, manage, and share their health information. The PHR can include information entered by the consumer and/or data from other sources such as pharmacies, labs, and health care providers. The PHR may or may not include information from the electronic health record (EHR) maintained by the health care provider and is not synonymous with the EHR. PHR sponsors include vendors who may or may not charge a fee, health care organizations such as hospitals, health insurance companies, or employers.

The concept of a PHR is not new; patients and their informal caregivers have always used paper-based systems—lists, diaries, calendars, and other memos—to track symptoms, medical history, medications, appointments, and other noteworthy health events. Although functions and features vary across systems, most PHRs share a fundamental goal—"to give patients better access to their own healthcare data and enable them to be stewards of their own information" [44]. Many early electronic PHRs were stand-alone tools untied from specific healthcare systems and into which consumers could self-enter their personal health information. These "static-repositories" [45] have since given way to web-based PHRs and mobile applications that are linked or tethered to specific healthcare syetems (e.g., an electronic health record) and offer a range of associated functionality [46, 47]. Examples of PHR features supporting various health-related tasks and activities are shown in Table 24.2.

Table 24.2 Tasks and supporting PHR examples

Health-related tasks	Examples of supporting PHR features
Accessing and sharing personal health information	Blue Button, OpenNotes, consumer mediated health information exchange
Educating one's self about their health and making informed decisions	Consumer-oriented online health education libraries, personalized education, decision support tools
Tracking personal health information	Apps, Journals, logs, diaries, Devices etc.
Managing medications	Online prescription refills, medication lists, medication reconciliation tools
Managing appointments	Appointment views, appointment reminders, appointment scheduling capabilities
Communicating with stakeholders	Secure messaging
Changing health-related behaviors	Reminder tools, health assessments, motivational tools, web-based interventions
Coordinating care across providers and systems	Consumer mediated health information exchange

Patient Portals and Shared Access to Electronic Health Records

The tethered PHR model requires that consumers have a secure, Internet, or web-based location where they can access the personal health information available to them from the supporting healthcare system and access other functions. This is commonly referred to as a **patient portal**. In recent years, many patient portals have advanced, from offering consumers a means to view select portions of the EHR to providing collections of tools that support transactions, information tracking, and communication with clinical team members [43].

Some portals may also have a means by which consumers can identify a proxy or set of proxy users, delegate access to their personal health information, and use portal features on their behalf. Supporting delegation and proxy use embraces the collaborative nature of consumer health information seeking and personal health information management and also aligns with the tenants of alternative care models described earlier, including self-management and patient-centered care. It is important to note that many patient portals are tethered to one healthcare system, which often limits the ability for consumers to connect, share, and exchange data with other healthcare systems.

Moving forward, the next generation of PHRs and patient portals will likely support consumer access to personal health information that is dispersed across multiple healthcare systems and aggregate that information to create a more comprehensive record of their health [43]. Networked PHRs of this kind inherently require interoperability across systems. They have profound implications for consumer efforts to coordinate the care that they receive in different settings, along with the associated transactions.

Secure Electronic Communication between Patients and Healthcare Providers

One common function supported by many tethered PHRs is the ability for patients to send and receive asynchronous, secure electronic messages with their healthcare providers. In many cases, patients and healthcare providers exchange messages automatically become part of the healthcare system's EHR. In addition to serving as a convenient, protected channel for non-urgent communication [48–50], secure electronic messaging also can strengthen patient/provider relationships [49, 51, 52]. The sense of "digital anonymity" that accompanies the exchange of electronic messages can empower patients to broach topics that they might not feel comfortable discussing in the course of a face-to-face clinical visit. In addition, whereas patient recall of verbal communications tends to deteriorate over time, patients can access and review secure messages from their healthcare providers at any time.

Having such information "at the ready" can facilitate the comprehension and recall of care plans, medication instructions, and other complex information. If used effectively, secure messaging also has the potential to realize the principles of patient-centered care by fostering a focus on the patient-as-person and promoting shared power through improved access to information and communication, shared decision-making, and ongoing support.

Sharing and Integration of Patient-Generated Data

As noted above, many PHRs provide patients with the ability to self-enter various kinds of information about their health, for example, personal and family medical history, use of alternative treatments, and details about dietary habits, exercise routines, and measurements like weight and blood pressure. This **patient-generated data** can be a valuable complement to information included in a healthcare system's EHR—potentially clarifying, expanding upon, or filling in gaps in the medical record.

As patient-generated data continues to accumulate, there are important questions about how best to use it in the course of clinical practice and how best to store and integrate it with information from other sources, principally, the EHR [53]. These are questions that the field of Consumer Health Informatics will have to address moving forward. Clinical informaticians will play a key role in collaborating with clinical experts and patients to define optimal solutions.

Internet or Web-Based Interventions

With the increasing availability of Internet access and its capacity to deliver content and functions in engaging and understandable ways, many clinicians and scientists have turned to the Internet or **web-based interventions** to promote health and support the management of health conditions. These have been described as self-guided interventions executed through prescriptive online programs comprised of quality health materials and interactive components and used by consumers seeking health-related assistance [54].

Whether they were developed specifically for a web environment or based on previous interventions originally offered through a different channel (e.g., in-person), web-based interventions are intended to promote awareness and understanding of one's health and support desirable health behaviors. They have been implemented in various contexts, including chronic disease self-management, mental health, and substance use.

Three broad types of web-based interventions have been described in the literature:

1. Web-based education interventions designed to support consumer access to information about a specific aspect of health (e.g., an online self-management tutorial for those recently diagnosed with a chronic disease);
2. Self-guided web-based therapeutic interventions designed to create desirable change in consumer thoughts, behaviors, or emotions (e.g., an online self-management skills-building program comprised of educational information, interactive skill-building activities, and automated feedback); and
3. Human-supported web-based therapeutic interventions designed to create desirable change in consumers and involving a person to offer support, guidance, or feedback (e.g., the aforementioned online self-management skills-building program augmented with feedback from a peer or professional) [55].

Although adherence to their content can be challenging [55, 56], previous analyses have revealed improved outcomes for individuals using web-based interventions to achieve desired knowledge or health behaviors compared to non-web-based

interventions [57]. More so than interventions delivered through other channels, web-based interventions can reach large numbers of consumers and can be used at the time, place, and pace most suitable for the individual.

Consumers' experiences, the healthcare processes in which they engage, and the technologies they use to support those processes will continue to evolve with changes in healthcare and advances in technology. As previously emphasized, clinical informaticists have an important responsibility to foreground the interactions among these elements and understand the forces that influence those interactions. These drivers are the subject of the next section.

Major Drivers and Trends in Consumer Health Informatics

As described at the outset, there has been a fundamental sea change in how consumers use technology. Along with dramatic increases in access to and overall use of the Internet and digital technologies, a societal consumer expectation that online services will be commonplace—at work, at home, and throughout their daily lives. Such anticipation exists for health care as well. While healthcare systems have invested substantially in computerized systems and other technologies for healthcare professionals, they have continued to lag behind other businesses like banks, airlines, and retail companies to fully leverage the power of computers and networks for consumers to connect remotely and interact seamlessly. Still, remarkable strides have been made to provide patients and caregivers with electronic information and services. This section explores current drivers of Consumer Health Informatics, including current trends in technology availability and use, increased focus on consumer information needs, consumer desire for engagement, meaningful use of health information technology (HIT), and continued pressure to control mounting health care costs.

Increased Availability and Use of Technology

A major stimulus for consumer adoption and use of technology-enabled tools and services (ICTs) has been growing public engagement with technology. Pew Research Center's Internet & American Life Project continues to serve as a rich source of data on consumer perspectives and behavior [58]. Nationally, 87% of American adults now use the Internet, reflecting a rapid rise over the past decade [59]. While Internet use remains generally lower among individuals age sixty-five and older or with a lower level of education, rates of use continue to rise within these subgroups.

As younger cohorts get older, the 'digital divide' is expected to narrow substantially. More than nine out of ten teenagers use the Internet regularly, including those who reside in households with lower incomes. Factors playing a role in increased Internet adoption include the geographic expansion of broadband and mobile device availability and usage changes. Desktop and laptop computers are giving way to greater use of mobile devices. Presently, 91% of adults own cell phones, and more than half are smartphones (see Fig. 24.1). As people transition from accessing the Internet intermittently to carrying a personal 'always on' portable device, online activity continues to soar.

Consumer Information Needs and Desire for Engagement

Consumer need for health information and a growing desire to engage in shared decision-making have also helped drive the evolution of consumer ICTs. Patients and families have always sought answers to their health issues. The exponential growth of readily available information, previously inaccessible before the Internet, offers consumers the promise of greater control of their health and greater participation in healthcare decisions. Fully 60% of adults report searching online for health information on a range of health topics, and 35% attempt to diagnose a problem they experience or search on behalf of someone else [61]. Today, many consumers are active in gathering and sharing health-related information, both online and offline, to be informed and participate more fully in decisions about their care. Caregivers, in particular, take part in a wide range of online health-related activities.

Patients and caregivers are also highly interested in using various tools to participate in their health and their health care, such as virtual visits, home health monitoring, and online communication with providers and patient communities [61]. Health care has been slow to embrace such technologies fully, but this is changing.

Pioneers, such as Dr. Tom Ferguson, characterized traditional care as "industrial age" medicine that did not assist patients with self-management [62, 63]. Believing such care to be expensive and inefficient, he advocated for health care to empower consumers, including developing computer systems specifically designed for their use. He and his contemporaries coined the term **e-patients** to describe individuals who are equipped, enabled, empowered, and engaged in their health and care decisions [64]. Interestingly, e-Patients report two effects of their online health research—'better health information and services and different (but not always better) relationships with their doctors' [64]. These activated patients can improve their self-rated health status, cope with fatigue and other generic features of chronic disease such as role limitation, and reduce disability and dependence on hospital care [65].

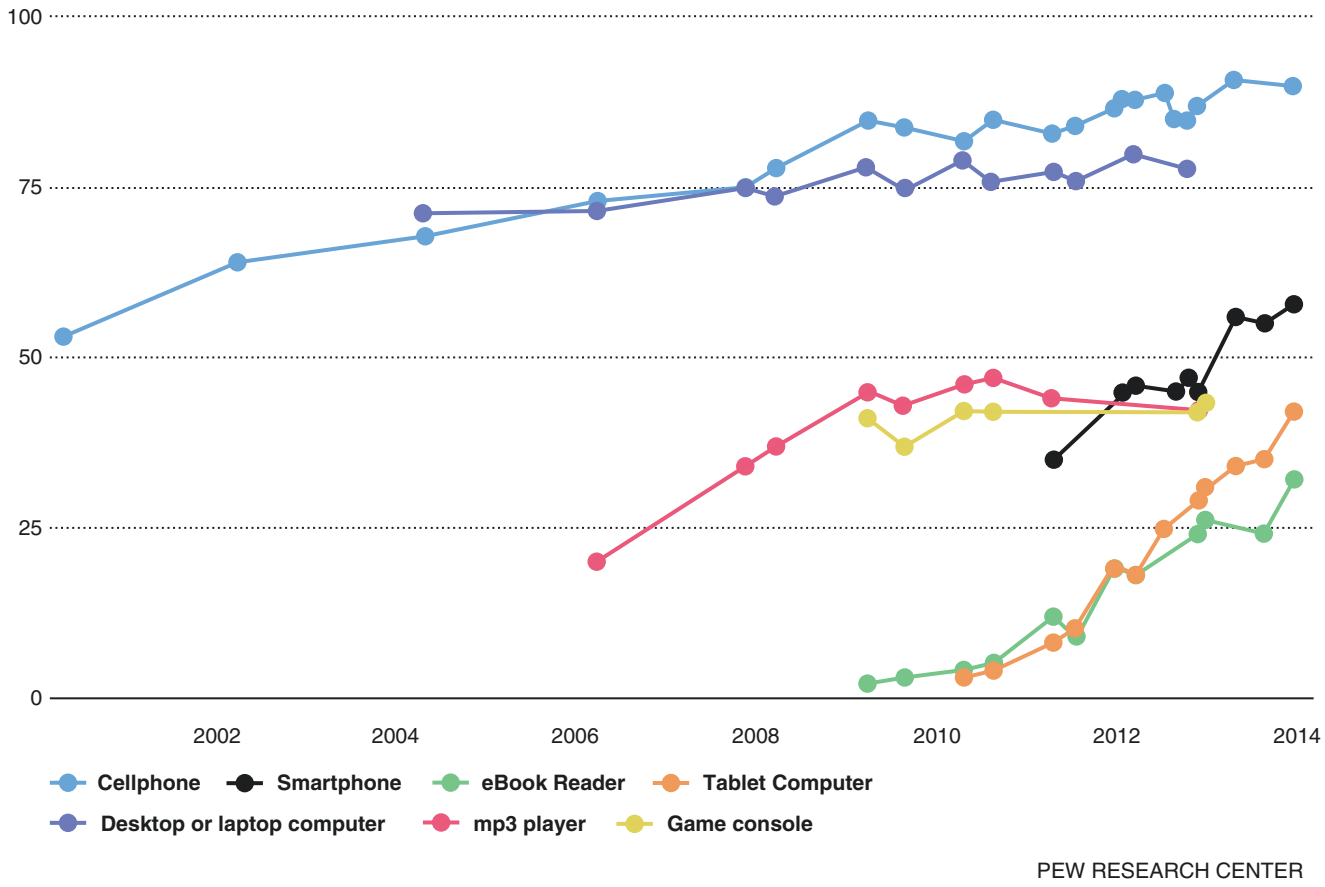

Fig. 24.1 Device ownership over time (Reproduced from Ref. [60] with permission from Pew Research Center)

Financial Incentives

An equally important factor currently driving Consumer Health Informatics is the transformation happening inside the medical community. As noted at the beginning, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 accelerated the investment in and use of EHRs to improve care and enhance patient outcomes [66]. The $30 billion program, regulated by the National Coordinator for Health Information Technology and administered by the Center for Medicare & Medicaid Services, authorizes financial incentive payments and penalties based on compliance with criteria for Meaningful Use [67]. Practices and providers across the nation are incentivized to deliver functions that demonstrate the meaningful use of HIT to improve the quality of care while reducing costs.

At the same time, many of these measures focus on how electronic records are used within health systems, several calls for HIT functions that directly impact patients. Meaningful Use Stage 2 criteria include providing patients with (1) the ability to view online, download, and transmit their personal health information; (2) timely access to clinical summaries for each visit; (3) secure electronic messaging to communicate with clinicians for health issues; (4) patient-specific educational resources. To receive incentive payments and avoid penalties, eligible professionals and systems must follow a specific set of criteria for each measure.

Impact of Major Drivers

Taken together, EHRs with integrated patient online services are foundational tools that can help meet the needs of consumers to access and aggregate their own health information and to access their healthcare providers remotely [44]. While shared health data and secure electronic messaging can enhance patient experience and health outcomes [52, 68], these tools also have significant ramifications for healthcare teams. Providers express concerns about patients finding poor quality information on the Internet, risks arising from patients reading clinical notes and test results without accompanying interpretation, and workflow challenges with secure electronic messaging. Yet national surveys demonstrate that consumers still perceive health professionals as the most trusted source of health information [68, 69]. Further, providers who encourage patient self-management and shared

decision-making report having more engaged patients and improved patient-provider relationships [70].

Finally, consumer-facing ICTs are increasingly seen as mechanisms to deliver new care models, achieve greater efficiency, and reduce healthcare costs. As a result, many industry vendors are advancing consumer health technology development. Health systems, insurers, and payers increasingly cite remote encounters and patient self-monitoring as important strategic ventures with the potential for clinical and financial benefits. However, consistent, high-quality data reporting evidence of such tools to achieve desired outcomes is still needed [71]. As these drivers continue to foster and shape changes in health care, clinical informaticists will play a critical role in addressing both opportunities and related challenges.

The twenty-first Century Cures Act included rules on **information blocking** and potential penalties for failing to share information with patients with a few exceptions. The impact of this legislation will also be a major driver for rapid two-way sharing of information with consumers [72, 73].

Major Factors Influencing Adoption and Use

Despite the influence of major drivers and the increasing availability of various consumer ICTs, most of these technologies have not yet been fully integrated into usual care across large populations. Moreover, while consumers continue to express high interest in eHealth tools and services, with some notable exceptions, adoption on average remains relatively low [74, 75]. This section discusses some of the major factors that influence the adoption and use of consumer ICTs. In keeping with our emphasis on the sociotechnical perspective, we include both social and technology-related factors. Our understanding of patient adoption and use of consumer ICTs comes largely from roughly a decade of experience with web-based patient portals in large integrated delivery systems and academic medical centers. Using patient portals as a representative technology, we draw upon this experience and the related literature to discuss these factors in this context, keeping in mind that they have broader applicability across the field of Consumer Health Informatics.

Access and Usability

Evidence accrued to date highlights the importance of ensuring equitable and open access to all points of care when implementing consumer ICTs, whether online, in-person or over the telephone. Fundamental barriers to the use of consumer ICTs can include a lack of computer and/or Internet access. However, these trends have changed as access to broadband networks increases, and consumers adopt portable Internet-enabled devices. In addition, a more nuanced understanding of access also includes computer and **health literacy** [76] to ensure that users have the ability and necessary functional and cognitive skills to enable effective use [77]. As ICTs are increasingly provided to enable consumer access to healthcare resources and services, care must be taken to prevent inadvertently creating or exacerbating disparities; especially among vulnerable segments of the population [78].

Patterns of adoption in large delivery systems suggest that patient portals have the potential to exacerbate existing disparities among patients related to race, age, literacy, socioeconomic status (SES), and other characteristics. Online use of portal services is less likely among older patients [78, 79], racial and ethnic minorities [80, 81], non-English speaking patients, the insured [82, 83], and patients without broadband Internet access or with lower income, computer abilities, health literacy, and education [84–86]. However, if carefully designed and implemented based on user needs, abilities, and preferences, consumer ICTs may also potentially eliminate disparities [87].

Unfortunately, many patient portals are limited in usability [88, 89], particularly for vulnerable populations [90]. In addition to addressing general usability principles related to user interfaces and navigation, patient portals and PHRs present additional challenges related to the complexity of health information, the lack of a universal user population, and the longitudinal scale of the information [91]. Usability improvements that are needed include the ability to import easily, export, and trend information [92]. Importantly, mobile health approaches, such as text messaging outreach that requires only a basic feature phone, show particular promise in some of these populations [93]. As portal features are further tailored, and consumer access to mobile devices and the Internet continue to increase, the use of portal services may also grow in vulnerable populations. However, clinical informaticists must remember that some patients will continue to be less capable or less interested in using them.

Awareness, Motivation, and Usefulness

Despite efforts to promote the availability and potential benefits of using patient portal systems and other consumer-focused ICTs, lack of awareness among consumers continues to be a significant factor inhibiting use [78, 91, 94]. An assessment in 2011 revealed that more than half of consumers were still not familiar with the concept of a PHR [93]. More recent data demonstrate that lack of awareness of portals and their features continues to be a major factor in inhibiting use [95–97].

Having adequate knowledge of technology and its features is a prerequisite for adoption and assimilation [98]. Research continues to emphasize that consumers must be educated and encouraged to adopt and use portal services. Notably, in integrated delivery systems and academic centers where patients are actively made aware of the availability of a patient portal, patient use has continued to grow over the past decade, with as many as 70% of enrolled populations signed up for the technology [99].

Like other technologies, motivation to utilize consumer ICTs depends on perceived relevance and value [99, 100], including the relative advantages of use among available alternatives. To facilitate ongoing use, portals need to be seen as reliable tools characterized by quality interactions.

Among the different services available through patient portals, patients most commonly use and report the highest satisfaction with exchanging secure electronic messages with providers, ordering medication refills, and viewing the results of medical tests [98–101]. However, the adoption of patient portals also appears to depend on providing a constellation of convenient and functional services rather than selected functionality [98].

In healthcare systems that engage with patients online, secure messaging encounters can become an important component of patient-provider communication. Two large healthcare systems recently reported that one-third of all primary care contacts with patients were conducted through secure messaging [102, 103].

Offering portal services also appears to be important to the retention of patients by providers and health plans [103–105]. While the evidence about the use of patient portals by specific patient populations remains mixed [105], some studies show that patients with chronic health conditions and new healthcare needs are more likely to use them, including those with diabetes, depression, and HIV [78, 99, 104].

Clinician Endorsement

Healthcare professionals are key determinants of whether patients use the technologies available to them, including patient portals. Although portals and PHRs have historically been cast as tools for patients, provider endorsement is an important factor in a patient's choice to adopt such tools [55, 106]. Additionally, clinician engagement with portals and PHRs may be required to achieve and sustain anticipated positive outcomes [97, 107].

Although there has been a prominent focus on portals and PHRs as tools to support consumers, much of the value that consumers derive from using these ICTs will be directly affected by the attitudes and actions of healthcare providers within clinical settings. Providers can increase patient portal use by encouraging patients to enroll and use them [53, 108] or further impede use by actively discouraging or failing to address patient assumptions about provider engagement, interruptions, or reimbursement [109]. As patients continue to see healthcare providers as a source of expert information, encouraging and demonstrating consumer ICTs will be crucial [49].

Research also reveals that patients are more likely to use portals if they had a primary care provider or switched to one, who regularly used secure messaging to communicate with patients [76, 77]. Patients are also more likely to use a portal when they trust their primary care provider and report better communication with their provider [106] and when a provider is female and younger [81, 103]. The role that providers play in influencing patient adoption and the use of portals highlights the importance of the portal as an environment for ongoing collaboration in the processes of care [107].

Despite the evidence and the opportunity for building enhanced partnerships with patients, some providers remain reluctant to communicate through the secure messaging features of patient portals, citing several barriers. Chief among them is the lack of reimbursement [109]. Electronic communications with patients are not regularly reimbursed in the fee-for-service environment. Financial incentives have partly addressed this barrier through meaningful use attestation and patient-centered medical homes by coupling secure messaging with care coordination [110].

The second most commonly cited barrier for providers is added workload. Even for salaried providers, adding electronic communication to a busy schedule of in-person visits can be a resource strain [111, 112].

Finally, many providers cite concerns about data security and privacy and medical liability issues as barriers. However, secure messaging systems and patient and family online access to visit summaries is now required of all certified EHRs, which, in part, will help to address these barriers.

Provider reimbursement and sufficient time remain significant barriers to further engaging patients and families through patient portals' secure electronic messaging features. In the next section, we describe implementation strategies that can be developed and deployed to encourage the adoption and effective use of consumer ICTs.

Implementation of Consumer Health Informatics

Addressing the factors described above to realize the IOM vision for delivering safe and sustainable health care in an era of greater consumer access and empowerment will require effectively leveraging technology. Clinical informaticists play a key role in designing health informatics technology for consumers, and equally important, in promoting

effective implementation within healthcare settings as complex adaptive systems. Like any innovation, the implementation of consumer ICTs often precipitates change for stakeholders, particularly in their existing activity, practice, and behavior patterns.

Drawing upon implementation science, specific strategies can be employed to thoughtfully plan and execute implementation programs for consumer ICTs tailored to specific settings and contexts. In their systemic review, Powell and colleagues define these implementation strategies as "a systematic intervention process to adopt and integrate evidence-based interventions into usual care" [113].

In this section, we describe four general strategies that can enhance the implementation of consumer ICTs. They include (1) following the principles of user-centered design; (2) integrating ICTs with existing activities, practices, and workflow; (3) engaging stakeholders, leadership, and clinical champions; and (4) providing education and incentives.

User-Centered Design

To be useful, eHealth applications and tools must be designed to be easy to adopt and use [114] and meet patients' actual needs and capabilities [115]. User-centered design (UCD) is a design philosophy that focuses on the end user's needs, preferences, and limitations at all stages within the design process and development lifecycle [116]. The emphasis is on understanding the end user's tasks and goals and optimizing the product for the user to fulfill these, rather than adapting to the designer's preferences [117]. UCD is covered in detail in Chap. 9.

User-centered design of eHealth applications and tools necessitates understanding and incorporating relevant consumer perspectives. If it also connects to clinical functions and workflow (e.g., secure electronic communication), then it must also be informed by healthcare professionals' perspectives.

Integration with Existing Practices and Workflows

Consumer Health Informatics entails not only providing patients with useful and usable tools that empower them to be active participants in their health care but also creating an environment that supports the use of the tools within the organizational context of healthcare delivery; from patient/physician interactions (e.g., secure electronic communication) to the representation of information within the clinical information system (e.g., patient-generated data). Understanding how patient use of ICTs integrates within the context of the healthcare interaction and impacts the provision of services by healthcare professionals in organizational settings is critical to achieving broadly anticipated benefits [53].

All types of work involve some creation, capture, application, or exchange of information. In health care, activities often pivot around such information use [118–120]. Implementing technology in healthcare settings must consider the collaborative nature of healthcare work, the primacy of information in this work, and the importance of the flow of information between participants as key elements of this collaboration [121]. In some cases, implementation of ICTs may even require a fundamental redesign of healthcare processes to focus on a patient-centric model with careful attention to ethical and policy considerations to avoid unintended consequences [122].

Changes in the type or flow of information may have profound implications for the activities and work practices that are part of the delivery of healthcare services [123]. Workflow represents a commonly understood set of procedures for and sequence of work tasks, along with assigning specific roles for individuals to accomplish these tasks. Taken together, these comprise processes that organizations manage to accomplish work. In healthcare settings, if a technology is to be implemented successfully, alignment with the larger clinical workflow is needed to be effective and efficient for the healthcare team. In addition, integration with existing organizational systems and business practices is crucial, or the consumer-oriented technology will be disconnected, resulting in minimal benefit. For example, implementing a triage team model for secure electronic messaging allows many incoming messages to be handled appropriately and efficiently by members of the broader healthcare team(e.g., physician assistant, pharmacist), reserving the more complex clinical issues for review and response by a physician. This approach can alleviate some of the potential workload strain described earlier, while aligning new technology with existing processes.

Engaging Stakeholders, Leadership, and Clinical Informaticists

Although traditional implementation efforts often focused on the technical aspects of information technology, a significant body of literature emphasizes the importance of social and organizational factors that influence the technology's implementation and use [124–126]. An ecological perspective that emphasizes the interactions between people, processes, and technology [127] highlights the need for all stakeholders to be involved in the decision-making process, for example, ensuring that healthcare professionals are engaged in planning efforts related to consumer-oriented tools and services. Since implementation may involve a new

or modified practice for healthcare professionals, it is crucial to consider their perspectives, professional values, and local practice patterns. Ensuring visible leadership support and engaging clinical champions is an important strategy for effective implementation [128, 129].

Drawing upon diffusion of innovation theory [99], implementation efforts require effective communication processes in which relative advantages are highlighted while ensuring compatibility with existing norms, values, and beliefs. In addition, the technology and the impact of its use by consumers must be perceived by individuals as relevant to their work and as having greater value than the available alternatives for accomplishing specific work tasks, e.g., using secure electronic messaging as an efficient alternative to telephone communication).

Providing Education and Incentives

Implementation science recognizes the importance of education and training to ensure that intended users have the knowledge and skills to use the technology [130] effectively. In the past, Consumer Health Informatics initiatives have often focused on providing education and training for consumers while neglecting similar needs for healthcare professionals. Yet, the single most effective strategy for promoting patient adoption and use of PHRs is encouraging a trusted health professional and concordant support from administrative and clinical staff [131]. Providing staff with opportunities for training that fit with their needs is a key implementation strategy to ensure a cohesive approach to patient endorsement, encouragement, and support [53].

If the implementation of new technology is accompanied by incentives that affect intended users, the adoption and use of the technology can also be facilitated. Incentives can drive the prioritization of staff activities, the allocation of resources to meet established goals and targets, and the continuous measurement and monitoring of progress. Incentives can operate at the organizational level or the individual and/or team level. Organizational incentives for performance can be financial (e.g., performance pay) or non-financial (e.g., transparency of performance indicators both internally and externally). At the individual level, incentives can include remuneration for work efforts that can be financial (e.g., reimbursement for a specific activity) or non-financial (e.g., workload credit for activity). Where fee-for-service models incentivize the quantity of workload, pay-for-performance models incentivize the accomplishment of organizationally defined performance measures. Although performance measures have previously been focused mostly on clinical quality measures, the addition of measures related to technology use exemplifies the application of incentives at the organizational level to facilitate the role of healthcare professionals in patient adoption and use of consumer ICTs.

Although the strategies mentioned above can be effective at furthering the implementation of consumer ICTs, it is also important to recognize that various factors can also influence the degree to which consumer health informatics implementation efforts will be successful. We provide an overview of such factors in the next section.

Assessing the Impact of Consumer Health Informatics

As the field of Consumer Health Informatics continues to evolve, measuring the impact of consumer ICTs on healthcare stakeholders and the delivery and receipt of healthcare services is similarly beginning to take shape. Emblematic of a developing field, studies to date have primarily focused on descriptions of consumer health informatics tools and their features, characterizations of users, and the need for additional research to generate scientific evidence of impact [132–134].

This section begins with overarching recommendations for future research directions of special importance to clinical informaticists. We then describe the current state of published evidence regarding the effectiveness of two classes of consumer ICTs—patient portals and mobile health technology—to exemplify the state of the science, followed by a discussion of actual and potential unintended consequences of consumer ICT interventions. We conclude with areas that warrant further research.

Methodological Approaches to Consumer Health Informatics Research

Analysis of the evidence available to date points to three needed directions for research in Consumer Health Informatics, each of which has important implications for clinical informaticists. First, as evidenced throughout this chapter, the range of consumer ICTs available or in development is vast and quickly evolving and represents diverse technical systems. Assessments of impact should be stratified to examine the effects of distinct functions and the mechanisms by which these capabilities influence explicit outcomes, recognizing that the heterogeneity of platforms, populations, and other contextual variables will still have considerable influence on the relevance of findings to other settings.

Secondly, there is a need for greater methodological pluralism, including both qualitative and quantitative approaches. Studies that focus either on the technical aspects or anticipated outcomes may fail to consider social, organizational,

professional, and other contextual considerations [135]. Ethnographic approaches to studying consumer ICTs as they are used in healthcare settings are crucial [136], avoiding a limited focus on pre-determined outcome measures and further enabling the identification of unanticipated consequences or "emergent effects that may be enduring" ([135], p. 41). Indeed, we advocate examining Consumer Health Informatics as a component of healthcare work, influenced by and influencing organizational actors and their work within the healthcare ecosystem [53]. As such, research and evaluation must inherently include examining processes of care and associated health behaviors [42], employing participatory research approaches to engage both consumers and health care professionals [137]. Informaticists will play an important role in constructing a bridge between the technology and its use, ensuring that the analysis and mapping of processes engage all of the participants involved in the nexus of patient care, with careful attention to the flow of information.

The third needed direction for research in Consumer Health Informatics is advancing patient-centered outcomes research (PCOR) [138]. PCOR extends the concept of patient-centered care discussed earlier to health care research by "helping people and their caregivers communicate and make informed healthcare decisions and allowing their voices to be heard in assessing the value of healthcare options" [139]. This research, in turn, informs patient health care decisions by providing patients and their caregivers with evidence on the effectiveness, benefits, and potential harms of different treatment options for different patients. Including the perspective of end-users can inform the research and enhance the relevance of research findings while also improving the likelihood that patients will achieve the health outcomes they desire.

Patient Portals

Characterizing the impact of patient portals on outcomes must consider the various ways in which a patient portal could affect patient health and behavior, including the use of specific features. However, simply enrolling (or being enrolled) in a patient portal may have positive outcomes, based on patients having improved ability to view (and sometimes modify) elements of their own medical record, review laboratory test results, and communicate securely with their healthcare providers via electronic communication. Additionally, a patient portal creates the opportunity for the healthcare system to reach out proactively to enrolled patients, with targeted and perhaps even tailored interventions that can further engage patients and potentially change behavior. Research studies will need to disentangle the nuanced effects of patient enrollment from targeted outreach efforts.

Evidence remains limited on the impact of patient portals and other consumer health technologies on healthcare quality and utilization. Studies from early adopting healthcare providers and integrated delivery systems have found that portals that offer secure electronic messaging can improve access to care [140], patient satisfaction [101, 102], and chronic care outcomes [102] for many patients. Patient portals may be particularly valuable when combined with new primary care models, such as the patient-centered medical home (PCMH) [141, 142]. Patients using portals that provide access to electronic health records report a better understanding of health conditions and the plan of care [98]. Better patient adherence has also been reported among those using a portal-based medication refill function [143] and accessing their provider's clinical notes [98, 104].

To date, evidence remains mixed on the impact of patient portals on traditional forms of healthcare utilization. Some studies suggest that using a patient portal increases the utilization of in-person outpatient visits, emergency room visits, and hospitalizations. In contrast, other studies suggest it leads to less outpatient and urgent care utilization [102, 144]. Most studies of utilization have thus far been observational and challenged by the difficulties of comparing healthcare use among those who sign up and use portals with those who do not.

In terms of the effects of patient portal enrollment, a 2011 systematic review [145] identified four controlled studies published between 1990 and 2011 reporting the effects of electronic patient portals on patient care; three randomized controlled trials (RCTs) and one retrospective cohort study. In the two RCTs that examined the effects of patient portals on health outcomes, such as mortality or hospitalization, there was no statistically significant difference between the intervention and control groups [146, 147]. In the third RCT, the use of the patient portal did not affect indicators of patient engagement [148]. More recently, four additional RCTs published in 2012–2013 further evaluated the effects of patient portals on health outcomes [149–152]. These studies also showed heterogeneity in their results.

In contrast, one study showed convincing increases in rates of herpes zoster vaccination among patients randomly identified to receive an outreach message delivered electronically via a patient portal [149]; another study showed no effect of a patient portal on rates of adverse drug events [153]. Randomized trials engaging patients through outreach over portals with secure messaging have shown improvements in glycemic control in type 2 diabetes patients, blood pressure control in hypertensive patients, easing depression in patients recently starting antidepressants, and improved receipt of preventive care services [132]. As more interventions that utilize patient portals and other consumer health technologies are developed and adopted over the next five to ten years, the evidence base assessing the impact on health

outcomes will continue to grow for increasingly sophisticated and diverse interventions.

Mobile Health (mHealth) Technology

Owing to the exponential growth in the number of patients who have mobile phones, health systems and researchers have increasingly attempted to use this medium to change patient behavior and, ultimately, improve health outcomes. Although smartphone applications (apps) hold immense promise for patient engagement and health behavior change, most studies to date have capitalized on the more widely accessible Short Message Service (SMS) or text messaging. A 2014 systematic review identified 20 comparative studies, including 13 RCTs, that used SMS to improve adherence to medications, with interventions targeting patients with human immunodeficiency virus (HIV) infection or other chronic conditions (e.g., hypertension or diabetes mellitus) [154]. The review indicated that adherence to medications improved in the SMS-intervention group in a majority of studies. Similarly, another systematic review assembled 59 trials investigating the use of mobile technologies to improve disease management and 26 trials evaluating their use to change health behaviors [155]. The authors found strong evidence that SMS-based interventions improve adherence to medication treatment for patients with HIV and also found that texting interventions improved smoking cessation. Finally, mobile health interventions using text messaging are showing promise, including improvements in sustaining weight loss [156], improving immunization rates [157], and improving medication adherence [158].

While considerable evidence thus suggests that SMS-based interventions—a relatively primitive technological approach—can improve certain health measures, there is much more uncertainty about the potential for more technologically advanced mHealth strategies to improve health outcomes. Despite their widespread appearance and increasing use among patients and healthcare providers, mHealth interventions relying on smartphone applications have generally not yet been tested in rigorous RCTs.

Unintended Consequences and Emerging Trends

Moving forward, scientific evidence demonstrating the impact of consumer ICT use will be critical, including understanding the potential for unintended consequences [42]. These consequences could be desirable, enhancing health processes or outcomes, or undesirable adverse effects which could disrupt the care process or degrade outcomes. Various harms could be associated with consumer ICTs, including the risk of data breach and inadvertent disclosure of personal health information. With the US Department of Health and Human Services' documentation of more than 1600 data breaches involving 500 or more individual patients' health records since 2009 [159], consumer ICTs must inherently incorporate safeguards to protect patient privacy and ensure information security. Ozbolt and colleagues have assembled a comprehensive list of potential unintended consequences related to consumer ICTs along with strategies for mitigation [160]. These entail effectively striking a balance between enabling ease of information exchange and protecting patients' privacy rights, concerns, and preferences.

Unintended consequences that can result from the tension between the patient's desire for access to and control of health information and provider's need for full information about the patient include: (1) patients inadvertently or purposefully restricting access to information that healthcare providers may need for clinical decision-making, and (2) the introduction of non-curated and potentially imprecise data into the EHR with at least the potential for negative impact on clinical decisions. While researchers and policymakers need to be tuned to the emergence of unexpected behaviors or outcomes associated with the use of consumer ICTs, clinical informaticists are well-positioned to identify and proactively mitigate potential undesirable consequences.

Future Research

Over the next several years, the expansion of Meaningful Use and the enforcement of the twenty-first Century Cures Act is expected to increase the adoption of patient portal services, including secure electronic messaging and direct patient access to electronic health records. At the same time, a wide variety of new consumer health technologies will be developed, tested, and deployed. These changes in policy and technologies may extend the reach of consumer health technologies into populations that have not yet been able or interested in using the functions of traditional patient portals. These shifts may also provide new opportunities to improve the quality and cost of care.

As the examples of patient portals and mHealth illustrate, relatively few RCTs of consumer ICTs have been conducted. Many of these studies suffer from methodological limitations such as small sample sizes, inability to conceal allocation of the intervention, and limited generalizability. As previously noted, other methods will also be crucial to develop a robust evidence base around the impact of consumer ICTs. With their knowledge and skills, clinical informaticists represent key resources to support these tools' collaborative design, implementation, and evaluation.

Emerging Trends

"There is an APP for that"—the emerging landscape of independent Smart device-based solutions for self-care and self-management, the role of the Healthcare systems in consumer desire to use these solutions, how and when to integrate these solutions into EMR's, how the interpret data from these solutions to gain insight into patient's condition and care, how to leverage these solutions to address the Quadruple Aim.

The domain of Consumer Health Informatics is rapidly evolving both in terms of the paradigm shifts discussed earlier and in the explosion of available web-based services, mobile health applications, and other technology-enabled tools. In this section, we describe several important trends that are emerging in this field. We focus on tools and services becoming accessible to consumers, although not yet uniformly available to all, nor broadly adopted or institutionalized.

The Blue Button concept emerged in 2010 to enable more direct consumer access to personal health information by adding a 'Download My Data' button to patient portal systems [161]. Within the next six months, the US Department of Veterans Affairs (VA) added the Blue Button symbol (Fig. 24.2) to the VA patient portal, My Health*e*Vet, enabling Veterans to download their own health record electronically securely. Since then, the Blue Button has spread beyond VA to other government agencies and the private sector. Over time, technology developers have demonstrated innovative ways to enhance the visual representation of Blue Button data, and novel applications emerged to enable consumers to import and aggregate their Blue Button data from various sources [162, 163]. Responsibility for encouraging broader use of Blue Button and enhancing its technical standards was transferred to the Office of the National Coordinator for Health Information Technology (ONC), a division of the US Department of Health and Human Services, in 2012. In 2014, ONC also launched a Blue Button Connector website [164] to help consumers locate and access their personal health information sources.

Fig. 24.2 Blue Button® logo (Blue Button, the slogan, 'Download My Data,' the Blue Button Logo, and the Blue Button Combined Logo are registered service marks owned by the U.S. Department of Health and Human Services)

OpenNotes is a national initiative in the United States to give patients easier access to the clinical notes written by their healthcare providers. The OpenNotes movement began with an innovative 12-month study at three diverse medical institutions to explore how sharing clinical notes with patients may affect their health care [165]. Early evidence demonstrated positive effects with minimal impact on the provider's workflow. Patients with access to their doctors' notes felt more control of their care. They reported a better understanding of their health and conditions, improved recall of their care plan, and being more likely to take their medications as prescribed [104]. These findings were replicated nationwide when the VA enabled online patient access to all clinical notes in January 2013.

The experiences of early adopters demonstrated that patients both value and benefit from online access to their clinical notes [98]. Additional outreach and education are needed to inform and educate patients about their ability to access clinical notes and the potential role that this information can play in their care. While additional research is needed, advocates argue that transparency and access to notes for even sensitive topics like mental health issues may have an additional therapeutic benefit [166]. The VA study concluded that healthcare professionals authoring clinical notes should keep in mind the opportunity that patient note access presents for supplemental communication, for example, reinforcing the treatment plan and medication instructions. Future research should examine the kinds of support healthcare professionals need to capitalize on patient access to notes effectively.

Mobile Health-Devices, Monitors, Sensors and Wearables

Health information exchange (HIE) is the electronic movement of health-related information among organizations according to nationally recognized standards [167]. HIE aims to facilitate access to and retrieval of clinical data to provide safer, timelier, efficient, effective, equitable, patient-centered care across care settings. Organizational HIE models including query-based exchange (the ability for providers to find and/or request information on a patient

from other providers, often used for unplanned care) and directed exchange (the ability to send and receive secure information electronically between care providers to support coordinated care). Despite anticipated benefits from HIE, some challenges remain, including workflow issues, privacy and security concerns, and the lack of a compelling business case for system sustainability [168]. More detail on HIE is provided in Chap. 14.

Recognizing that consumers can play an important role in ensuring timely access to information across care settings, Meaningful Use is also driving a new complementary model of HIE: **consumer-mediated exchange**. In this form of HIE, patients are provided with the ability to aggregate and control the use of their health information among providers through patient portals, sensors, devices, and wearables [169] that enable them to view, download, and securely transmit their personal health information [170].

While significant progress has been made, issues with interoperability and technical maturity will need to progress to accomplish the goal of enabling consumers to transmit their personal health information across systems and settings securely. Moving forward, understanding how organizational health information exchange and consumer mediated exchange models can meaningfully coexist and complement one another will be an important question for the field of Consumer Health Informatics.

Mobile health or "mHealth" is an emerging trend in this chapter mainly because of the rapidity with which the area is evolving and expanding and its considerable implications for health care practice, research, and public health. As noted by Susannah Fox, "in 10 years, we have seen the Internet go from a slow, stationary, information vending machine to a fast, mobile, communications appliance that fits in your pocket. Information has become portable, personalized, and participatory" [171].

The term "mHealth" was coined by Robert Istepanian in 2005 to describe the emerging use of mobile communications and network technologies for healthcare [172]. More recently, mHealth has been described simply as "the delivery of healthcare services via mobile communication devices" [173]. These devices include a growing array of mobile phones (including smartphones), tablet computers, personal data assistants (PDAs), and patient monitoring systems and sensors and wearables that enable consumers to access and share information, track data, communicate, exchange information, and/or accomplish other health-related tasks. Increasingly, the consumer marketplace also includes wearable technologies and remote sensors, enabling consumers to measure and monitor various types of data: from fitness activity to sleep patterns and other measurements.

An alternative model to an institution-centric health information infrastructure is a patient-centric model that can enable a more comprehensive and longitudinal patient health record: health record banking [174, 175]. A health record bank is an independent organization that provides a secure electronic repository for storing and maintaining an individual's lifetime health and medical records from multiple sources while assuring that the individual always has control over who accesses those records [172]. A health record bank model may offer distinct advantages, including more comprehensive information for clinical decision-making, simplified patient access to aggregated data from multiple care settings, centralized management of patient permissions, more effective record deposits and retrievals, and more sustainable economies of scale [176].

The convergence of portable computing power and increases in broadband and wireless Internet access has resulted in new opportunities, shifting consumer access to eHealth tools with some potential to reduce the digital divide [177]. Advocates of mobile health technologies point to many advantages, including anytime/anywhere access, the convenience of portability, cost-effectiveness, and increased consumer adoption rates. Analysts predict that the mobile market is poised for growth [178]. However, advances in technology are outpacing the science of mHealth, and more research is needed to understand evolving trends in consumer behavior and also to assess the impact of mHealth tools with scientific rigor [179].

Clinical informaticists will play a crucial role in the evolution of mHealth, as early pilots move towards fuller implementation. The rapid adoption for future mHealth adoption is supported by the twenty-first Century Cures Act, which states that putting the patient first in health technology enables (1) the health care system to deliver transparency into the cost and outcomes of their care, (2) competitive options in getting medical care, and (3) modern smartphone apps to provide them convenient access to their records. This app economy provides patients, physicians, hospitals, payers, and employers with innovation and choice.

Complimentary Models of In-Person and Virtual Care

Consumer Health Informatics tools and services have also laid the foundation for complementing traditional in-person care with virtual care. With the growing recognition that some types of patient-physician encounters can be appropriately completed without requiring face-to-face contact, the use of alternative methods such as online assessment forms and/or secure email messaging offer the advantages of convenience, efficiency, and cost-effectiveness [177].

One method of incorporating these technologies into clinical practice settings is providing patients with the option of online electronic office visits or "eVisits." Increasing numbers of healthcare systems are now beginning to offer eVisits to their patients for certain types of health care needs, allowing physicians to provide a patient consultation online syn-

chronously or asynchronously. Enabling this functionality more broadly will require addressing several challenges, including establishing effective reimbursement structures, ensuring patient health and computer literacy, and developing models that allow for integration with existing clinical workflow, organizational structures, and business and clinical processes [180].

Early assessments reveal that these forms of virtual care may also attract a younger patient population who place a high value on convenience [181]. There has been rapid adoption of Video Visits and Telephone visits for just-in-time Provider interactions instead of Face to face visits driven by the Covid 19 Pandemic. Yet, it remains to be seen if this high adoption rate will continue to sustain post-pandemic and if the payers will continue to support this reimbursement model. It remains to be studied in large numbers if health outcomes with Virtual care are similar to face-to-face care.

Remote Patient Monitoring

With relatively simple applications to monitor patients, technology has developed to the extent that the patient can be allowed normal daily activities at home while still being monitored using modern communication and sensor technologies. Sensors for monitoring essential vital signs such as electrocardiogram reading, heart rate, respiration rate, blood pressure, temperature, blood glucose levels, and neural system activity are available today.

The range of remote healthcare varies from monitoring chronically ill patients, elders, premature children to victims of accidents. These new technologies can monitor patients based on the illness or based on the situation. The technology varies from sensors attached to the body to ambient sensors attached to the environment. Breakthroughs show contactless monitoring, which requires only the patient to be present within a few meters from the sensor. Fall detection systems [182] and applications to monitor chronically ill patients have already become familiar to many. This study provides a review of the recent advances in remote healthcare and monitoring in both with-contact and contactless methods [183].

Summary

As the nascent field of Consumer Health Informatics evolves, driven by unprecedented technological advances and the rise of a new consumer e-patient, the stakes are high. As Dr. William Frist cautions, "America's health care delivery sector stands at a tipping point—a convergence of a growing, graying, and highly consumptive population with increasingly limited financial and human capital resources" [181]. He also notes, however, that the combination of newly empowered consumers armed with actionable information plus significant advances in information technology has the potential to "radically transform and improve health care delivery." Clinical informaticists will be essential in realizing that potential.

Equipped with the fundamental knowledge and diverse skill sets, clinical informaticists will create strong foundations to support the effective design, implementation, and evaluation of technology-enabled systems. They will serve as expert consultants, innovators, and problem solvers. They will create collaborative approaches that leverage the interactions between people, organizations, and socio-technical systems and help us to apply consumer ICTs in ways that complement and enhance traditional methods of health care delivery. Clinical informaticists will build the bridges connecting the science of technology and the art of medicine. As such, they play a key role in transforming health care.

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Public Health Informatics

25

Saira N. Haque, Brian E. Dixon, Shaun J. Grannis, and Jamie Pina

Learning Objectives

At the end of this chapter, the reader should be able to accomplish these objectives:

- Define public health informatics.
- Explain the impact of informatics on population health.
- Identify different types of information systems used to support public health.
- Describe how public health informatics relates to the field of clinical informatics.
- Discuss how clinical and public health informaticians work together to monitor and improve population health.

Practice Domains: Tasks, Knowledge, and Skills

The following core competencies are covered in this chapter:

- K021. Determinants of individual and population health
- K047. Social determinants of health

Key Terms

Disease registries, immunization registries, population health, public health, surveillance systems

Case Vignette

Local payers and hospital systems started Safe Community Health Information Exchange (SCH) to promote information sharing throughout the community. As SCH grew, additional stakeholders became involved in exchanging clinical data to support care coordination and quality improvement activities within the hospitals and physician practices. These stakeholders included laboratories, long-term and post-acute care facilities, federally qualified health centers, and local and state public health agencies.

Providers in the community used the SCH infrastructure to submit electronic laboratory results for communicable diseases to public health authorities, and public health agencies used the electronic health records (EHRs) to investigate disease outbreaks. For example, a local measles outbreak originated from a group of people who had not received the vaccine. This was discovered by tracing a cluster of children who arrived at different emergency departments.

SCH's functionality was tested during the novel coronavirus (COVID-19) pandemic. During the pandemic, SCH looked up patient information to support contact tracing, identify those with exposure, and give them directions about quarantining. Once vaccines became available, the connection among the state's immunization information systems (IIS, also known as immunization registries) became of increased importance. However, some challenges occurred because SCH and the IIS possessed fragmented information about vaccines administered, where they were administered, and by whom. The IIS tracked those who had been vaccinated at a site with an IIS connection, whereas SCH had access to data on those vaccinated at clinical sites with commercial EHRs. SCH was able to share clinical data with the local Department of Veterans Affairs (VA) clinic, but federal law prohibited the VA from submitting vaccine administration records to the IIS.

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As states moved towards broader vaccination coverage of the population, providers wanted to ensure that specific patient populations (e.g., those with cancer or hypertension) were vaccinated. Providers became frustrated when they could not access information on those who visited public health-operated mass vaccination and mobile vaccination sites as well as VA clinics because data from those sites were not connected to SCH. Moreover, it was difficult to query the regional health information organization (RHIO) for unvaccinated people because the IIS was not integrated into the RHIO's infrastructure.

Lack of integration was determined to be mainly due to lack of funding at the state health department, which receives most of its revenue from federal grant dollars. Because the state agency's budget had mostly flatlined and had been periodically reduced, it had only enough funding to support minimal services provided by SCH. Although SCH leadership was passionate about public health, business owners had to be good stewards of their limited funding. They could not afford to offer many free-of-charge services to the state health department. A local philanthropic foundation stepped up to provide the funding necessary to support integration between SCH and the IIS.

As SCH and IIS integration was completed, state health authorities could query records to identify teachers and school-aged children who had not yet been vaccinated for COVID-19. Analysis of the results identified three geographic areas with a high concentration of unvaccinated people. The health department then set up vaccine clinics at public schools in those areas, providing information to community residents about the benefits of vaccination and offering free vaccines. With support from health care, school, religious, and community leaders, vaccination rates increased, and the outbreak subsided, so schools could reopen. From that point, epidemiologists could more efficiently monitor community vaccination rates for COVID-19 and other vaccine-preventable diseases, and clinicians in SCH could efficiently query the IIS to receive up-to-date vaccine forecasts for their patients. For the VA clinic, the state health department had to implement a workaround with SCH to enable epidemiologists to view VA immunization records.

Introduction

Informatics is the *science of information*, studying the representation, processing, and communication of information by computers, humans, and organizations [1]. Informatics draws on a broad spectrum of theories from the computer, information, and social sciences. It seeks to fill the gap between (1) the correctness problem (how to assure the correct working of a program) and (2) the pleasantness problem (how to build adequate programs and systems to support the people using them) [2]. In practice, informatics often requires three components: (1) knowledge of the domain in which it is being applied (e.g., business, health care), (2) knowledge of how information systems are to be designed and developed to appropriately manage data and information, and (3) knowledge of how organizations and people interact with or use information systems to achieve their goals (e.g., treat patients, transact business).

The term *public health informatics (PHI)*, the subject of this chapter, is often used synonymously (or confused) with a host of similar-sounding but distinct "adjectives" as noted by Hersh [3], including *clinical informatics*, *health informatics*, and the broader field of *biomedical informatics (BMI)*. BMI is an interdisciplinary field that studies and pursues effective uses of biomedical data, information, and knowledge for scientific inquiry, problem-solving, and decision making, driven by efforts to improve human health [4]. BMI is often conceived of in the United States as encompassing health informatics in addition to clinical and public health informatics, as depicted in Fig. 25.1 [5]. Although clinical informatics applies health information technologies in the provision of individual clinical care [6], PHI seeks to apply health information and technologies to improve population health, including the surveillance and prevention of disease and general health promotion [7].

The Scope of Public Health Informatics

Although public health professionals have utilized information and communication technologies (including the fax machine) to capture, store, manage, exchange, and analyze information about populations, the rise of PHI as a discipline within public health and informatics began at the start of the twenty-first century. During the first decade, PHI efforts around the world were characterized by a focus on the core public health function of monitoring populations: early detection of bioterrorism [8], such as the anthrax attacks in the United States [9] and the Tokyo subway attacks [10], and global health threats such as severe acute respiratory syndrome [11], the H1N1 pandemic [12], and the COVID-19 pandemic [13]. The threat of a large-scale epidemic has not diminished in recent years, as evidenced in 2014 by Middle East respiratory syndrome [14, 15] and Ebola [16], but changes in national policies and funding priorities have steered PHI in new directions [17]. Today, PHI not only supports core public health functions [18] but also contributes to the following activities in support of population health and strengthening the public health infrastructure [19]:

1. *Implementations of informatics systems such as electronic health record (EHR) systems and health information exchange (HIE)*. PHI often contributes to an eHealth strategy established by a nation's health ministry by supporting capturing, managing, and exchanging data to

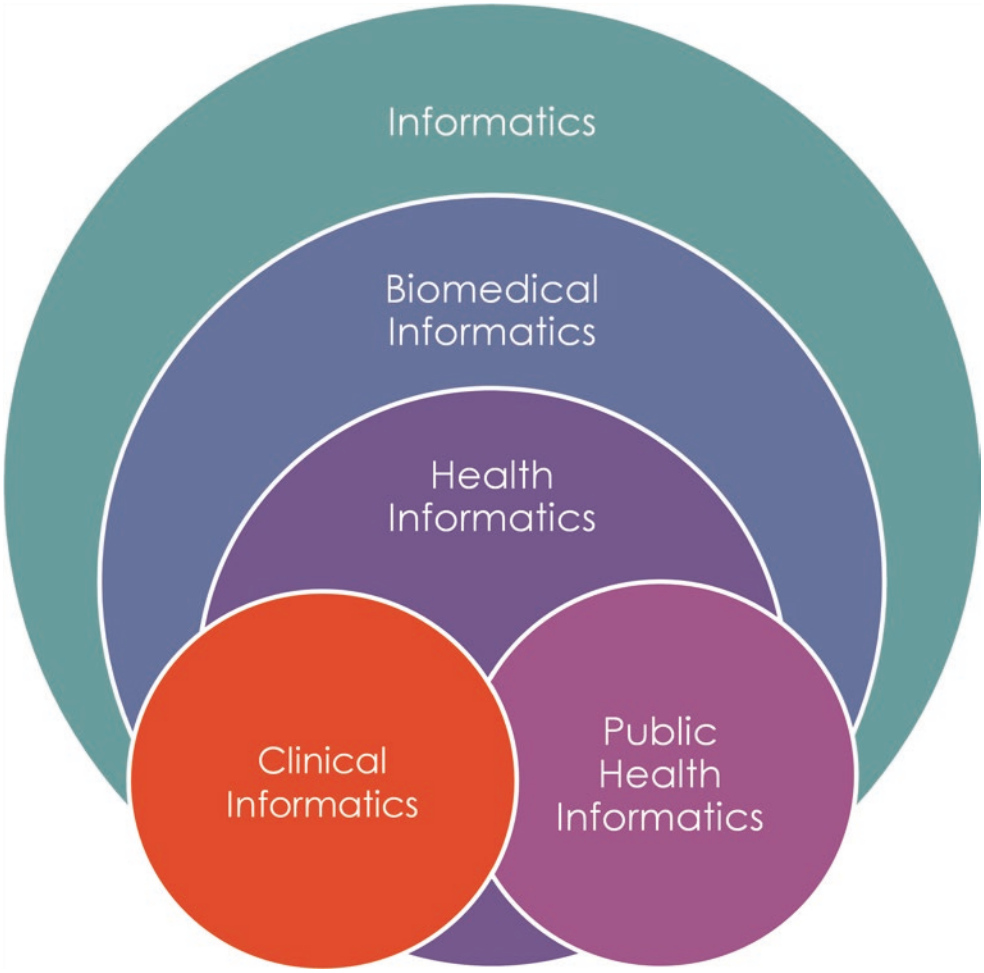

Fig. 25.1 Relationship of public health informatics to other areas in informatics

monitor population health across local, regional, and national levels. Recent efforts by the U.S. Centers for Disease Control and Prevention (CDC) have focused on the adoption of technologies related to meaningful use [20], including electronic laboratory reporting (ELR), syndromic surveillance, immunization information systems (IIS), and cancer registries.

2. *Measurement of population health indicators within and across jurisdictions*. Just as EHR systems contribute to better measurement of clinical outcomes using e-measures (refer to Chap. 5), PHI focuses on developing population-level health indicators. Public data sets, including CDC's Behavioral Risk Factor Surveillance System and the US Census Bureau's American Community Survey, are integrated and leveraged to create the County Health Rankings [21], composite scores representing the health of the population living in a geographical county within the United States [22].
3. *Implementation of patient-centered care models that support broader public health system strategies to achieve better, coordinated care while reducing costs (e.g., the Triple Aim)*. Patient-centered care models seek to consider patient preferences, self-management, and self-reported outcomes in clinical decision-making (refer to Chap. 24). Contributions from PHI include leveraging social media and short message service (SMS) text messages (1) to identify disease outbreaks [23], (2) to improve maternal and child health outcomes [24, 25], and (3) to inform at-risk populations about methods for lowering their risk of infection [26].

Informatics Capacity in Public Health Agencies

Informatics is challenging in public health, given limited resources and a limited workforce. Budget reductions in public health following the 2009 American economic recession as well as H1N1 pandemic limit the ability of public health agencies to develop, purchase, and deploy new informatics systems [27, 28]. For example, although the Health Information Technology for Economic and Clinical Health (HITECH) Act provided billions of dollars for health care providers to adopt EHR systems, it provided only $30 million for public health agencies to enhance their infrastructure to receive and analyze data from EHRs [29]. The lack of

support for public health agencies is particularly problematic because with increased provider EHR implementation comes more data in different formats for public health agencies to process. A shrinking public health workforce compounds limited financial resources. In a 2017 survey of the public health workforce, nearly half of workers in state and local agencies reported they planned to leave within 5 years [30]. Fewer experienced workers places stress on agencies to compute and analyze increasing volumes of data with fewer human resources.

The most up-to-date information on the PHI workforce comes from the same 2017 survey of local and state public health agency workers. Approximately 1% of the public health workforce is employed to deploy or operate PHI systems [31], and this proportion is lower in local health departments versus state health agencies. Moreover, less than one-third of public health informaticists report working in an informatics division. Most are employed in epidemiology, vital records, and communicable disease divisions [31].

The CDC currently sponsors an official, registered apprenticeship program in PHI [32] that supports approximately ten fellows each year placed in state and local health departments. Anecdotal information suggests that the volume of fellows has picked up in recent years, especially in the wake of the COVID-19 pandemic. However, it is unlikely that the fellowship at the CDC can fulfill the training needs of the nation's public health system. Therefore, more investment in PHI education and training is required [28, 31]. It is hoped that a recent training program in PHI announced by the U.S. Department of Health and Human Services' (HHS) Office of the National Coordinator for Health Information Technology (ONC) [33] will train approximately 4000 PHI specialists who can transform the nation's public health infrastructure.

Public Health Informatics Education and Training

Although the current PHI workforce is limited, recent shifts in opinion are favorable to the future. Since 2012, several stakeholder groups have convened independently to discuss the challenges facing modern public health. First, CDC reorganized its division responsible for national public health surveillance coordination. The division hosted strategic planning sessions culminating in several reports detailing national surveillance activities' challenges [34]. Second, the Council of State and Territorial Epidemiologists updated its "Blueprint" for public health surveillance, outlining the challenges facing state-level surveillance activities [35]. With support from the Robert Wood Johnson Foundation, the Public Health Informatics Institute (PHII) convened a series of meetings with local health department epidemiologists to discuss and outline future requirements for surveillance systems at that level of public health. Finally, the Association of Schools and Programs of Public Health (ASPPH) convened a panel to review and update the Master of Public Health (MPH) core to reflect twenty-first century challenges [36].

Although convened independently, these groups reached very similar conclusions regarding the role of informatics in public health. CDC created a division within its surveillance core to focus on PHI. The revised Blueprint for surveillance and PHII workshops identified PHI as critical to the future of surveillance practice. Finally, ASPPH identified PHI as a core competency for future public health leaders. These efforts in recent years should stimulate change within schools of public health and other public health training programs that will lead to a public health workforce knowledgeable about PHI and a larger segment of the workforce that concentrates on PHI.

There is a range of approaches to meet the goals of PHI education [37]. Approaches include integrating literature search training, hands-on/real-world experiences, didactic modules, and case studies. Topical areas cover the disciplines of health and health care, social and behavioral science, and information science and technology.

Major Players in Public Health Informatics

Numerous entities are interested in the public health system is complex, with various organizations at local, state, and federal levels. At the federal level, CDC remains the leading public health institute in the United States. Although many groups within CDC are engaged in PHI work, the largest and most active center is the Center for Surveillance, Epidemiology, and Laboratory Services [38]. This center is driving data modernization and informatics innovation for public health and has increased efforts in the wake of the COVID-19 pandemic, highlighting the need for public health to improve data coordination across all stakeholders [39]. In 2008, several public health associations came together to form the Joint Public Health Informatics Taskforce (JPHIT). Since then, others from the public health and informatics communities have joined JPHIT to create an open forum that enables coordinated and collaborative development and implementation of PHI priorities, a unified voice on national PHI policy issues, and a focus on improving the performance of the public health system through informatics [40]. The list of members and affiliates of JPHIT provides a "who's who" of PHI and includes (as of 2021) the following associations:

- American Immunization Registry Association (AIRA), which promotes the development, implementation, and interoperability of IIS.
- American Medical Informatics Association (AMIA), the professional home of leading informaticians: clinicians, scientists, researchers, educators, students, and other informatics professionals who rely on data to connect

people, information, and technology. Specifically, its PHI working group focuses on the intersection between technology and public health.
- American Public Health Association (APHA) is focused on improving public health. The Health Informatics Information Technology member section is specifically focused on PHI.
- Association of Public Health Laboratories (APHL), which advocates for public health laboratories and provides guidance on the development and implementation of laboratory information management systems.
- Association of State and Territorial Health Officials (ASTHO), which represents public health agencies and includes an e-Health portfolio that provides resources to state health agencies.
- Council of State and Territorial Epidemiologists (CSTE) works to advance public health policy and epidemiologic capacity.
- National Association of County and City Health Officials (NACCHO) serves local health departments in the United States and fosters informatics in local health agencies.
- National Association of Health Data Organizations (NAHDO) seeks to improve health care data collection and use.
- National Association for Public Health Statistics and Information Systems (NAPHSIS) represents the state vital records and public health statistics offices in the United States.
- North American Association of Central Cancer Registries (NAACCR) develops and promotes uniform data standards for cancer registration, certifies population-based registries, aggregates and publishes data from central cancer registries, and promotes the use of cancer surveillance data and systems.

Several groups are working on various aspects of PHI. No matter the effort, PHI's success is predicated on a large volume of available individual patient data. As more providers implement EHRs, the availability of information that can be used in the aggregate to support public health will also increase. Examples of specific systems that are used to support public health are outlined in the next section.

Examples of Public Health Information Systems

Public health practice uses a wide variety of data types, data sources, and data management techniques. Although many data necessary for public health processes are generated during routine clinical care, public health agencies require a broader set of data captured directly or indirectly from non-clinical sources. Clinical data are often insufficient to address environmental, genetic, social, and behavioral factors required to address major population health challenges [41, 42]. For example, consider the challenge of addressing increasing rates of diabetes in a community. Clinical data sources, including the EHR, will have robust data on patients with known diabetes diagnoses and/or patients taking prescription medications to treat diabetes. However, EHR systems may not be the best source for identifying individuals with undiagnosed diabetes who are not currently receiving care.

Moreover, individuals in the community who are prediabetic may not be in care or receive regular screenings for diabetes. To identify these individuals, public health agencies may need to hold community screening events. They may further need to work with clinics and hospitals to encourage all residents to schedule a wellness exam with a primary care provider to identify individuals with undiagnosed diabetes.

Non-clinical information can include a patient's geospatial location, socioeconomic status, school affiliation, and proximity to risk factors such as elevated soil lead levels within a community [43–47]. Civil registration records, such as birth and marriage certificates and tax records, are examples of data sources that could provide useful non-clinical data for assessing population health. Thus, clinical data must be augmented with additional, non-clinical data sources to fully inform public health processes and improve population health outcomes. This is often a critical role public health agencies play in their community.

Additionally, clinical systems often lack sophisticated information extraction techniques and case detection algorithms to identify clinical data needed for public health processes [48]. For example, although EHR systems can route the results of a laboratory culture for methicillin-resistant *Staphylococcus aureus* (MRSA), clinical systems cannot consistently identify whether the result was positive or negative. Case detection techniques and strategies may include natural language processing (NLP), rules engines, and machine learning algorithms; these techniques can substantially improve case identification [49, 50]. Finally, because clinical and non-clinical data are often stored in separate databases as separate islands of information, public health agencies often lack efficient access to integrated population-level health data, hindering the ability to identify and manage a community's specific public health needs. Thus, effective integration with EHR systems, HIE networks, and other health data systems is needed to optimize digital support of public health processes [51].

Electronic Laboratory Reporting

ELR refers to the process of electronically transmitting laboratory reports that identify reportable conditions from laboratories to public health stakeholders and has been

shown to improve the timeliness and completeness of disease reporting [52]. Most states can receive electronic reports from laboratories [53], and the volume of electronic reporting to state agencies is expected to increase given that the meaningful use and Promoting Interoperability Programs [20] require eligible hospitals and encourage eligible providers to submit notifiable disease laboratory results to public health agencies using ELR. However, limitations of ELR have been reported [54]. Laboratories often lack detailed patient demographic information required by public health departments. Certain diseases cannot determine when a test result reflects a new case or chronic disease.

As clinical data are increasingly captured electronically, there is greater potential for more complete and timely reports through increased automated electronic public health reporting. An automated ELR system that leverages data from an integrated HIE can overcome some of the aforementioned limitations by enhancing population-based reporting with additional data such as recent laboratory results, improved patient and provider demographics, and medication history [8, 55]. For example, Overhage and colleagues [52] compared ELR messages identified by an HIE with manually reported cases from physicians and hospital infection control professionals (Fig. 25.2). The analysis revealed that an automated ELR detection system implemented with fairly basic rules could significantly improve the identification of cases that need to be reported to public health authorities.

Electronic Case Reporting

Although ELR messages move laboratory results directly to public health agencies, ELR data alone is often insufficient to support disease surveillance efforts. Public health agencies also desire to receive electronic case reporting (eCR) messages sent from physician practices or hospitals. These messages include details beyond what can be sent in an ELR message, such as the patient's disposition at the time of clinical diagnosis and medication prescribed for disease treatment. An eCR message might also contain details about the patient's vaccination history, social determinants, and symptoms. Disease investigation specialists at the public health department can use these details to identify suspected or probable cases before laboratory reporting. In the 2019 Promoting Interoperability Program, the U.S. Centers for Medicare & Medicaid Services (CMS) promoted eCR as a valid public measure for hospitals. The requirement nudges hospitals to send "production data" to public health authorities in their jurisdiction.

Today, most eCR messages are electronic faxes sent from physician offices. Although known to most public health informaticians, the whole world now knows that clinician reporting is largely fax-based, thanks to the COVID-19 pandemic. Reporters from *The New York Times* and other major news outlets ran stories showing how piles of faxed reports were accumulating in local public health agencies during the crisis [56]. Because faxed reports had to be manually entered into information systems during the pandemic, it could take

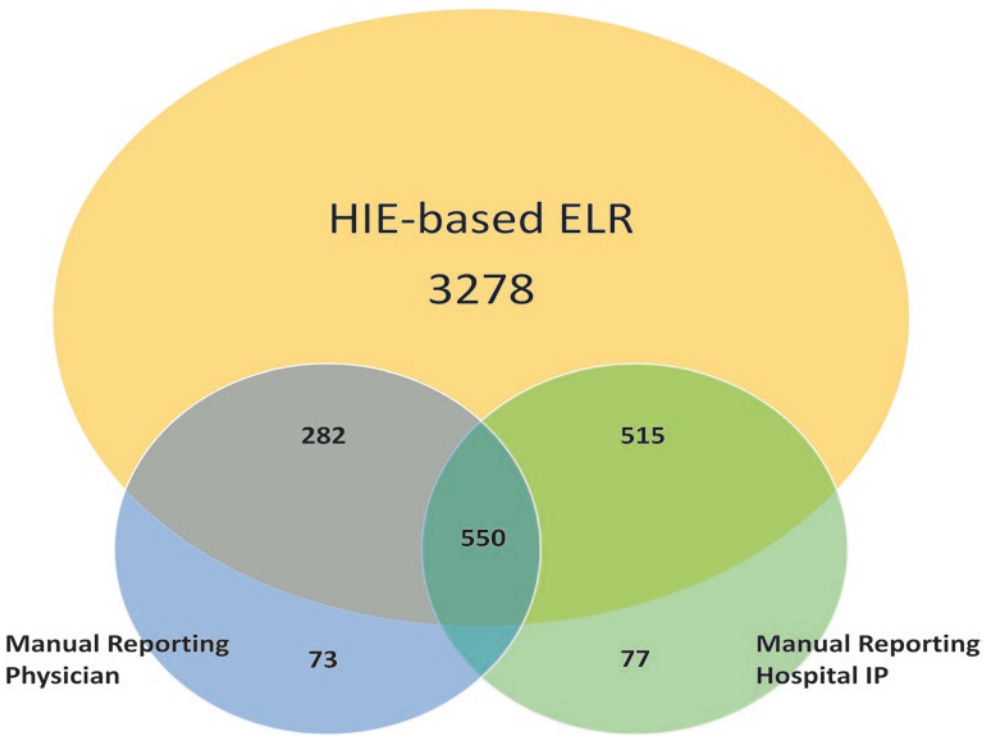

Fig. 25.2 Overhage and colleagues' comparison of ELR messages identified by an HIE to manually report cases from physicians and hospital infection control professionals [52]

at least two weeks for a case to be entered and sent to CDC for surveillance. Reporters and the public were shocked to find out that in 2020, the world relied on 1980s technology to track disease spread in communities.

To advance the transition to eCR, CDC and multiple health agencies are working to improve US public health infrastructure [35]. For example, the Digital Bridge initiative facilitates a series of pilot programs across the United States [36, 37]. Public health agencies receive structured eCR messages from hospitals exported from EHR systems. Major EHR vendors partnered with the Digital Bridge consortia to implement a standards-based data exchange on notifiable disease cases. A more experimental demonstration project involving CDC, Georgia Tech Research Institute, and the Regenstrief Institute leveraged the emerging standard FHIR (Fast Health Interoperable Resources, detailed in the chapter ***Health Information Exchange and Interoperability***) to query eCR data elements from an EHR after an ELR message is received from a physician practice [41]. In 2021 and beyond, these initiatives are hoped to bring production-grade solutions to HIE networks and EHR systems.

Syndromic Surveillance

Syndromic surveillance refers to a spectrum of processes that focus on real-time use of early disease indicators derived from prediagnostic data to detect and characterize events requiring public health investigation before definitive diagnoses are made [55]. Many states leverage syndromic surveillance systems for their entire populations [8, 57]. Furthermore, CDC created the National Syndromic Surveillance Program (NSSP) to support national surveillance efforts [38]. Local and state health agencies, as well as CDC, use the NSSP to monitor health trends.

Several studies demonstrate that electronic data from emergency department encounters, hospital admissions, and retail and pharmaceutical sales can signal the onset and evolution of disease outbreaks earlier than traditional surveillance methods [58]. Today, most syndromic surveillance systems utilize emergency department information in combination with hospital admissions data (e.g., ICD-10-CM codes). However, syndromic data can come from any one of the following sources [59]:

- Emergency department visits
- Laboratories
- Over-the-counter medication sales
- School absenteeism records
- Social media
- Emergency medical and management services
- Poison control center records
- Nurse call (triage) lines

The aforementioned data sources provide public health agencies with a wide range of structured and unstructured (free-text) data. Syndromic surveillance systems increasingly use NLP techniques to examine unstructured data to find disease indications or combinations of symptoms that constitute a syndrome (e.g., influenza-like illness). The performance of syndromic surveillance systems can be improved with better techniques for parsing and interpreting unstructured data. However, modern approaches are useful for tracking influenza and other seasonal illnesses, including heatstroke. Some health departments further use syndromic surveillance systems to identify bicycle accidents and food poisoning events.

Population Health Disease Registries

Population-based registries contain records for individuals residing in a defined geographical area who meet the criteria for a specific disease. Public health has traditionally maintained disease-specific population registries to support various public health functions, including traditional epidemiological analyses and emerging use cases that closely coordinate population health management with clinical stakeholders [60–62]. These registries increasingly rely on integration with electronic clinical systems.

Chronic Disease Registries

To allow public health officials to capture and analyze chronic disease data, the Council for State and Territorial Epidemiologists identified six categories of information captured by chronic disease registries: cancer, cardiovascular disease, tobacco and alcohol use, physical activity and nutrition, other diseases, and risk factors, and overarching conditions [63]. Because chronic disease registries span a wide spectrum of conditions, their implementation and supporting systems vary.

Immunization Registries

Immunization registries, often called IIS, have demonstrated the ability to increase population coverage rates for vaccines and mitigate the administration of duplicate immunizations [64, 65]. The Promoting Interoperability Programs encourage health care providers to transmit immunization records to IIS. The introduction of the COVID-19 vaccine in late 2020 also pushed many public health agencies to require electronic submission of vaccination data from hospitals, clinics, pharmacies, and local health agency sites where the vaccine was offered. Consequently, clinical care systems have deployed automated unidirectional electronic transmission of immunization data to public health. However, although routine bidirectional information exchange between clinical systems and IIS is not widely deployed, strategies for doing so are emerging [66, 67].

Cancer Registries

Cancer registries capture details on each cancer case in the United States to effectively monitor and address cancer burden, including patient history, diagnosis, treatment, and status. Data are first collected by local cancer registries and contribute to population-based registries. The data support various analyses, including determining cancer incidence, calculating survival rates, evaluating clinical outcomes, treatment modalities' efficacy, quality of life; assessing referral patterns; and informing geographic distribution of resource allocations [68, 69]. Although cancer case reporting is comprehensive, early case reporting can be delayed and incomplete [70, 71]. Electronic sources may help address these shortcomings [72].

Community Health Assessment

Integrating EHR data with non-clinical data holds great promise for addressing the social determinants of health (SDOH) [73] and health inequities such as lack of access for racial and ethnic minorities [74]. Although EHRs are rich in location-specific clinical data that allow us to uncover geographically dependent inequities in health outcomes, several other information systems outside of health care delivery complement those data to support analysis of community-level characteristics relating to health. For example, the US Census Bureau's American Community Survey captures data on education, housing, and transportation in a community at levels more granular than the ZIP Code. These SDH account for a significant proportion of a person's overall health and well-being. When meaningfully integrated, clinical and social determinant data enable clinicians, researchers, and public health professionals to actively address the social etiologies of health disparities [52, 75, 76] (see Fig. 25.3).

Although efforts are underway to increase support for capturing SDH data in EHR systems, some experts contend that the EHR may not be the best system for capturing and managing SDH data [77]. Instead, efforts are underway to enable EHR- and HIE-based tools that allow providers to identify patients at risk for social and behavioral needs [78] and connect them to services, including community-based organizations, that can address those needs in support of health and well-being. For example, Aunt Bertha (company.auntbertha.com) is a popular tool that allows medical practices to find social and behavioral services in the community to refer their patients. Tackling upstream problems, such as housing instability, through a population health program designed to address economic needs can reduce morbidity and increase life expectancy in a community when paired with robust screening and treatment plans for medical needs.

Contact Tracing Applications

The COVID-19 pandemic put a spotlight on contact tracing, a long-standing epidemiological process in which individuals with a newly diagnosed case of a notifiable disease are linked to their social network to identify individuals who may have transmitted the disease or those who may have received the disease. Contact tracing is an important tool for identifying sexual partners in cases of HIV, syphilis, chlamydia, and gonorrhea [79]. In previous outbreaks of international concern, including an Ebola outbreak in 2014 [80] and a measles outbreak on an international flight [81], contact tracing was considered to play a key role in identifying secondary cases.

The COVID-19 pandemic highlighted the need for better and more integrated digital contact tracing solutions that scale across local, state, and federal levels. Several countries, including Taiwan, South Korea, and China, touted the benefits of digital contact tracing apps in helping to flatten the curve in those nations [82, 83]. In the United States, Apple and Google provided tools to help states integrate contact tracing capabilities in mobile phones with case reporting systems. Yet, only a few states implemented the standards-based platform. Mistrust in big technology companies, fueled by concerns over privacy of the data captured in contact tracing apps, limited adoption and use of the technology in the United States [84]. So, although promising, digital contact tracing has a long way to go before it can be scaled and effective in the next global pandemic or national disease outbreak.

Toward Public Health Decision Support

As discussed in Chap. 7, clinical decision support (CDS) provides clinicians, staff, patients, or other individuals with relevant knowledge and person-specific information, intelligently filtered or delivered at appropriate times, to enhance health and health care decision making [85]. Among other quality and safety outcomes, CDS has been shown to effectively improve clinician adherence to preventive care guidelines and alert clinicians to potentially adverse medication outcomes [86–88]. Various forms of CDS have been introduced into current care processes through the implementation of EHR systems [89, 90].

Illustration

In recent years, the scope of CDS has been expanding to incorporate public health contexts and use cases. Traditional examples of patient-centered CDS alert clinicians when abnormal, unexpected, or harmful clinical results are noted,

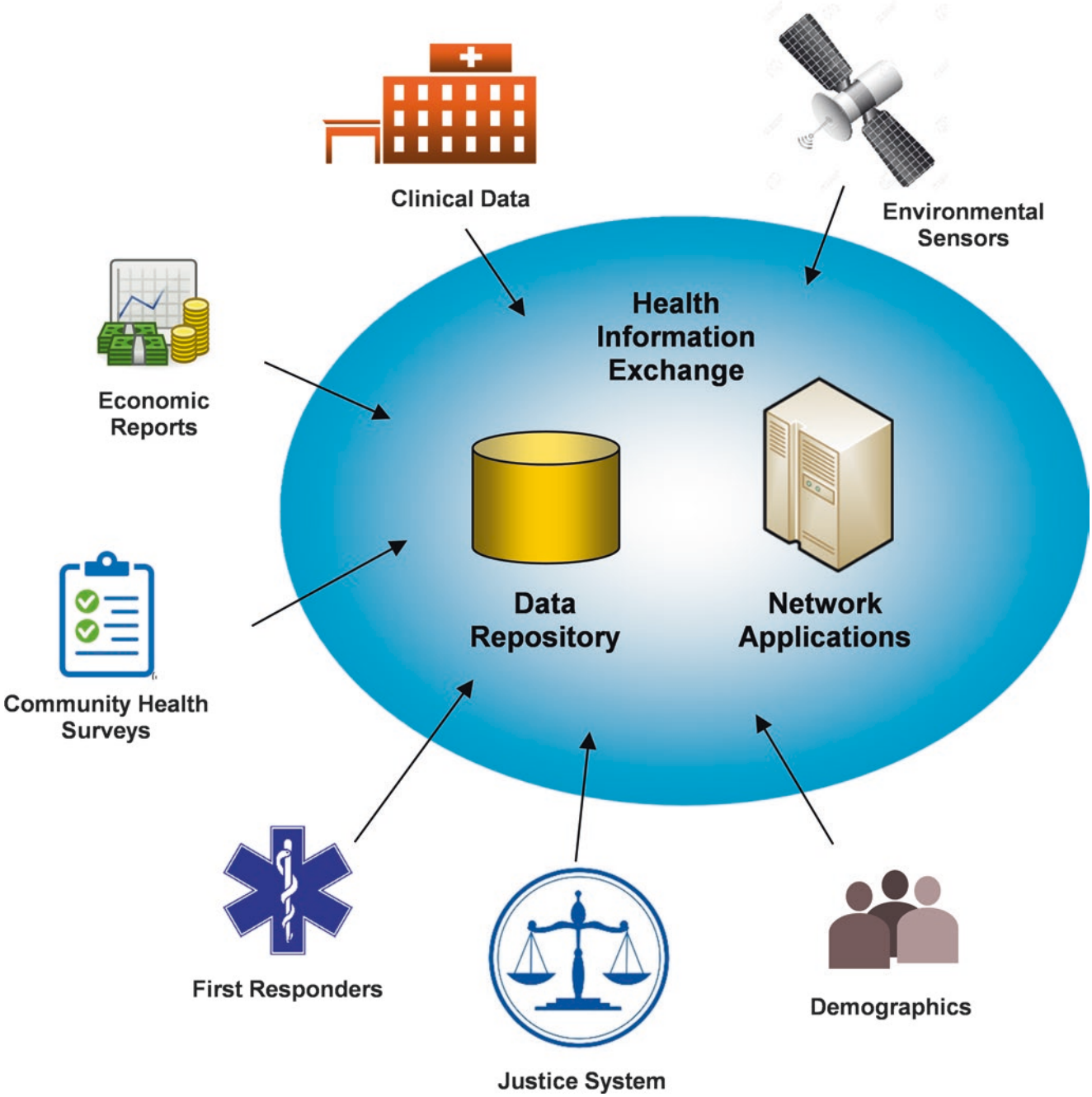

Fig. 25.3 Example of integration of different types of information in Indiana

such as when a laboratory value is out of the normal range or when a patient may be allergic to a newly prescribed medication. Extending that model, public health decision support (PHDS) can be exemplified in a scenario where clinicians receive an alert from the local health department that describes a newly discovered contaminant in the water supply that impacts neighborhoods near the clinic, placing its patient population at risk for waterborne illness. The alert may further recommend ordering stool samples for patients who present with gastrointestinal symptoms. This scenario illustrates computer-based PHDS, providing relevant knowledge to inform decisions involving the health and well-being of populations using electronic information [91].

Public Health EHR Alerting

The New York City Department of Health and Mental Hygiene developed and deployed 40 PHDS alerts, such as screening measures for influenza and pneumococcal vaccines, to more than 2000 physicians via commercial EHR systems [92]. This work enabled public health stakeholders

to distribute public health alerts during important events, such as infectious disease outbreaks.

Case Reporting Reminders

Conventional reporting processes require health care providers to complete paper-based notifiable condition reports, which are transmitted by fax and mail to public health agencies. These processes result in incomplete reports, inconsistencies in reporting frequencies among different diseases, reporting delays [93], and time-consuming follow-up by public health agencies to get needed information [94]. To address these issues, medical informatics scientists at the Regenstrief Institute electronically prepopulate report forms with available clinical, laboratory, and patient data to streamline reporting workflows, increase data completeness, and ultimately provide more timely and accurate access surveillance data for public health organizations. This work has continued to demonstrate promise as a resource to increase the frequency and reliability of reporting [95].

Infrastructure to Support Bidirectional Exchange

Although these examples highlight the promise of PHDS, to fully realize its potential, advanced clinical information systems must transmit data to public and population health systems and consume information from public health agencies. Immunization data exchange represents one such use case [96]. Today, many clinical systems transmit vaccination data to an IIS, which increased dramatically in 2021 due to COVID-19 vaccination efforts. Electronically exchanging information to and from public health, so-called "bidirectional communication" [97], requires a robust HIE infrastructure, which remains nascent in many communities.

Current public health infrastructures tend to focus on unidirectional approaches, maximizing the ability to receive and analyze health care data typically originating from clinical systems. Suboptimal and often manually intensive methods are used to communicate information back to providers. For example, health departments commonly send letters via US Mail when informing clinicians about events such as influenza disease burden and localized enteric outbreaks. These messages are likely to arrive outside of clinical workflow, making the information unusable by frontline clinicians. Furthermore, current methods may render the information obsolete if clinicians read it many days or weeks after the public health threat.

A more promising approach would leverage available population or contextual information to inform clinical decision-making in real-time. For example, a recent clinical trial could automate the query for adolescents' human papillomavirus (HPV) vaccination status [98]. The trial used the information to identify whether the adolescent in the pediatric clinic had received zero, one, or two doses of the HPV vaccine series. This information triggered a CDS prompt for the clinician to ask whether the adolescent and/or guardian would like to initiate or finish the vaccination series while in the office. The CDS prompt was effective [99], and the information further supported the delivery of educational resources to the adolescent and family while the patient awaited the provider in the exam room [100]. Targeting education and just-in-time prompts supported significant increases in vaccination rates, especially among boys who are often under-vaccinated for HPV.

Emerging Trends

As the context in which health care is delivered changes, the application of informatics to public and population health will evolve. Especially in the wake of the COVID-19 pandemic, broad changes to health care delivery and system reorganization are likely to impact public and population health efforts. For example, the pandemic highlighted the need for better system-level integration between hospitals or clinics and public health agencies [28]. Efforts within health systems to evolve EHR systems, expand telehealth services, and align operations with public health efforts to address SDOH will affect population health's information systems and informatics needs. In this section, we describe trends and emerging needs in public and population health informatics.

Post-Pandemic Recovery and Health System Evolution

The COVID-19 pandemic significantly affected health systems across the globe. Routine care, especially primary care, was disrupted, and urgent care facilities and hospitals were overrun with large populations in acute respiratory distress. By the time of this publication, the acute phase of the COVID-19 pandemic may have passed, and the next phase [101] of any pandemic is recovery.

Recovery from COVID-19 will take many forms, but fundamentally, it will require the evolution of the health systems. Scholars and health leaders in the United States have begun to advocate for a new health system that aligns with the Public Health 3.0 framework created before the pandemic by the US Department of Health and Human Services [102, 103]. The Public Health 3.0 framework urges a transformation in which there is a greater focus on building a culture of health, including cross-sector collaboration and an emphasis on health and health equity in all policies [28].

Implementing a new, evolved health system will require significant investment in information technologies and

infrastructure to support collaboration across health care delivery and public health. Not only will data need to flow seamlessly from clinical to public health operations, but knowledge from public health will also need to flow down to hospitals and clinics to keep providers aware of community health trends and incidents. Health care and public health systems will need to work together to address community health needs, including chronic disease burden. Immediately after the COVID-19 pandemic, we anticipate the nation's need to address mental health needs and pent-up demand for primary care services. There were national shortages of providers in both these areas before the pandemic, which will require health care delivery organizations to work closely with public health systems and community organizations (e.g., churches, Red Cross, older adult alliances) to organize efforts to screen, refer, and treat mental health disorders such as post-traumatic stress disorder, major depression, and anxiety induced by months of lockdown and/or social isolation. Primary care providers will be needed not only to support mental health needs but also to focus on preventive health needs for individuals who put off care during the pandemic and potentially exposed themselves to poor health behaviors, such as overeating, overconsumption of alcohol, and substance abuse, to mitigate impacts of the pandemic.

Information systems will play a critical role in standardizing and analyzing data and information captured across the health system and shared among the various private and public health partners. Interoperability will be critical to Public Health 3.0 efforts, requiring the development and use of standards and governance of information shared broadly across primary care, mental health, and public health providers (and community organizations). Referrals to public health and providers outside an integrated delivery network will be necessary to address patients' SDOH and community health needs fully. Documentation of those services provided outside clinical environments will need to be captured and shared with primary care and other providers. Patients will also likely share data and information on community and public health platforms that will require integration with clinical systems. All of these innovations are largely nascent with some current pilot work. Continued research and development will be necessary to realize the Public Health 3.0 concept.

Policy Landscape

The HITECH Act and related policy activities (refer to Chap. 3) enhanced the adoption and use of EHR systems in clinical settings. The meaningful use (MU) program enhanced health care delivery and public health activities within local and state health departments. For example, several MU criteria for public health, including syndromic surveillance and ELR, increased data transmission to public health authorities. At the same time, other MU measures, such as the requirement to document smoking status in the EHR, support public health authorities' capacity to aggregate data at a community level to monitor health behaviors and risk factors. Policies like MU are important to stimulate clinical–public health partnerships and interoperability.

The MU program sunset just before the COVID-19 pandemic. Currently, CMS encourages providers to send syndromic and eCR information to public health agencies through the Promoting Interoperability Program [20]. This program expanded the menu of public health options, which will continue to encourage interoperability between EHR systems and public health information systems. Public health agencies will receive billions in investment from CDC due to the American Rescue Plan Act of 2021. This legislation appropriated significant funding for data modernization efforts in local and state health departments. These efforts will likely focus on the information systems described in this chapter, strengthening efforts to streamline receiving ELR and eCR data from clinical providers. This will shift efforts away from faxing information to stronger integration with commercial EHR systems—finally!

The functions called out specifically in programs like MU and Promoting Interoperability are only the tip of the iceberg concerning PHI's possibility. For example, monitoring community levels of MRSA or antibiotic resistance is possible only when public health agencies can integrate data from multiple sources. Some health departments are using syndromic surveillance systems to capture not only data streams from emergency departments, hospitals, and primary care settings but also from poison control centers [104], over-the-counter pharmacy sales [105], and social media [106, 107]. Other ideas include merging geotagging or enhancing syndromic surveillance data with geospatial characteristics, with environmental information such as clean air ratings to support asthma management or extreme weather alerts to address heat- and cold-related injury and mortality. Newer uses of surveillance systems are in their infancy, necessitating more work to develop the most appropriate algorithms and methods for computing and inferring knowledge from the growing number of electronic data sources available to public health authorities.

Improvements in Technology

HIEs are playing an increasing role in coordinating care and in addressing outbreaks of disease. HIEs are gaining favor as the centralizing authority in a complex group of stakeholders that impact public health, including physicians, laboratories, and state and federal health agencies. As public health informaticians work to integrate these sources, COVID-19 has served as a catalyst to reconsider (and reconfigure) the policy and technology that drive interoperability [108].

Health care reform is similarly changing the relationship between clinical and public health informatics. The shift toward accountable care organizations has also brought the need for community health assessments at the hospital and health system levels—work that public health authorities Public health informatics: have traditionally performed. Change has ushered in new partnerships between health systems and public health, including much-needed resources to support health assessment in a community. The informatics front has also brought new ideas around how best to leverage EHR data for measuring health in a community. EHR systems and HIE networks might be sources of more objective data around health status or at least sources to complement the traditional population-based surveys conducted by public health authorities [109]. Such approaches are promising, but they need to be studied and refined over time. This is another area for collaboration between clinical and public health informaticians.

Technological changes will also impact PHI and the capture of electronic data for use in population health. The vast array of patient-centered devices and technologies (refer to Chap. 24) entering the market could open public health authorities to new sources of data on population behaviors and health status. For example, health agencies are increasingly interested in the potential of social media information and internet user search queries [109, 110]. In 2020, Zhang and colleagues identified 25 major themes to describe the use of data from social media platforms to supplement or develop public health research, including a variety of diseases and public health concerns [111]. In the context of health and disease outbreaks, social mobility refers to the movement of individuals and their proximity to others. Recent research has explored the use of mobile devices and mobile applications to assess the physical proximity of individuals during times where social distancing is recommended to prevent disease transmission using Twitter data and Google mobility data [112, 113]. Yet although there was initial promise and excitement with the release of data sources such as Google Flu Trends [114], later analyses concluded that "[Google Flu Trends] data may not provide reliable surveillance for seasonal or pandemic influenza and should be interpreted with caution until the algorithm can be improved and evaluated" [23]. There is an even greater promise with consumer devices such as the new Apple Watch and many Fitbit devices. These devices and new data sources will need to be evaluated and refined in the coming years to produce accurate, current assessments and predictive models of population health.

Consumer-facing mobile applications could impact public health by collecting information about vaccine hesitancy, mask-wearing, and social distancing during the COVID-19 pandemic. Various mobile applications have been developed, with research now emerging to explore the utility of this approach [115].

Improving Health Equity and Creating a Culture of Health

Health IT, and PHI by extension, can play a role in the reduction of health disparities. This can occur by identifying and addressing SDOH through technology-enabled assessments and interventions [116]. In addition, data standards that codify SDOH in EHRs are now supporting public health practice [117].

Summary

Information systems and technologies are revolutionizing the delivery of health care and the practice of public health. Just as we have observed a growing demand for informatics capacity in health care organizations, we have seen a similar process unfolding in the public health sector. Public health authorities today are using a growing array of information systems to capture, manage, use, and exchange data. Many of the data, like in medicine, are fragmented; and a growing number of new clinical and non-clinical data sources is on the horizon. There is an opportunity for clinical and public health informaticians to work together to incorporate novel uses of technology while enhancing the science and practice of public health, leading to better population health outcomes for communities.

Questions for Discussion

1. How does public health informatics complement clinical informatics? In what ways are they distinct?
2. What roles do various stakeholders and information systems play in public health informatics?
3. Why is increased electronic health record adoption important for public health informatics?
4. What is the importance of syndromic surveillance?
5. Which methods, tools, or systems from public health informatics might be useful for clinical informaticians within health systems?
6. How has COVID-19 changed public health information systems?

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Precision Health

26

Feliciano B. Yu Jr

Learning Objectives

- Define precision health and other related concepts.
- Describe the components that enable precision health to flourish.
- Present clinical examples of the application of precision health.
- Identify the healthcare informatics and technology considerations that support precision health.
- Discuss the barriers and future opportunities of precision health.

Practice Domains: Tasks, Knowledge, and Skills

- Domain 4: Data Governance and Data Analytics
  - 4.05. Access and incorporate information from emerging data sources (e.g., imaging, bioinformatics, internet of things (IoT), patient-generated, social determinants) to augment the practice of precision medicine
  - K108. Precision medicine (customized treatment plans based on patient-specific data)

Case Vignette

Sid is a 16y/o boy who is currently being treated with atomoxetine in the adolescent clinic for Attention-Deficit Hyperactivity Disorder (ADHD) at your healthcare institution. His parents report that he has been on this medication for over a year, and they have not observed any significant changes in his behavior in school and at home. His parents also noted that he has recently lost weight, constantly complaining of vague abdominal pains, headaches, and feeling fatigue, especially after his atomoxetine dose was increased a few weeks ago. The physician suspects side effects from the medication. Learning about the recent pharmacogenomics pilot in the health system, the physician wondered if Sid is a candidate for pharmacogenomic testing. Upon discussion with Sid's parents, a blood sample was taken and sent for genetic analysis. The laboratory test result returned, documenting that Sid has the genetic mutation that causes decreased CYP2D6 enzyme activity ("poor metabolizer"), leading to increased levels of atomoxetine and increased risk of side effects compared with the increased risk of side effects CYP2D6 normal metabolizers. Learning about this test result, the physician contacted his parents and decided to discontinue atomoxetine and move the patient to an alternative medication.

Your health system's clinical and research leaders plan to invest in a precision health pharmacogenomics program to pave the way for "personalized medicine." As their CMIO, you were asked to present the informatics infrastructure needed to support such a program. The leaders want to use the patient's genetic data to determine the best treatment options for improving outcomes and minimizing adverse drug reactions. They want to pilot their pharmacogenomics program on patients with behavioral problems. ***How would you explore this opportunity and present an informed discussion regarding the required informatics infrastructure to support the effort?***

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Introduction

Precision Health (PH) offers a very broad and all-encompassing view of health, and it has very important considerations for clinical informatics. It aims to support individualized care to address wellness opportunities and provide targeted therapies to prevent, predict, and treat diseases. At the same time, it provides "dynamic linkages between research and practice as well as medicine, population health, and public health" [1]. This integrated view of health also incorporates a wide swathe of efforts, ranging from promoting health, preventing, diagnosing, and treating illnesses using actionable data derived from genomics, environmental, behavioral, and social antecedents of health and diseases.

PH is often interchanged with terms like "Personalized Medicine" or "Precision Medicine". While they may be similar in some respects, Personalized Medicine is concerned with a medical practice that leverages the patient's "genetic profile to guide decisions made regarding the prevention, diagnosis, and treatment of disease" [2]. Similarly, providing an updated view of personalized medicine, Precision Medicine is concerned with treating and preventing diseases by factoring in the patient's variations in genetic, environmental, and lifestyle considerations [3].

It is also noteworthy to distinguish between "genetics" and "genomics", as they are often coined interchangeably. The World Health Organization (WHO) describes that the "main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene whereas genomics addresses all genes and their interrelationships to identify their combined influence on the growth and development of the organism" [4]. Genetics is concerned with the hereditary aspects of the genes and their health effects. In contrast, genomics, a more recent term, is concerned with the patient's whole genome, including the genetic interaction between the individual's genes and the environment [5]. Genes undergo mutation in somatic or germinal tissues. Somatic mutations are not hereditary, whereas germline mutations can be transmitted from parent to offspring [6]. For example, some mutations are acquired after birth (somatic), causing cancer in specific cells in the body. Cancer cannot be inherited by offspring.

On the other hand, mutations in the germ cells (via parent's eggs and sperms) are represented in all offspring cells. Its presence predisposes the offspring to certain diseases, depending on its gene expression or whether the mutation is an inherited dominant or recessive trait. Distinguishing between the two types of mutation is important in counseling the family regarding the risk of transmitting the mutation and taking proactive measures to reduce the risk for those with hereditary or germline mutations.

Precision Health

One of the main goals of PH is the ability to tailor the care plans based on the individual's specific risks and predisposition, including the person's genes, environment, and lifestyle. PH is often contrasted with "Population-based" healthcare, where care is often ascribed to a "one-size-fits-all" approach, in contrast with the "tailored" approach in PH. For example, in population-based healthcare, typical recommendations of a healthy diet, exercise, smoking, and alcohol consumption is standard fare, including following clinical pathways and care guidelines for specific disease processes. With the advent of more precise health markers such as genetic mutations, blood types, and other biologic indicators, it is possible to "tailor" the treatment based on the specific individual risk profiles. More importantly, in PH, it is also possible to identify the individual's specific gaps in their behavioral, social, and environmental determinants of health and further design the interventions based on the person's needs, hence the term "one-size-does-NOT-fit-all". PH seeks to leverage molecular, digital, and epidemiological information to manage and personalize the care to the individual.

The goal of PH includes the prediction, prevention, and treatment of disease so that the individual patient can maximize health and wellbeing. It considers the variables beyond healthcare and genetics medicine and includes social, environmental, and behavioral determinants of health, thereby expanding the lens of health from a broader perspective. PH is concerned with (1) predicting disease risk or preventing disease onset before the disease symptoms become apparent, (2) detecting disease onset as soon as it is clinically present and being able to provide a set of differential diagnoses, and (3) treat the disease with utmost precision and efficacy, while avoiding adverse events.

"Imprecision" Healthcare

Today's "one-size-fits-all" approach to medicine is considered "imprecise healthcare", where treatment interventions are aimed at a specific disease population under very common and generalized scenarios. This means that, on average, the treatment will be efficacious in generalizable clinical settings. The Number-Needed-to-Treat (NNT) is often used to measure the efficacy and safety of the medical intervention [7]. It is the average number of patients who need to be treated to avoid one additional adverse outcome. An NNT of 1 is the perfect treatment where all patients who received the intervention improved, whereas an NNT of 100 means that you have to treat 100 people to prevent one additional adverse outcome. The rest of the patients would not have benefited from the treatment or could even suffer an adverse effect. For example, the NNT to prevent one atherosclerotic cardiovascular disease for the cholesterol-lowering class of statins

over ten years ranges from 3 to 61, depending on other patient risks and associated cholesterol levels [8].

Precision health is an alternative "one-size-does-NOT-fit all", where the treatment is tailored to the individual's specific risk profiles. Hence, patients with a specific mutation on the gene SLCO1B1 are more likely to incur statin-induced myopathy. Learning about this unique aspect of the individual offers an opportunity to present a specific set of recommendations. Therefore, learning about the patient's genetic predispositions can maximize drug efficacy and improve safety [8].

It is often believed that the patient's zip code is a major determinant of health. For example, the "Delmar Divide" in St. Louis, MO depicts a stark contrast between economic, literacy, and health outcomes of people living in the neighborhoods north of the Delmar Boulevard, where it is predominantly poor and African American, less educated, and individuals have a higher prevalence of heart disease and cancer, compared to the people living south of the Delmar Divide, where they are more white and more affluent, with better educational status, and health outcomes [9]. PH envisions a future wherein healthcare is focused on the treatment of the disease and considers the patient's genetic code and lifestyle as inputs into the calculus for improving health.

The ability to access the patient's genome, phenome, biome, and home (i.e., social determinants of health, environment, lifestyle) data and information can provide a more holistic view of the individual's health and healthcare opportunities.

PH Is an Informatics Opportunity

Clinical informatics is the application of computer science and information technology in healthcare [10]. Furthermore, clinical informaticians are concerned with the analysis, design, implementation, and evaluation of clinical information systems to improve the quality and safety of care, enhance the patient-provider experience and improve individual and population health outcomes [11]. As PH becomes more ingrained into clinical practice, informaticians will be intimately involved in the planning, design, implementation, optimization, and evaluation of the PH tools. Being an interprofessional field of practice, informaticians coordinate and integrate knowledge about the different variety of domains involved in PH; they are also vital in the optimal delivery of clinical decision support aimed at predicting, preventing, and treating diseases [12].

It is estimated that medical knowledge will double every two months [13]. To support the full breadth of PH, clinicians must be able to integrate a broad range of information pertinent to the individual's care delivery, including not only medically relevant information but also considering the biomedical, social, environmental, and behavioral determinants of health [14]. This is a great opportunity for informatics and how clinical decision-making can be best supported by an information resource that complements the limitations of human cognition [15].

Big data and PH are linked together. The recent increase in the adoption of electronic health records presents an opportunity to cultivate large data sets for healthcare analytics, natural language processing, machine learning, and artificial intelligence [16]. Clinical informaticians supporting PH will be increasingly skilled in using data science tools to support the growth of computable health care data and information resources [17]. In addition, the disparate nature of the healthcare data supporting PH will need robust interoperability and integration profiles. Combining data sets from different sources, such as the genome, phenome, social, environmental, or electronic health records, will need modern informatics and data science tools to transform these vast heterogeneous datasets into meaningful and actionable knowledge [18]. The rapid advancement of healthcare-related data science technologies presents a great opportunity to apply predictive analytics to support integrated precision medicine and population health initiatives [19]. Healthcare data science will be among the important core competencies of informaticians in the era of PH [20].

Precision Health Examples

Oncology

The promise of identifying the specific genetic sequence mutation that predisposes a cell to turn cancerous and target treatments to address the molecular aberration is a goal of precision oncology [21]. A mutation in the Bcr-Abl tyrosine kinase gene was identified as the trigger for chronic myelogenous leukemia, previously thought to be untreatable. The drug imatinib is cytotoxic to cells containing the Bcr-Abl, thereby selectively inhibiting tyrosine kinase activity in leukemic cells [22]. The BRCA genes (short for "BReast CAncer") are known to suppress cancer growth in cells via DNA repair functions. A mutation in the BRCA genes has been associate with a person's risk for breast cancer [23]. Learning about this mutation early allows for early detection and treatment, reducing the potential health risk to patients and their families.

Immunology

Advancements in understanding how the immune system mediates the expression of cancer and other immune system diseases led to several novel and targeted precision immunotherapies [24]. For example, our immune system is regulated by stimulating or inhibiting the function of the cell's immune receptors. Monoclonal antibody drugs such as pembroli-

zumab and nivolumab bind to specific receptors on lymphocytes and blocking the effects of immune-suppressing ligands, thereby restoring T-cell response [25]. Compared to traditional chemotherapy and radiotherapy, immunotherapy harnesses the patient's natural immune cells to selectively target cancerous and avoiding normal cells, making the treatment safer and more effective.

Infectious Diseases

Precision medicine advancements in infectious disease therapy are brought about by integrating molecular and genomic technologies and applied to individual patient care and population health. More precise diagnostic tests that detect pathogenic DNA or RNA via microbial nucleic acids, broader and more rapid testing offers rapid pathogen identification, exact antibiotic selection, developing better vaccines, leading to early diagnosis, more effective use of medications, and reduce disease burden. For example, the traditional way of detecting bacterial pathogens is through plating and culture methods, where the "detection" is made by humans inspecting the organism growth in the culture medium. This has built-in delay and uncertainty due to observer and process variability. Detecting the specific nucleic-acid signature of the bacterial pathogen's DNA offers a more rapid, accurate, and precise detection [26].

Pharmacogenomics

Pharmacogenomics is a promising field in medicine that utilizes the knowledge of the individual's genetic makeup to help predict the likelihood of adverse drug events or subtherapeutic response to treatment [27]. As described in the clinical vignette early in the chapter, pharmacogenomics contributes to precision health vision by targeting therapies based on the patient's specific genetic predispositions and associated response to the medication. For example, patients with sickle cell disease are often plagued with recurring pain crises, and it is typical to manage the pain with the opioid drug codeine. Codeine is metabolized to morphine primarily by the cytochrome P450 2D6 (CYP2D6) enzyme. A mutation in the CYP2D6 gene can affect enzyme activity. Depending on the variant, it can lead to either a decrease or increase in drug metabolism, causing ineffective treatment or increased side effects, respectively [28].

Antecedents to Precision Health

The current advances in biomedical and health information technologies, increasingly available computable biomedical data, changing regulatory programs, advances in high-performance computing resources, and data science set the foundation for innovations in precision healthcare.

Biomedical Knowledge and Scientific Discovery

The healthcare industry has seen rapid development in all areas of biomedicine due to advances in technology. One of the more recent examples of informatics-led precision immunology is mRNA technology in developing the COVID-19 vaccine [29]. Immediately upon discovering the SARS-CoV-2 gene sequence, the scientific, healthcare, governmental, and drug companies worked together and developed the COVID-19 vaccines with great speed and immunogenic efficacy [30]. We now have the technology to accelerate vaccine development in a faster, more effective manner.

Following ongoing trends in genomic medicine, genome data has become more affordable. As of August 2020, the National Human Genome Research Institute (NHGRI) reported a continued downward trend in genome sequencing cost, with a rate of declining cost better than Moore's Law (Fig. 26.1). It has also made genome data are more available now more than ever [31] (Table 26.1).

There are more publicly available clinical data sets available to scientists and researchers. For example, the National Institute of Child Health and Human Development (NICHD) established the Data and Specimen Hub (DASH) to provide online access to data from its research and provides several resources and tools (tissue banks and repositories, datasets, and databases, model organisms, genome and DNA sequences, and resource libraries) for researchers [32]. It includes, among others, every data produced by the Adolescent Brain Cognitive Development (ABCD) Study, which is a landmark, longitudinal study of brain development and child health [33]. Another publicly available clinical dataset is MIT's Medical Information Mart for Intensive Care (MIMIC) database [34]. MIMIC is a robust collection of de-identified clinical information derived from a large academic medical center's intensive care units. Data from the dataset is used by teaching institutions, researchers, and by quality and safety stakeholders [35].

Digital and Information Technology

The continued rise in digital technologies continues to drive innovation in all sectors of our society. During the COVID-19 pandemic, the digital platforms were ready to support the societal and public health endeavors needed to adjust to the crisis. Work/learn from home, social distancing, and lockdown protocols necessitated digital technologies such as video conferencing, eCommerce, online entertainment, cloud computing, among others, to flourish [36]. Telehealth

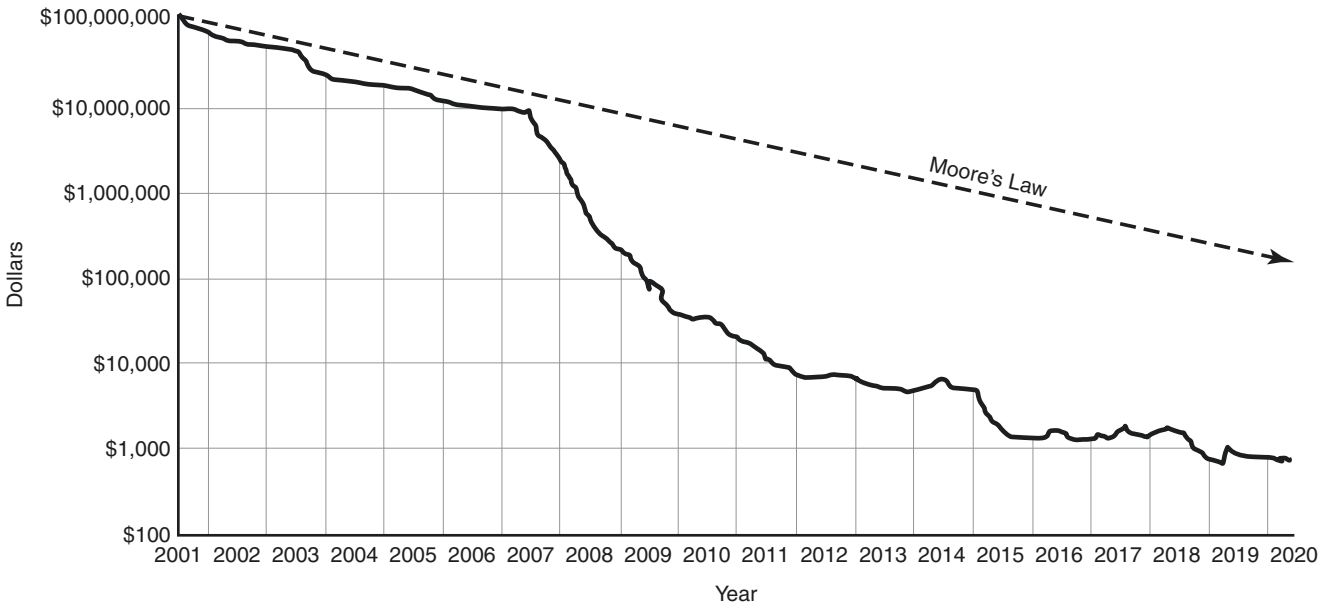

Fig. 26.1 Cost of Genome Sequencing. The decreasing costs associated with genomic tests allowed providers and patients to assess individual risks to medications (pharmacogenomics), learn about familial relationships (genealogy), as well as confirm presence or absence of genetic marker associated with diseases and other individual risks to health. Source: The National Human Genome Research Institute (NHGRI)

Table 26.1 Examples of online genomic research resources

Resource	URL	Notes
The National Human Genome Research Institute (NHGRI) Genome Sequencing Program (GSP)	https://www.genome.gov/Funded-Programs-Projects/NHGRI-Genome-Sequencing-Program	Genome sequencing projects currently in production and funded by NHGRI.
National Center for Biotechnology Information (NCBI) Human Genome Guide	https://www.ncbi.nlm.nih.gov/genome/guide/human/	One-stop shop for browsing online information about the human genes
University of California Santa Cruz (UCSC) Human Genome Browser Gateway	http://genome.cse.ucsc.edu/cgi-bin/hgGateway	Human genome browser, as well as other species
Ensembl Human Genome Server	http://useast.ensembl.org/Homo_sapiens/Info/Index	Human genome browser, as well as other species
GeneMap99	https://www.ncbi.nlm.nih.gov/projects/genome/genemap99/	A New Gene Map of the Human Genome
Marshfield Comprehensive Human Genetic Maps	https://www.biostat.wisc.edu/~kbroman/publications/mfdmaps/	Contains links to comprehensive human genetic linkage maps

The links above are examples of genomic online resources compiled by the National Human Genome Research Institute (NHGRI). The NHGRI NHGRI is also at the forefront of exploring the ethics, legal, social aspects of genomics, as well as leading the efforts in genomic research and education. The NHGRI website is a good resource for informaticians wanting to learn about the role of genomics in precision health.
Source: The National Human Genome Research Institute (NHGRI). https://www.genome.gov/10000375/online-research-resources#nhgri. Accessed 25 Jun 2021

technologies became a key modality to provide continuity of care during the pandemic [37]. This digital front is also driving fast-paced growth with consumer technologies. Consumer spending on technologies in the US posted over $420 billion in record sales in 2020 and is projected to increase to $460 billion by the end of 2021 [38].

Big tech companies are adopting healthcare once again. Fueled by the pandemic and healthcare consumers' and providers' heavy reliance on a digital platform to support business continuity, 2021 saw the shift of efforts by big tech to adopt healthcare solutions. Amazon, for instance, is moving into the urgent and primary care services with Amazon Care for patients and leveraging their cloud computing platform in offering data science and analytics services with Amazon Healthlake [39, 40]. Apple is leveraging its consumer-facing products to link patient data to healthcare providers, researchers, and payers [41]. As early as iOS version 11.3 in 2018, Apple has opened its Health app to interoperate with EHRs, interfacing via HL7 CDA (Clinical Document Architecture) and FHIR (Fast Healthcare Interoperability Resources) standard [42]. Google Health leverages Alphabet's artificial intelligence tools to improve consumer and healthcare providers to support search and research activities to improve health [43]. Finally, Microsoft leveraged its cloud computing

technologies to provide healthcare institutions the ability to manage their healthcare data [44]. For their natural language processing and healthcare artificial intelligence products, they also recently acquired Nuance to increase their presence in the healthcare market and beyond [45]. Meanwhile, IBM's Watson Health continues to innovate on its artificial intelligence capabilities, despite growing concerns about its ability to provide accurate clinical treatment advice [46, 47, 48].

Social and Environmental Determinants of Health Data

According to the U.S. Centers for Disease Control and Prevention (CDC), social determinants of health (SDOH) are the "conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes" [49]. Scientists and researchers can have access to SDOH data sets available from CDC and AHRQ [50, 51]. (Table 26.2) Integrating disparate data sources at the patient level requires robust patient identification protocols and interoperability standards, as well as data sharing, privacy/confidentiality preserving policies. To address the technical and implementation aspects of SDOH data sharing, the U.S. Office of the National Coordinator for Health Information Technology (ONC) has established a set of programs that can serve as a foundation and a catalyst for the capture, sharing, and use of SDOH with health IT [52].

Changing Regulatory Efforts

Governmental and regulatory efforts that promote the use of health IT are very important in creating PH conditions. Adopting healthcare standards for interoperability, health information exchange, privacy and security policies, patient identification standards are crucial to integrating disparate data about the individual and population health.

The integration of disparate data sources that will enable the coordinated care that supports PH must be supported by robust interoperability standards. The information exchange must support syntactic and semantic data transfer, allowing for the clinical, genomic, social, and environmental data to be used to coordinate care from the individual patient to the public health level. An itemized list of the clinical systems interoperability standards useful for PH can be found in Table 26.3.

The Health Information Technology for Economic and Clinical Health (HITECH) Act was implemented as part of the American Recovery and Reinvestment Act of 2009 to incentivize providers and hospitals participating in Medicaid and Medicare programs to adopt and meaningfully use of certified health information technology and electronic health records [53]. The HITECH Act also included disincentives or penalties for non-compliance in the latter phases while promoting the documentation and submission of electronic clinical quality measures [54]. By 2017, towards the end of the program, 96% of the community hospitals in the US and 86% of office-based providers have adopted EHR under the incentive program, paving the way for the increased EHR functionality and adoption of interoperable systems that allow for electronic submission of population-based health measures, patient electronic access to their health information, bidirectional EHR communication with immunization registries and health information exchanges, as well as increased e-prescribing capabilities, among others [55]. In 2018, the program was renamed as Promoting Interoperability Program to align more with ongoing federal programs and set the sights beyond the HITECH act focusing on furthering the EHR-based measurement program, adopting robust interoperability functionalities, and improving patient access to their own personal health information [56]. In concert with other public and private health IT adoption efforts, the incentive programs allowed for the rapid increase in EHR uptake by healthcare providers and institutions. Coupled with the adoption of interoperability standards, this led to the increase in the availability of computable clinical data that can be used to advance quality and safety initiatives, care coordination activities, data mining, and analytics and foster the clinical data foundations for precision health.

The 2015 Precision Medicine Initiative, spearheaded by the Obama administration, was launched to include a broad set of initiatives that can serve as a substrate for the adoption of precision health. The initiatives include programs that will advance clinical science, informatics, advocacy, and policies supporting individualized care [57]. The Precision Medicine Initiative envisions a future where clinicians can customize the prevention, treatment, and coordination of patient care based on the "unique characteristics, including their genome sequence, microbiome composition, health history, lifestyle, and diet" of the individual patient [58]. The program rightfully identified the informatics infrastructure needed to support the integration of a variety of data types, including clinical data, microbiome, metabolome, among others, and the interoperability standards that support the secure exchange of data for clinical and research purposes.

The twenty-first Century Cures Act was established into law on December 16, 2016, to hasten the development of medical innovations (drugs, devices) and deliver healthcare products to patients more efficiently. The law also included health IT provisions for the ONC to establish programs to increase the adoption of technology standards that ensure patients' access to their healthcare information [59]. Adopted broadly by the healthcare industry in the latter part of 2020, the "information blocking" provisions of the Cures Act was

Table 26.2 Examples of Social Determinants of Health (SDOH) data sources

Data resource	URL	Level of data available	Notes
Chronic Disease Indicators	https://www.cdc.gov/cdi/index.html	state, territory, select large metropolitan areas	Publicly available state and selected metropolitan-level data for chronic diseases and risk factors, including overarching conditions such as SDOH.
Chronic Kidney Disease (CKD) Surveillance System	https://nccd.cdc.gov/CKD/default.aspx	national	National database that offers interactive, trending, surveillance information on CKD, it's risk factors and complications. It also includes SDOH information such as household food insecurity score.
Compendium of Federal Datasets Addressing Health Disparities	https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=4	multiple	Established by the Interdepartmental Health Equity Collaborative (IHEC) and the HHS Office of Minority Health to foster inter-agency efforts and provides data about the socioeconomic factors, social determinants of health, and health equity, including > 250 available databases containing population-based opioid use/research, and other biorepositories
Disability and Health Data System (DHDS)	https://www.cdc.gov/ncbddd/disabilityandhealth/dhds/overview.html	state	State-level database containing information about adults with disabilities (six functional disability types: cognitive, hearing, mobility, vision, self-care, and independent living) as well as other adult health topics including smoking, obesity, heart disease, and diabetes. DHDS allows customizable data maps, charts, and tables, as well as categorize by disability, age, gender, race and ethnicity.
500 Cities: Local Data for Better Health	https://www.cdc.gov/places/	city, census tract	Database containing city- and census-tract-level small area estimates for chronic disease risk factors, health outcomes, and clinical preventive service use for the largest 500 cities in the US. It also includes health insurance status.
Interactive Atlas of Heart Disease and Stroke	https://nccd.cdc.gov/dhdspatlas/	national, state, territory, county, census tract	Contains county-level mapping of heart disease and stroke by race/ethnicity, gender, and age group, including social and economic factors by census tract and county along with the locations of health services.
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) AtlasPlus	https://www.cdc.gov/nchhstp/atlas/index.htm	national, state, select territories	Provides information to CDC's surveillance data on HIV, viral hepatitis, sexually transmitted diseases (STDs), and tuberculosis (TB), including social and economic data. Users can view interactive maps, graphs, tables, and figures showing geographic patterns and time trends.
National Environmental Public Health Tracking Network	https://ephtracking.cdc.gov/	national, state, county	Integrated online data on population-based health, exposure, and hazard information and data from a variety of national, state, and city sources, including maps, tables, and charts with data about environmental indicators (e.g., particulate matter in the air).
The Social Vulnerability Index	https://www.atsdr.cdc.gov/placeandhealth/svi/index.html	census tract	Contains US census data about specific community's predisposition to require help during external stresses as natural or human-caused disasters, or disease outbreaks. Users can use this information to estimate human suffering and economic loss during disasters.
Vulnerable Populations Footprint Tool	https://www.communitycommons.org/collections/Maps-and-Data	state, county, city, census tract	Interactive tool that identifies poverty rates and low education levels in specific areas.
Social Determinants of Health Database (Beta Version)	https://www.ahrq.gov/sdoh/data-analytics/sdoh-data.html	county, zip code	Comprehensive online resource established by the Patient Centered Outcomes Research (PCOR) Trust Fund at the Agency for Healthcare Quality and Research (AHRQ). It contains SDOH domains such as social context (e.g., age, race/ethnicity, veteran status), economic context (e.g., income, unemployment rate), ncing the visioneducation, physical infrastructure (e.g., housing, crime, transportation), and healthcare context (e.g., health insurance).

Social determinants of health (SDOH) data are not routinely gathered in computable forms in the electronic health record. The data sets that are available in the links above are examples of data resources that can help the clinical informatician learn about the types of SDOH information that can impact precision healthcare delivery.
Source: Centers for Disease Control and Prevention. https://www.cdc.gov/socialdeterminants/data/index.htm. Accessed 25 May 2021
Agency for Healthcare Quality and Research. https://www.ahrq.gov/sdoh/data-analytics/sdoh-data.html. Accessed 25 May 2021

put in play by ONC to allow for immediate and timely electronic access to patient data, as well as establishing HIT certification criteria for software applications to integrate with EHRs via application programming interfaces, or APIs. This has broad implications not only for the ability of patients to gain access to their own healthcare data but also allows the patients to use interoperable software to access disparate sources of data via standard APIs.

Table 26.3 Examples of interoperability standards relevant to precision health

Standards	Notes
Vocabulary/Terminology Standards	
Current Procedural Terminology (CPT®)	Billing codes for healthcare procedures maintained by the American Medical Association (AMA)
Healthcare Common Procedure Coding System (HCSPCS)	Healthcare procedure codes for Medicare services, maintained by the Centers for Medicare & Medicaid Services (CMS)
The International Statistical Classification of Diseases and Related Health Problems (ICD)	Code sets for classifying diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. Maintained by the World Health Organization (WHO), its current version is ICD-10; ICD-11 is targeted to be available in January 2022.
Logical Observation Identifiers Names and Codes (LOINC®)	Code sets for health measurements, observations, and documents, maintained by the Regenstrief Institute.
National Drug Code (NDC)	Codes for medications that are manufactured, prepared, propagated, compounded, or processed for commercial distribution, maintained by the US Federal Drug Administration (FDA)
RadLex	Radiology code sets for indexing and retrieval of radiology information resources, maintained by the Radiological Society of North America. It complements other standard code sets such as SNOMED-Clinical Terms and DICOM.
RxNorm	Terminology for clinical drugs, maintained by the US National Library of Medicine. It specifies standard codes and identifiers for the combinations of ingredients, strengths, and dose forms of medications in the US market.
Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)	Code sets for clinical concepts, maintained by The International Health Terminology Standards Development Organization (IHTSDO). Often used by EHRs to represent computable clinical concepts. SNOMED codes are often considered as the "answers" to the "questions" posed by the lab tests posed by LOINC terms.
CVX and MVX vaccine codes	Codes for vaccines [Vaccines Administered (CVX)] and manufacturers [Manufacturers of Vaccines (MVX)], maintained by the Centers for Disease Control and Prevention (CDC), useful in bidirectional immunization registry interoperability efforts.
The Unified Code for Units of Measure (UCUM)	Code sets for units of measures used in international science, engineering, and business, typically adopted by other standards such as DICOM, HL7 to support semantic interoperability. Maintained by the Regenstrief Institute and the UCUM Organization.
Content Standards	
HL7 Version 3 Clinical Document Architecture (CDA®)	An XML-based document markup HL7 standard that provides specifications for the structure of clinical data, or "CDA documents", while maintain semantic interoperability during health information exchange between clinical information systems.
Consolidated CDA (C-CDA)	A package containing a library of standardized HL7 CDA formatted documents (care plan, consult note, continuity of care, diagnostic imaging report, discharge summary, procedure note, history and physical, operative note, progress note, transfer summary), used by certified EHRs in compliance with Meaningful Use. The CCDA incorporates references to terminologies and value sets required by federal HIT program.
HL7 Version 2.x (V2)	A widely adopted health industry messaging standard that provides specifications for the exchange of administrative and clinical data between clinical information systems.
HL7 Fast Healthcare Interoperability Resources (FHIR)	A recent and upcoming standard in HL7 that codes for resources (file format and data elements) and application programming interface (API) specifications EHR interoperability. The HL7 FHIR Release 4 version includes standards for collecting, coding and retrieving genomics data (FHIR Genomics)
The Global Alliance for Genomics and Health (GA4GH) Browser Extensible Data (BED) Format	The GA4GH is a policy-framing and technical standards-setting institution that promotes responsible sharing or genomic data. It has established an API and data model (GA4GH BED, currently on version 1.0) for the exchange of full sequence genomic information across multiple research organizations and platforms.
Transport Standards	
Digital Imaging and Communications in Medicine (DICOM)	The standard for communicating and managing medical imaging information and related data. DICOM is used for storing and transferring of medical images across systems and devices (scanners, workstations, network, picture archiving and communication systems, or PACS). DICOM is maintained by the American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA).
Direct Secure Messaging standard	Direct is a health information exchange (HIE) HIPAA compliant standard messaging protocol that allows providers to securely move healthcare information to other providers over the internet using encryption services, usually as part of complying with federal health IT mandates such as Meaningful Use. Just like a regular email services, the Direct messaging is managed by a Health Information Service Provider, or HISP, which an accredited network service operator that enables nationwide clinical data exchange using Direct Secure Messaging (aka Direct, Direct Messaging and the Direct Project).

Table 26.3 (continued)

Standards	Notes
HL7 Fast Healthcare Interoperability Resources (FHIR®)	See above.
Privacy and Security Standards	
HIPAA Privacy Rule	Defines the national standards to safeguard patient's medical records and other personal health information. It applies to health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. It defines how institutions use and disclose health information without patient authorization. It also provides patient's the rights to manage how their personal health information (PHI) is used by healthcare institutions. In 2013, the Privacy Rule was modified to include genetic information as PHI.
HIPAA Security Rule	Defines the national standards for safeguarding the confidentiality, integrity, and availability of electronically protected health information. It requires institutions, or "covered entities", to have the technical and non-technical mechanisms to secure patient's protected health information.
General Data Protection Regulation (GDPR)	The GDPR is a regulatory effort that defines the privacy and security regulations for managing data about individuals in the European Union (EU). This data includes healthcare information.
Genetic Information Nondiscrimination Act of 2008 (GINA)	In Title II of GINA, it is illegal to discriminate against employees or applicants because of genetic information. Law took effect in the US on November 21, 2009.
The Freedom of Information Act (FOIA)	The Cures Act provided provisions to amend the Section 301 of the Public Health Service Act to include genomic information as exemptions from FOIA requests.

Integrating information across disparate data sources will require syntactic and semantic interoperability. More importantly, as more computable information is exchanged between healthcare information systems, it is vital to ensure that the patient's privacy and confidentiality preferences are protected during health information exchange

Adapted from The Healthcare Information and Management Systems Society (HIMSS): Interoperability in Healthcare. https://www.himss.org/resources/interoperability-healthcare. 7 Jun 2021

The HIPAA rules that were defined in 1996 were also updated in 2013 to support the patient data sharing provisions of the HITECH Act. During the COVID pandemic, some of the HIPAA provisions were relaxed to support the telehealth programs needed to address the social distancing and lockdown of public health protocols [60]. The Office of Civil Rights proposed in December 2020 to amend the current HIPAA rules to address the interoperability standards that limit the coordination and communication across patients and healthcare stakeholders. In such a way, it continues to support the privacy and security of protected health information [61].

More recently, 2021 saw a dramatic change in how healthcare providers are reimbursed based on their documentation. To reduce the administrative burden associated with billing and the well documented "note bloat" attributed to the advent of EHRs, the CMS "Patients over paperwork" program, led by the Office of Burden Reduction & Health Informatics, established the framework for provider reimbursement based on medical decision -making and time spent with the clinical interaction [62, 63]. This initiative can potentially improve the quality of clinical documentation and accounting of the time allocated to patient care in ambulatory care settings.

Finally, one of the key foundations for properly identifying unique patients across disparate data sources is having a robust set of patient identifiers [64]. It took a while for the US government to open to the possibility of a national unique health identifier [65]. Although HIPAA of 1996 calls for a unique patient ID, strong federal law language prevents the adoption of such a standard. In September 2017, the Senate recommended that CMS work with ONC on accurately identifying patients' health information [66]. However, in May 2017, President Trump signed the "National Patient ID" law to allow federal funds to develop a national patient-matching process that can safely and accurately identify the patient [67].

Components of Precision Health

The overall health of an individual is determined by five major contributing factors, namely the person's genetics (30%), social situation (15%), environmental exposure (5%), behavior (40%), and medical care (10%) [68]. Therefore, addressing the overall health of an individual goes beyond medical care, which accounts for a smaller contribution compared to the person's genome or behavioral patterns, as an example. An informatician needs to pay attention to the different components that impact the person's overall health because they become fodder to the development of predictive models, analytics, and other methodologies that evaluate health risks, diagnostic accuracy, and health outcomes. In addition, precision health requires a solid data science infrastructure. The necessary integration of heterogeneous and disparate data sources while maintaining data validity and semantic interoperability will be an ever-increasing informatics opportunity.

Clinical Care

Today, clinical information systems collect a lot of primary clinical data. EHRs collect and store patient-level healthcare information such as health problems, procedures, vital signs, diagnostic test results, images, notes, other patient identifiers, administrative, communication, clinical decision support, and reports surrounding the patient's healthcare. It also contains data about the care team and clinical processes and workflows derived from the EHR logs [69]. Personal Health Records (PHR) are also good sources of clinical information. While EHRs are primarily geared towards providers' information needs, the PHRs collect health information capture from patients and allow patients to view their healthcare information. PHRs are often tethered to EHRs (aka patient portals) or can also be a standalone system. When integrated with the EHR, PHRs allow providers and patients to collaborate and develop a shared understanding of the healthcare goals [70]. The increasing adoption of wearable sensors, both commercial and consumer-grade, provides a new way of collecting patient-level clinical data that can be used for care delivery and science. In contrast to EHRs and PHRs, clinical data can be collected with our human intervention, representing relevant physiologic measurements and lifestyle and behavior-related data about the person [71] (Table 26.4).

Genetics and Biology

Genetics and biology have a big influence on a person's health [72]. Informatics plays a major role in collecting, processing, storing, and distributing biospecimen information for healthcare and research purposes. The growth of microarray technologies allowed healthcare institutions to perform genomic sequences and other analyses with relative ease and efficiency [73]. The use Next-Generation Sequencing (NGS) technologies (i.e., whole-genome sequencing (WGS), whole-exome sequencing (WES)) are increasingly common in the clinical to help clinicians detect genetic variants that could influence diagnosis and treatment decisions. When merged with information from the EHR, lifestyle, social or environmental exposure information, the resulting wide-ranging dataset can serve as the foundation for data science and advanced analytics to help uncover insights for delivering individualized diagnostics and treatment [74, 75].

Behavioral Factors

Behavioral health data is often challenging to find in EHR data [76]. Knowledge about the patient's health behaviors such as alcohol or drug use, mental health, nutrition, and physical activity can provide insight into the barriers and gaps in the individual's healthcare. Systems interoperability is vital to connecting healthcare institutions across the continuum of care, from the primary care and specialty care services to the inpatient and behavioral care settings. Traditionally, these care settings are siloed, and in the precision healthcare setting, bridging behavioral health with clinical care will improve the effective delivery of care to the individual and support population health.

Environmental and Social factors

The person's physical and social environment affects individual and population health. Exposure to harmful substances (e.g., air pollution, toxic gases), access to health optimizing services and resources (e.g., healthy foods, recreational spaces, clinics), and local community development, or lack thereof (e.g., good transportation system, road access), among others, can impact people's health [77, 78, 79, 80]. Many of these factors are influenced by the person's

Table 26.4 Example of wearable sensors

Device type	Clinical data	Example commercial devices
Wrist worn sensors	Actigraphy, Heart rate, Blood Pressure, Electrodermal activity	Actiwatch Spectrum by Phillips, ActiGraph Link by ActiGraph, E4 by Empatica, ViSi Mobile by Sotera Wireless
Skin patch sensors	Electrocardiography, actigraphy, skin temperature	BioStampRC by MC10, HealthPatch by Vital Connect, BodyGuardian by Preventice
Cuff sensors	Heart rate, Blood Pressure	Intellisense Digital BP Monitor by Omron Healthcare
Finger worn sensors	Heart rate, Oxygen Saturation	iSpO2 Pulse Oximeter by Massimo
Clothing embedded sensors	Heart rate, Heart Rate Variability, electrocardiography, respiratory rate, actigraphy	Smart shirts by Hexoskin
Headband sensors	Electroencephalogram, Electromyography	EEG (Electroencephalogram), EMG (Electromyography)

Wearable healthcare devices and technologies allow for real-time monitoring of the person's activities, lifestyle, behavior, and can also detect biochemical and physiologic data. Some of these technologies connect wirelessly to smartphones and other connected devices. Wearable devices collect large amounts of data that can be mined and used as a component of delivering precision healthcare

Source: Izmailova ES, Wagner JA, Perakslis ED. Wearable Devices in Clinical Trials: Hype and Hypothesis. Clin Pharmacol Ther. 2018;104(1):42–52

socioeconomic situation, as exemplified by the "Delmar Divide" mentioned earlier in the chapter. Data about the person's environment and social situation are usually collected outside of the clinical care settings and are not routinely captured in the EHR [81]. However, with the increasing adoption of health IT and integration across disparate systems, EHRs are poised to support the longitudinal collection and capture of vital data that can help address disparities in health, environmental and social wellbeing [82]. The CDC has established the National Environmental Public Health Tracking Network (Tracking Network), coordinating health-related and environmental data from local, regional and national resources. It has also exposed these tools via their "Data Explorer" tool, allowing users to interact with the data related to environmental and environmental hazards, health effects, and population health [83].

Informatics Infrastructure and Considerations for Precision Health

A strong informatics foundation is needed to support Precision Health initiatives. The ability to synthesize heterogeneous, complex, and disparate datasets and derive useful and actionable information at the point of decision making is an important informatics objective. More importantly, informatics tools and processes must allow for the democratization of the data, providing the average non-technical decision maker unfettered access to actionable information promptly and without delay.

Supporting Discovery Activities

Informatics infrastructure that supports precision health should allow end-users to perform discovery activities with relative ease. They have access to tools that enable them to connect to multiple relevant data sources that are of good quality, can share their data across the organization, and be able to perform analytics to gain more insights into the healthcare opportunities, as well as exploring ideas for care improvement or research. Academic institutional tools such as the Informatics for Integrating Biology and the Bedside (i2b2) [84] and TriNetX [85] offer a well-curated set of deidentified clinical data via standardized, normalized data models to consumers and researchers of healthcare information, where users can choose from a variety of clinical variables, biomarkers, procedures, genetic information, among others, without learning how to code or programming. Increasingly, EHR systems offer end-user tools to query clinical information directly from its databases. For example, the Epic EHR system has a built-in analytics tool (SlicerDicer) that allows clinicians to perform robust data searches and database queries, customizing searches to particular groups of patients, diagnoses, or interventions [86].

Supporting Hypothesis Generating Activities

A hypothesis is a theory about the mechanisms that led to the observed phenomenon. Scientific methods and statistical tools are used to prove or disprove the hypothesis. Hypothesis generation is concerned with "how knowledge is activated about plausible hypotheses which should be considered during hypothesis evaluation—the calling to mind of possible hypotheses." [87] The investigator can explore a set of information resources or databases to look for specific patterns and associations or scenarios worth looking into and then identify which hypotheses can be tested later on. The discovery tools described above can also be used for hypothesis-generating activities within healthcare organizations. Informatics tools such as DiseaseConnect are an example of a public-facing online resource that can integrate complex omics, research literature, genome, and gene expression to visualize disease-disease, drug-disease relationship, and molecular mechanisms [88].

Support for Hypothesis Testing Activities

In seeking new knowledge, investigators develop hypotheses about the relationships, collect data and perform statistical tests, and then draw inferences on the test results. Hypothesis testing is concerned with evaluating the evidence from the data source or sample and then determining the generalizability of the results to a different or a broader population [89]. Hypothesis testing is usually performed using statistical software. A commercially available product such as SAS, SPSS, and Stata, among others, are used to manipulate, visualize, test, and report the results in a meaningful way. Meanwhile, R (r-project.org), CDC's Epic Info (www.cdc.gov/epiinfo/), and pandas (pandas.pydata.org), among others, are readily accessible as open-source packages. Consumer-grade tools like Microsoft Excel® can perform robust statistical tests and reporting capabilities.

Informatics Tools for Treatment and Maintaining Precision Health

Not all EHRs are created equal in terms of their ability to support all the healthcare enterprise's business, clinical, and administrative activities [90, 91]. In particular, precision health's far-reaching aim to deliver individualized care to the patient will need more robust tools and capabilities to support personalized clinical decision-making at the point of care [92].

Clinical Decision Support Systems

Maintaining PH information is complex and always evolving. Human cognition will no longer be sufficient to manage these vast and constantly updated sources of information that will be relevant to provide individualized care. Integrating clinical decision support systems (CDSS) into clinician workflow will be necessary to support the practice of PH [93]. Indeed, Friedman's Theorem of Biomedical Informatics holds true for PH, in that "a person working in partnership with an information resource is 'better' than that same person unassisted" [94]. For example, for a clinician to keep up with the information from the genetic predispositions, social and environmental, medications, and other clinical information will require augmentation by an "information resource". In the clinical vignette above, where the patient is being prescribed the drug atomoxetine for ADHD, a CDSS mechanism that will alert the prescribing clinician about the presence of the CYP2D6*10 variant, which is known to be common in individuals who lack CYP2D6 activity, posing a significant risk for adverse events and poor drug efficacy [95]. Several CDSS modalities can support precision medicine activities. Order sets, flowsheets, dashboards, note templates are a form of passive CDSS, while the commonly known alerts, reminders, and prompts are considered active CDSS [96]. They are often integrated into the EHR or PHR and interact with the end-user managing the information resource. EHR systems must be able to incorporate complex decision rules, integrate data from disparate resources, and present the most timely information at the time of decision making. Informaticians will be heavily involved in implementing and managing precision health's five (5) "rights" of clinical decision support [97].

Health Information Exchanges

Healthcare Information Exchange (HIEs) is the electronic transmission of health care data across disparate organizations and systems, enabling clinicians and healthcare decision-makers to securely access and share vital medical information. The HITECH Act was instrumental in promoting the adoption of state-based HIEs in the US [98]. A recent ONC report to Congress noted that less than 50% of ambulatory physicians' offices could exchange electronic healthcare data across HIEs. Less than a third of them can integrate this information into their EHRs [99]. In precision health, new HIE standards and protocols will need to seamlessly and securely integrate genetic, social and environmental, wearables and clinical data across disparate systems.

Care Coordination Toolsets

Getting the right information is important, but taking action with the information is among the most important aspects of delivering precision health. Since the patient's care goes beyond the physician's office, the hospital, or the emergency room, what happens to the delivery of care outside traditional medical brick-and-mortar facilities impacts the patient's overall health. Systems of care must be able to support care coordination services so that the patient's personal, behavioral, or financial concerns are addressed promptly and help alleviate gaps in food insecurity, inadequate shelter, lack of transportation, access to medication, and home assistance, among others. EHR systems in conjunction with a robust HIE will enable the care team to review the patient's most current health visits, medications, diagnoses, and problem lists, procedures, functional, behavioral, and developmental evaluations, and screenings, scheduled visits, treatment guidelines, and other social-medical services, and have the opportunity to coordinate the services along the care continuum [100].

Telehealth

Telehealth adoption surged with the COVID pandemic as healthcare institutions provided continuity of care to overcome the public health protocols for lockdowns and social distancing [101]. The US federal government also relaxed several regulations (i.e., HIPAA, CMS and Children's Health Insurance Program, medical licensure), billing and reimbursement, insurance coverage, and telehealth sites to ensure that the public can safely, securely, and with minimal delay, deploy telehealth services using the most available and practical information and communication technology platforms that are at hand [102]. Telehealth is poised to support the demands for precision health. The care team can provide safe and cost-effective ways to integrate care in the patient's homes and provide chronic care management and coordination among specialists, primary care providers, nurses, and ancillary team members. Informatics consideration for telehealth will include modalities that support synchronous (real-time), asynchronous (store-forward, secure messaging), and remote monitoring capabilities [103].

Integrating telehealth technology into the EHR workflow will streamline the care team's workflow, increasing its usability. Personal health monitoring devices such as wearable heart monitors, Bluetooth-enabled weighing scales, blood pressure monitors, glucometers, among others, can provide patient-level data to the care team, augment remote monitoring telemedicine technologies. Integrating personal healthcare devices will play a significant role in care coordination and virtual care monitoring [104]. Integrating the telehealth platform to the healthcare institution's EHR and

patient portal or PHR greatly improves acceptance and usability by providers and patients. This workflow integration reduces multiple logins, duplicate documentation, the need for technical support, and the overall technology burden. Informaticians need to keep this in mind when implementing telehealth solutions to support a broad set of use cases for precision healthcare (Table 26.5).

Bench to Bedside Research Informatics Tools

PH will require an informatics infrastructure that can translate massive amounts of disparate information acquired from bench research, new discoveries in diagnostics and therapeutics, and patient-level to population-level databases [105]. For example, emerging programs such as the NIH's All of Us Research Program, https://www.researchallofus.org/, previously known as Precision Medicine Initiative (PMI) Cohort, collects health information from a large sampling of the population, allowing individuals to contribute personal information (lifestyle, medical history, utilization, physiologic measurements, etc.) for research. The program allows researchers to access this de-identified data securely for research. The data includes participant-provided information such as surveys and physical measurements and EHR-based data (diagnoses, procedures, lab tests, etc.) contributed by healthcare providers [106]. Sync for Science (S4S, http://syncfor.science/) is another government-industry collaboration project that utilizes HL7's SMART on FHIR (Substitutable Medical Apps, Reusable Technology on Fast Healthcare Interoperability Resources) standard to enable patients to share their health data securely via an API for purposes of care coordination and research. These tools set the foundation for a more robust informatics platform for precision health science.

Health Services Research

Health services research is the "multidisciplinary field of inquiry, both basic and applied, that examines access to, and the use, costs, quality, delivery, organization, financing, and outcomes of health care services to produce new knowledge about the structure, processes, and effects of health services for individuals and populations" [107]. Similar to PH, HSR aims to determine the best way to deliver safe, high-quality healthcare cost-effectively while reducing adverse events and medical errors. New sources of data, such as EHR and PHR data, increasingly available data from insurance companies, person-level social media data, patient-generated data (see Chap. 24), and provider-originating data from sites like http://sermo.com offers new opportunities to perform research and informing policies on caring for individuals and population health in the context of precision health [108].

Learning Health System Informatics Infrastructure

Friedman laid out the infrastructure that would support the LHS from an informatics perspective. He describes that (1) Learning is the ability to support "continuous improvement through the collection and analysis of data, creating new knowledge, and the application of the new knowledge to influence practice; (2) overall Health is the ultimate outcome of interest, similar to PH; and finally, (3) System refers to the subcomponents of the structure that act in alignment to achieve its goals. The informatics infrastructure supporting LHS is also important in PH, where each person's information is a vital data point for learning, where

Table 26.5 Telehealth Use Cases for Precision Health

Use case	Description	Timing	Video	Information transferred
Provider to Provider Communication Services				
e-Consultations	Clinician consults another clinician (i.e., primary care provider consulting a specialist) about a patient	Asynchronous	No	Medical records, images
Video consultation	Clinician video conferencing another clinician in real-time (i.e., telestroke consultation)	Synchronous	Yes	Medical records, images
e-ICU monitoring	Clinicians monitor patients remotely using video, telemetry data in real-time	Synchronous	Yes	Medical records, images, telemetry
Direct to Consumer Communication Services				
Second Opinion	Patient communicates electronically to clinician requesting for a second opinion on a health concern	Asynchronous	No	Medical records, images
e-Visit	Clinician communicates with patient using secure messaging to provide formal medical recommendations and services	Asynchronous	No	Patient reported information, medical records, images
Remote Patient Monitoring	Clinicians monitoring patients directly from their connected electronic medical devices, or wearables	Synchronous	No	Telemetry, patient reported information
Video visit	Clinician interacts with patient in real-time using video conferencing technology (i.e., virtual office visit)	Synchronous	Yes	Patient reported information

The COVID-19 pandemic proved the importance of telehealth in providing continuity of care remotely. The use cases itemized above are examples of how telehealth can serve a role in the overall precision healthcare delivery framework

Adapted from the American Hospital Association: Telehealth, A Path to Virtual Integrated Care Report. https://www.aha.org/system/files/media/file/2019/02/MarketInsights_TeleHealthReport.pdf. Accessed 25 Jun 2021

knowledge about processes, workflows and healthcare practices and resulting outcomes are incorporated back into the decision-making and learning process, and where learning and improvement are continuous and on-going and are supported by a socio-technical framework within organizations, large or small [109].

Healthcare Information Technology (HIT) Considerations for Precision Health

The HIT innovations that will ultimately support PH will need to focus on human factors, clinical workflows, and clinical decision support. Human-centered design should promote usability and end-user functional requirements and allows the technology to support real-world activities such as care coordination, patient engagement, continuous improvement, and timely, safer care [110]. Figure 26.2 depicts the ecosystem of information resources, actors and stakeholders, and the interplay of data science and decision support opportunities that foster the implementation science of precision health [111]. The key technologies that clinical informaticians likely play a big role in rolling out precision medicine initiatives are described below.

Electronic Health Records

Electronic health records play an important role in Precision Health [112]. The ability of the EHR to collect, store, retrieve, share, and organize clinically relevant data from a variety of data sources is vital for PH. In addition, by following interoperability standards, EHRs can interact with external systems to gain access to patient-level information outside of medical care. Moreover, social determinants of health and genomic data will also increasingly become more important data that need to be captured in the EHR. Accurate, discrete, and computable data offers a great opportunity for deploying CDSS. The ever-increasing role of EHRs in the care settings will continue to evolve in delivering personalized care. This also involves EHR vendors becoming more engaged with their end-users, improving its usability and human factors design to become an efficient tool for delivering efficient, individualized care.

Patient Portals

Like EHRs, patient portals and personal health records are important components in the precision health technology stack. They become very important communication, patient engagement, care coordination, scheduling platform, and a source for patient-oriented outcome data. Patients who have access to their own healthcare information have a great opportunity to become more engaged with their care. Patient portals also allow patients to get involved in research, similar to NIH's All of Us Research described above.

Internet of Things

Internet of Things (IoT) are interconnected technology devices that constantly bidirectionally communicate across the internet without any human intervention. This includes appliances, wearables, biometric scanners, and other "smart" devices like Amazon's Alexa, Google's Home, or Apple Watch. Healthcare-related IoT such as health monitors, mobile apps, medical devices, and other electronic wearables integrate seamlessly over the cloud and connect with EHRs, PHRs, telehealth, and other healthcare applications. The healthcare, well-being, and other big data collected across IoT networks can be used by healthcare providers to develop customized preventative, proactive treatment, therapies, and services for the patient [113].

Laboratory Systems

Laboratory Systems have long been leaders in healthcare digitization, moving data about individual patient's laboratory results across healthcare information systems. To support Precision Health, laboratory systems will need to develop more robust in vitro diagnostic testing, including genomic, epigenomic, proteomic, metabolomic, theragnostic testing capabilities, in addition to supporting streamlined workflows for ordering clinicians as well as efficient reporting capabilities between laboratory testing instruments, laboratory information systems (LIS), EHRs and other facilities or external systems. Data derived from the LIS and connected instruments can be used to support day-to-day lab operations, quality and safety efforts, and research. For precision health, a fully integrated laboratory system can provide high-quality clinical, genomic, and other diagnostic data that can be used to develop personalized care and treatment strategies [114].

Genetic Analysis Instruments

Genomics plays a very important role in advancing precision health. Genetic testing instruments identify the variations in genes, chromosomes or proteins, and confirm the presence or absence of a genetic disorder. Clinically, genetic testing is often performed in newborn screening, carrier testing, prenatal testing, forensic and other diagnostic testing, using blood, hair, skin, amniotic fluid, or other tissues. As of 2018, it was

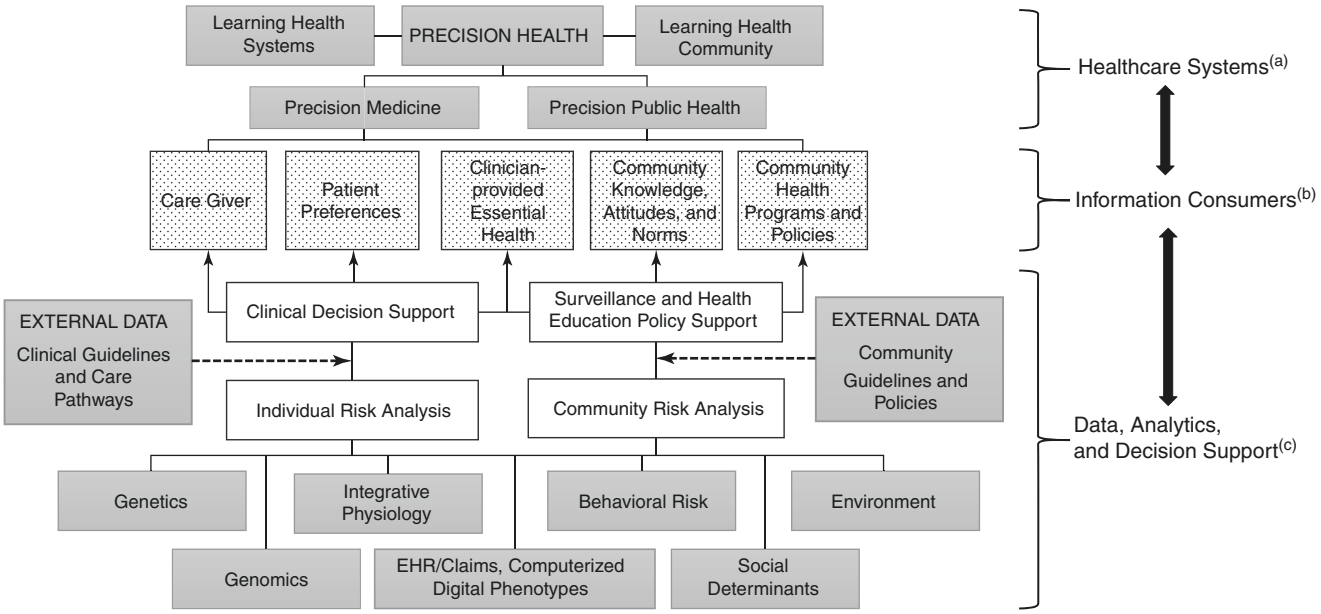

Fig. 26.2 Informatics Opportunities Supporting Precision Health. Precision Health requires the integration of information resources, analytics and clinical decision support systems, regulatory and policy frameworks, as the healthcare provider workflows in order to maximize its health value for patients. Informaticians will need to consider the specific areas where they can make a significant contribution. (**a**) Healthcare Systems are integral to the implementation of Precision Health. Institutions must have the infrastructure (people, process, technology, policy) in place to leverage the care coordination, continuous learning and the healthcare team culture to incorporate the individual's specific healthcare opportunities and preferences across the care continuum. (**b**) Information Consumers are the actors in the healthcare ecosystem, which includes the patient and their families or care givers, the healthcare providers and the care team, as well as the community decision makers that develop programs that influences the care that is being provided to the patient. (**c**) Informaticians play major role in this category. Data, Analytics and Clinical Decision Support serves as the foundation for the information flow the decision makers and consumers of health. Adapted from Pearson TA, et al. J Am Coll Cardiol. 2020; 76(3):306–320. (Used with permission from Pearson TA and Elsevier)

estimated that there are over 75,000 genetic tests available for patients in the marketplace, and more are coming out daily! [115] Moreover, the rise of lower-cost consumer-based genetic testing engages the patient directly, offering diagnostic tests looking at the individual's ancestry, phenotype, lifestyle, biometric markers for informational and preventative purposes [116]. Genetic testing often requires collecting the patient's personal information through questionnaires or interviews, including other medical and family histories. The ability of the genetic testing instruments to become integrated with LIS, EHR, PHR, and other clinical applications will enable the care team to confirm, rule out, or predict genetic risks and individualize the therapy and healthcare services to the patient's individual's genetic markers.

Devices and Interfaces

The future of precision health will be transformed by various sources, forms, and amounts of healthcare data collected via medical devices and applications. These sources of information provide the care team, patients, and other decision-makers about personal and population-based health status, care gaps, and the processes and outcomes of care delivery. The data that are being generated will require a robust set of interoperability standards that maintain the syntactic and semantic qualities of the healthcare data [117]. In 2020, the US Food and Drug Administration launched the Digital Health Center of Excellence program to advance digital health innovations such as mobile health devices, software as a medical device (SaMD), healthcare wearable devices, and technologies that will further the benefit to individual patients. The program will establish efforts that promote innovation in digital health products, foster digital health science and research, as well as stimulate strategic partnerships with product developers, regulatory bodies, consumers to remove regulatory barriers to innovation and fast track the delivery of safe and quality digital health products for the patient and the consumer [118].

Data Standards

Finally, adhering to common data standards, including data elements, interchange formats, terminologies, and other knowledge representation artifacts, allow bidirectional communication across disparate systems [119]. ONC has been a

strong proponent for advancing the standards that supports precision health. In January 2021, ONC launched the "Advancing Standards for Precision Medicine" program to identify key data needs and establish testing standards that advance precision health, including data from mobile health, sensors, and wearable devices, and social determinants of health data, complementing its earlier efforts to support the data standards need to move clinical (Sync for Science) and genome (Sync for Genes) data [120, 121]. These programs enable individual patients to contribute research data using health app and standard APIs (i.e., HL7 SMART on FHIR, OAuth 2.0 Authorization Framework).

Barriers to Precision Health Adoption

Delivering precision healthcare is a paradigm shift. It is a culture change for care providers, healthcare administrators, health informatics stakeholders, policy and regulatory bodies, and patients. Below are some of the commonly known sets of constraints in realizing the practice of precision health as part of routine care.

Provider Awareness

Healthcare providers are important to promoting and adopting precision healthcare practices. One of the pivotal practices in PH is the shift of genomic testing and interpretation from the specialists (i.e., geneticists, genetic counselors) to primary care providers. Therefore, it will be necessary for healthcare providers to brush up on their knowledge of genomics, molecular biology, and biochemistry to convey vital information about the genetic test, results in interpretation, and the treatment strategies for the individual patient. Many front-line providers have concerns about their ability to provide accurate guidance and recommendations based on patient's genomic testing results [122]. They also are concerned with their preparedness, confidence, and knowledge about ordering genetic tests [123]. Informaticians and proponents of precision health will need to implement strategies for educating the care team on how to best incorporate precision health workflows into their practice.

Cost and Financing

One of the uncertainties in adopting practices that support precision health is the financing of precision care services [124]. Laboratory departments will need to install new instruments to support the "omics" studies, develop new mechanisms for testing and results in interpretation and counseling, training lab personnel with the new "omics" tests, integrate the test ordering and results in review with the EHR and other ancillary systems in support of personalized care [125].

Reimbursement

Testing for genetic predispositions is newer, and with associate costs, reimbursement from payors and insurance companies could be an issue. The technologies needed to support precision health may not readily fit into existing healthcare billing and reimbursement processes [126]. New approaches will need to be in place to manage costs and payment for more advanced personalized genetic tests [127]. Providers are unfamiliar with the patient's cost burden of the genetic testing, while institutions are not familiar with whether insurance will cover the genetic testing related to precision care [128].

Patient

One of the great opportunities for PH is to empower the patient to have greater control over the prevention, maintenance, and treatment options that impact their health. PH is concerned with massive amounts of personal data, coordinated to develop customized care recommendations. Clinical data can be de-identified, but genetic data cannot [129]. While the healthcare industry (providers, payors, regulators) becomes more permissive with data sharing, linking disparate data sources, collocating genomic data with clinical data to advance precision healthcare and research, the patient's privacy and confidentiality must be maintained to reconcile the patient's rights with the value being offered by the increasing transparency and disclosure of personal healthcare information in big data medicine [130].

EHR Integration Barriers

Finally, there are still technological barriers to fully adopting the promise of precision healthcare. While the US is enjoying fewer barriers to adopting EHRs and increasing the ability for healthcare applications to integrate via standard communication protocols, a few notable opportunities need to be described.

- *Data and Interoperability standards*—EHRs have been the beneficiary of intense focus on interoperability; however, patient-level digital health tools have limited success with being integrated into the EHR workflows. For example, the plug-and-play pairing of Bluetooth digital scales, blood pressure monitors, and glucometers continue to be

a challenge [131]. To address this, ONC launched the Advancing Standards for Precision Medicine (ASPM) project in 2018 to advance the implementation of interoperability and data standards needed to support the vision for precision health [132].

- *Genetic data*—Since much of healthcare now requires the care team to interact with the EHR, the EHR needs to capture and store the genetic data required to support PH. In 2007, the eMERGE project was launched to explore the issues vital to integrating genomic data into the EHR [133]. Discrete, actionable genomic data is vital to implementing the CDSS supporting personalized care. More recent standards like the HL7 FHIR offer great promise for incorporating relevant genetic data into the clinical workflows of the EHR [134].
- *SDOH data*—SDOH data must first be captured in discrete and computable forms in the EHR before it can be used to drive decision support mechanisms. This, however, requires clinical process changes (i.e., screening protocols) and configuration of the EHR so clinicians can leverage this information during the clinical interaction. The majority of the SDOH data are not captured within the EHR, and if available, they are found in unstructured data [135]. The emergence of tools like Aunt Bertha (https://company.auntbertha.com) and NowPow (https://www.nowpow.com) interface with EHR systems and offer services that allow healthcare institutions, patients and families to access local community resources that can help address social and environmental care gaps. The ONC advanced standards for collecting SDOH data across healthcare applications through its health IT certification program. Key to this effort is the adoption of standardized mobile healthcare and application programming interfaces (APIs) [136].

Emerging Informatics Trends for Precision Health

Informaticians play an important role in advancing precision health initiatives [137]. Innovation in health IT allows organizations and healthcare stakeholders to store, combine, access massive amounts of data from disparate sources, including clinical, omics, social, environmental, behavioral, wearables, among others. Informaticians will have to grapple with predictive models, algorithms, and high-performance computing activities as healthcare decision-makers increase their demand for transforming data into actionable information and knowledge that ultimately improves health outcomes. Informaticians will need to up their game, not only on knowledge management, human factors design, project management, research, leadership, and systems management but also on their data analytics abilities [138, 139]. In June 2021, the US federal government launched an ONC-led DHHS Public Health Informatics and Technology Workforce program that committed funds to train thousands of healthcare informatics and data science experts. It also aims "to root out pervasive health and socioeconomic inequities that have been exacerbated by the pandemic and ensure our health care system is better equipped for the next public health emergency", including strengthening the local and state public health reporting and data analyses capabilities around race and ethnicity-related issues [140].

Platform for Artificial Intelligence

One of the main challenges of precision health is that it requires the integration and analysis of multidimensional data from various sources to arrive at personalized care recommendations for the patient. This is an opportunity for healthcare data science to flourish. Artificial intelligence models and algorithms can leverage robust computing resources to provide insight from different biological and clinical datasets [141]. Combining patient and population-level data allow healthcare decision-makers to better correlate the clinical and biologic indicators, stratify and categorize specific intervention/outcome scenarios, classify cost-effectiveness profiles, and ultimately allowing the patient and the provider to arrive at the optimal plan of care that provides timely, safe, better care given the opportunity costs [142].

Synthetic Healthcare Data

One of the dilemmas for advancing healthcare big data efforts is the risk of violating patient privacy and confidentiality because of exposing identifiable personal health information. One of the emerging trends in data science is synthetic data, where the data are computer-generated and not derived primarily from real-world events. Synthetic data are often used to train machine learning models because they are readily available, eliminating the labor needed to collect, label, normalize real-world data, and generating big data in a very short period. Most importantly, it minimizes privacy concerns because the data was generated virtually [143]. Healthcare synthetic data can fabricate clinically, administrative, claims data about patients. Since they are not based on real individuals and events, there are no risks of exposing sensitive health information. The generated data can be further developed and validated to make it perform like real-world data. Then when the dataset is of sufficient quality, it can be used for simulation, integration with EHR, and other datasets, as well as used for research [144]. Testing scenar-

ios, machine learning models, and algorithms with synthetic data offer a low-cost, low-risk strategy that can then be validated using real-world data [145]. For example, open-source vendors like Synthea (https://synthea.mitre.org) offer "large-scale fictional data" about patients in the state of Massachusetts. The synthetic data follows the HL7 FHIR data model (i.e., faux demographics, immunizations, clinical, and SDOH data), and users can download the dataset in HL7 FHIR, CCDA, or CSV formats [146].

Learning Health System

The Learning Health System Model provides a great foundation for precision healthcare. Learning health systems leverage process and outcomes data to support the care teams' and institutions' continuous improvement efforts and recycle the knowledge learned from the results back to the decision-makers promptly to further improve patient care [147, 148].

Summary

Precision health is an informatics opportunity. With the advent of newer technologies and innovations and declining costs for "omics" testing, the increasing amount of clinical, environmental, social, behavioral, and lifestyle data that is being generated for patients in the healthcare setting, and the emergence of capable and integrated health informatics and technology infrastructures (EHRs, HIEs, interoperability standards, etc.), the opportunity to harness the massive amounts of data into meaningful and actionable nuggets of information for improving the overall health of the individual patient is so exciting. Informaticians are poised to support secure data curation, sharing, and access to vital patient information in quality improvement and research. The clinical decision support systems that are needed to support personalized preventative and therapeutic strategies specific to the patient's overall health profile requires a solid understanding of the physiologic mechanisms of the disease (omics, SDOH, clinical), the specific workflows of the care team, and its health system (providers, policies, care pathways, reimbursement), the health IT infrastructure (EHR, HIE, PHR, databases), and, more importantly, the patient's need for privacy, confidentiality and healthcare education.

Questions for Discussion

1. What is precision health?
2. List and describe at least two components of precision health.
3. What advantage(s) does precision health offer clinicians over traditional "one-size-fits-all" approaches to medicine?
4. How well do existing electronic health record systems support precision health?
5. What would you do to enhance EHR systems to better support precision health?
6. What role do patients play in precision health?

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