Clinical Informatics Study Guide

Text and Review

John T. Finnell
Brian E. Dixon
Editors

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Foreword

Information is not just necessary for delivering care, information arguably *IS* care. Although some clinicians, e.g., surgeons or physical therapists, do a lot with their hands, most of us clinicians work with our heads. We spend practically all of our time collecting, managing, processing, and transmitting information. This is a ubiquitous notion: Gonzalo Vecina Neto, the head of Brazil's National Health Regulatory Agency, has publicly stated, "There is no health without management, and there is no management without information." Amen to that!

In the 1960s, there was a well-known catchphrase "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. Information *IS* health care.

Most undergraduate medical education does not appreciate this. Medical students spend more formal didactic time memorizing Krebs' tricarboxylic acid cycle (and promptly forgetting it after the test) than being trained how 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 their management. Heretofore, clinical information management was a skill students picked up indirectly through digging haphazardly through whatever chart or electronic health record (EHR) system is available. Forty years of EHR research and development yielded a lot of data about their potential capabilities and benefits, but realizing these benefits required informal approaches to attaining EHR implementation and management that were scattered and poorly organized, if extant at all. There is a huge gap between the possible benefits of EHRs and the benefits realized by clinicians and health systems to date, enhanced by the US government that, through the HITECH Act, has invested billions in EHR systems resulting in three-quarters of US hospitals and more than half of the physician practices now having an EHR. Optimized for managing health system logistics, these EHR systems have disappointed and often frustrated clinicians whose innate,

human capability to access and manage cogent patient information has not improved and indeed may have worsened after installing EHR systems.

As with any major infrastructure or cultural change, hiccoughs are likely to occur. So it is not unexpected that health systems and clinicians would struggle to rapidly replace their paper-based information management systems with electronic ones. Workflows optimized using paper-based records became dysfunctional with EHRs. Alleviating clinicians' frustrations with EHR systems and reaping the benefits of EHRs and other health information technologies cannot and will not happen spontaneously. They need shepherding. Someone has to be responsible for the information environment in which clinicians practice, someone with deep knowledge of both clinical medicine and health information technology. It was therefore timely, if not perhaps overdue, when the American Board of Medical Specialty (ABMS) formally established clinical informatics as a formal physician subspecialty in 2011.

Diagnostic radiologists and surgical pathologists do not usually provide direct patient care. Yet their clinical specialties are essential for other clinicians to make treatment decisions. Similarly, the clinical informaticist's role is not one of direct patient care but to provide the right information to the right clinicians at the right time in the right way for patients to receive the highest quality and safest care. To accomplish this, clinical informaticists must be broad generalists in both medicine and informatics. They must have a good understanding of the practice of medicine across all specialties and in all inpatient and outpatient practice venues. They must understand workflows of health care delivery, the messiness of clinical data which can be missing and even wrong, and how health care providers must tolerate the uncertainty that accompanies each decision made and each action taken. Similarly, clinical informaticists must understand how each datum is generated, stored, transmitted, and processed to yield useful information. They must have a sufficient depth of technical knowledge to help health systems make decisions about purchasing and implementing EHRs and other health information technologies. Finally, clinical informaticists must understand organizational behavior and management to allow health data and meta-data enhance efforts to improve the quality, safety, and efficiency of health care. Because information *IS* care!

Forty years of rapidly evolving health information and information technology has characterized the field of clinical informatics. The editors and authors of this textbook on clinical informatics have collated and organized that information into a compendium of the field that will both inform budding clinical informaticists while defining the knowledge gaps that need filling. It is a journey into a young and exciting field where change is constant and an uncertain path lies before us. We will certainly be "sailing the ship while we are building it," but the knowledge and wisdom in this book will light the way, illuminate the shoulders that current and future clinical informaticists will stand on to give our patients, our country, and our planet the high-value health systems they want, need, and deserve.

Indianapolis, IN, USA William M. Tierney, MD

Preface

Although the need for managing data and information in medicine is centuries old, the medical subspecialty of clinical informatics has officially been in existence since 2011. During the process to becoming a clinical subspecialty, as well as the years following recognition by the American Board of Medical Subspecialties, we repeatedly discussed with each other the need for a foundational text to specifically support the preparation of the emerging, new generation of clinical informatics leaders. As we taught this content to our graduate students, we struggled to find a single text that sufficiently covered the core content. We therefore embarked upon a journey to create this text with the intent that it will be a useful resource for trainees in clinical informatics fellowships, clinicians who desire to independently prepare for the board exam, as well as those ineligible for the physician board exam but nonetheless are seeking to understand or advance in the field of clinical informatics.

We are so very pleased to have assembled the group of authors represented in these pages. Each of them has contributed significantly to the advancement of the clinical informatics field within their own area of expertise either as a teacher, researcher, practitioner, advocate, or policymaker. They have 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

This 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 in order to impress upon the reader core clinical content. This book is not intended to provide comprehensive details on specific informatics systems or components, nor does it go into 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 readers through the core content, referencing or directing the reader to additional materials that will provide greater depth. While providing a roadmap for faculty who wish to then go deeper in courses designed for physician fellows or graduate students in a variety of clinically oriented informatics disciplines (e.g., nursing, pharmacy, radiology, public health). This book can also serve as a reference for those seeking to independently study for a certifying examination or periodically reference while in practice.

Structure of This Book

This book is divided into sections that group related chapters based on the major foci of the core content: (1) health care delivery, (2) clinical decision-making, (3) information systems, (4) leadership and managing teams, and (5) professionalism. The chapters do not need to be read or taught in order, although the suggested order is consistent with how we have structured our curricula over the years.

Clinical informatics focuses on the application of computers and information systems to the delivery of patient care and population health. We therefore begin this 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 common roles for informaticians in a variety of clinical settings. This is followed in Chap. 2 by an overview of the US 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. In Chap. 3, the reader will find an overview of the US health policy context, emphasizing laws and regulations that pertain to health care system data and information. It is important for clinical informaticians to understand federal and state laws surrounding health information in addition to the technologies that manage them.

In the next section of this book, we focus 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: "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 4 reviews the complex process of making clinical decisions. To design effective electronic health record systems, one must understand how clinicians make decisions. In Chap. 5, we review how evidence-based knowledge is discovered and transformed into guidance for practicing clinicians. Chapter 6 discusses how 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. 7, we review tools

and models for analyzing and modifying clinical workflow. Finally, in Chap. 8, we present a more recent trend in clinical informatics – predictive analytics. Through analysis of larger volumes of data captured in electronic health records, analytics seeks to inform clinicians and health administrators about these key domains in health care delivery: cost, quality, and access.

In the next section, we describe key information systems found in health care settings and discuss the design, development, implementation, and evaluation of systems. Chapter 9 reviews the technical foundations upon which health information systems are built. Informatics leaders will need to make decisions not only about which systems support clinical decision-making but also 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. 10, readers will find an overview of the various information systems they will likely encounter and/or manage in their careers. Chapter 11 focuses on standards, technical building blocks that enable interoperability between systems. Supporting and selecting standards is an important role 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.

The final two chapters of this section focus on the development and implementation of information systems. Chapter 12 describes information system life cycles as well as the governance and ongoing maintenance necessary to keep systems operational. Then in Chap. 13, we focus on the design and evaluation of end users' interactions with information systems. Engineering systems to meet users' needs is critical in health care, because the systems we implement are used in the delivery of care so mistakes in data entry, analysis, or decision support can result in serious adverse events.

In the fourth section of this book, we focus on a critical aspect of clinical informatics: leadership. Clinical informaticians will be looked to within their organizations as leaders: be it team leads for the implementation of information systems or as an executive leader as a Chief Medical Informatics Officer (CMIO). In Chap. 14, we provide a review of various leadership models and guidance on the dimensions of leadership. Chapter 15 covers a wide range of strategies for managing people, teams, and meetings. Then in Chap. 16, we discuss the principles of project management, which includes the tools and theories behind successfully driving both small and large system implementations as well as informatics performance improvement. Chapter 17 focuses on the strategic and financial planning necessary for informatics leaders, especially CMIOs or Directors of informatics departments which will have a budget. Then in Chap. 18, 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 in the success of the system.

In the final section of this 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 important for clinical leaders, because (1) clinical informaticians will

likely interact with specialists in these areas in the course of their daily activities, and (2) these areas are increasingly interconnected to the practice of clinical informatics. Chapter 19 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 work to improve health and well-being while supporting patients' preferences in their care plans. Then in Chap. 20, 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 as well as outcomes.

There are a number of other related informatics disciplines we were unable to include in this book at this time. For example, translational biomedical informatics focuses on integrating data and knowledge from across the biomedical spectrum to support patient and population health. Such approaches will be necessary to make the goals of the US President's Precision Medicine initiative (https://www.whitehouse.gov/blog/2015/01/30/precision-medicine-initiative-data-driven-treatments-unique-your-own-body) a reality. We hope to include these additional areas of interest in the next edition of this book, by which time they will likely be recognized as core content and part of the clinical informatics board exam.

Structure of Each Chapter

Within each chapter, the reader will find a number of 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 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 in the chapter. Finally, chapters include discussion questions aimed at sparking dialogue in formal courses or fellowship programs.

Statement from the Editors

We hope that you derive both knowledge and enjoyment from this book. Clinical informatics is our passion, and we are delighted to share it with you. It is our hope that this book can support independent learners as well as many cohorts of clinical informatics fellows. It will take hundreds of clinical informatics specialists and

many thousands of informatics-savvy clinicians to design, develop, implement, and use advanced information systems to improve patient and population health around the world. We hope this book plays a role in making that vision a reality.

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Part I
Fundamentals

Chapter 1
Clinical Informatics: Emergence of a New Profession

Edward H. Shortliffe, Don Eugene Detmer, and Benson S. Munger

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 50 years ago and the expertise in the area has had a half-century to evolve and mature – while it has also tracked the remarkable changes in technology as well as in the delivery and financing of health care that have occurred during that same period.

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 and more on the effective practice of applied clinical computing and information management. Many questions arose regarding such individuals – questions that were vigorously discussed by early in the first decade of the new century. How might

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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 major portions of their careers to work in the area? How could an individual demonstrate to employers (typically health systems, hospitals, or other health-related entities) that he or she was 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 wide variety of health professional backgrounds, they became especially pertinent for physician informaticians, driven in part by the creation of chief medical information officer (CMIO) positions occurring within a culture of recognized medical specialties. In this chapter we summarize what happened to address and answer these questions, culminating in the creation of a formal subspecialty for board-certified physicians through the American Board of Medical Specialties (ABMS). With that new subspecialty now in place, the need for formal training options has become more urgent. This volume is intended to help in the education of individuals who are 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. Although the focus is on physicians who are eligible for formal ABMS certification, there are many other kinds of professionals who work in clinical informatics and the book will be valuable for them as well. Later in this chapter, we discuss efforts to create alternate certification pathways for individuals who work in the area but are not eligible to take the ABMS board examination.

Although this volume is intended for practitioners and does not prepare individuals to become researchers in clinical informatics, it does convey a body of knowledge and experience that is useful to researchers in the field, since all informatics research is driven by a desire to address real-world problems from the areas of public health, clinical care, or biomedical research. Accordingly, although readers will notice references to the clinical subspecialty for physicians throughout, the book is intended for a wider audience as training and certification options broaden beyond those available for practicing physicians.

Clinical informatics is an applied sub-discipline of the field of *biomedical informatics*, which has been defined by the American Medical Informatics Association (AMIA) 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 practice in health care settings where the concepts of informatics 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.

In 2009, AMIA published two key papers that introduce the notion of a clinical subspecialty for informatics physicians [2, 3]. They emphasize 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 heath 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.

This volume, then, introduces and summarizes those concepts, methods, and tools, offering 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 a period of decades as computing and computer systems entered hospitals and clinics — primarily for billing purposes but also for laboratory results management and, in particular, for results reporting. 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 both research and the training of researchers in the emerging discipline. National meetings engaging those sharing these interests emerged during the late 1960s and 1970s. It was the introduction of an annual Symposium on Computer Applications in Medical Care (SCAMC), beginning in 1977, that 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) 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. AMIA quickly became the professional home where both senior and junior informaticians, including those focused on clinical care, could present their work as well as find out what was current in the field. Such informatics specialists were not necessarily physicians, however. From the beginning, AMIA welcomed all health professionals, and other scientists (e.g., computer scientists, decision scientists, cognitive scientists, sociologists) with an interest in

the application of computing and communications technology in health and health care. The term *informatics* was still new in the 1980s, and many workers in applied settings such as hospitals referred to what they did as "health information technology" (HIT or *health IT*). The HIT and health IT designations are still common today and at times have led to confusion regarding the relationships between clinical informatics and health IT. There has also been confusion at the international level in that most other countries have come to refer to HIT as HICT or health ICT, explicitly mentioning "communications" in addition to "information." 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. AMIA, with its own annual informatics meeting, has complemented and cooperated with HIMSS while attracting a more scholarly audience, including both researchers and professionals who look beyond the technology to educational needs and the conceptual underpinnings of knowledge and information management in health care settings.

Defining the Characteristics of the Profession

Following the release of a professional code for informaticians in 2004 [4], 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 discipline across all of health care. Further, the AMIA Board decided to begin its formal efforts with just one of the health professions rather than to try to mount a certification effort across all disciplines at once. The decision meant that AMIA would first pursue certification for physicians and then, with insights and lessons from that effort, pursue interprofessional certification for other clinical informatics experts (see the discussion of this topic at the end of 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 of the standard specialties — 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 from medicine as a whole, 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:

- First, 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 that represents 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).
- Next, the subspecialty needs 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 also, through its constituent boards, creates and maintains the certification examinations that attest to the competence of medical subspecialists.
- Third, the Accreditation Council for Graduate Medical Education (ACGME) must be engaged since the ACGME exists in large part to review and accredit training programs capable of preparing candidates to sit eventually for the certification examinations of the constituent boards of the ABMS.

Accordingly, the President of AMIA approached the officers of CMSS to determine if they would consider making AMIA a member of 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. Within a few months, AMIA had been elected to membership in CMSS and its President, Don Detmer, was elected to serve as its Treasurer. He went on to participate actively at meetings of the organization.

In the late summer of 2006, John Lumpkin, Vice-President of the Robert Wood Johnson Foundation (RWJF), partnered with Detmer to request an informal meeting with the presidents of a number of medical specialty societies to discuss the potential for creating a new clinical informatics subspecialty. The result of this meeting was an expression of genuine enthusiasm for pursuing its development, although it was recognized that a number of formal steps and approvals would be required before an ABMS-approved certifying examination could be created for the discipline.

By March 2007, RWJF had awarded AMIA a grant to develop two key documents essential for formally approaching ABMS for review and approval as 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 address the core content of the field [2] and fellowship training requirements [3]. Reed Gardner (chair) and J. Marc Overhage (vice chair) were selected to lead the Core Content Task Force, while Charles Safran (chair) and Michael Shabot (vice-chair) assumed leadership of the Training Requirements Task Force. Over a number of months in 2007–2008, the task forces created documents that were reviewed and approved by the AMIA Board of Directors and, along with a descriptive piece by Detmer and Lumpkin [5], all three were published in the *Journal of the American Medical Informatics Association* (JAMIA) in 2009.

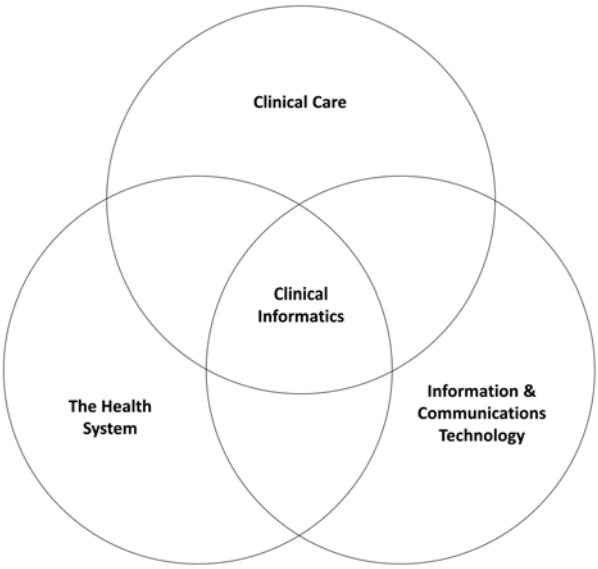

Fig. 1.1 Domains of clinical informatics (Reproduced from Ref. [2] with permission from the American Medical Informatics Association and the Journal of the American Medical Informatics Association)

A number of key concepts were critical at this early development stage. 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 view and a systems view, emphasizing that qualified subspecialists should be capable of leading organizations strategically as well as tactically with respect to all major aspects of integrating information and communications technology with information needs as they might evolve over time. A key visual was created to represent this perspective (Fig. 1.1).

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 a clinical informatics subspecialty. Leveraging his role on CMSS, Detmer began to approach the leaders of the various specialty societies, and in turn their cognizant boards, to discuss the possibility that they would handle the formal proposal process and, if successful, assume responsibility for the certifying board examinations that would follow. Although many Boards were supportive and expressed an interest, it was the American Board of Preventive Medicine (ABPM) that was most interested in submitting a formal

proposal and becoming the administrative board. As Detmer left his AMIA role in 2009, his successor, Edward Shortliffe, assumed the responsibility for working with the ABPM to finalize a plan. Meeting with their cognizant board committee, Shortliffe presented the case, supported by Munger and AMIA staff. ABPM would assume significant costs if they were to propose a new subspecialty that they would oversee, and they needed assurance both that there was a good chance the subspecialty would be approved by ABMS and that a significant number of individuals would be interested in sitting for the certifying exam when offered.

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 suitable data to help to demonstrate the potential demand for such a certifying exam. In addition, in mid-2009 at the meeting of AMIA's Academic Forum in Colorado, Shortliffe invited a senior leader from ACGME to meet with informatics program directors who, up until then, were most familiar with requirements for graduate (MS and PhD) 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 that option would be assessed by ACGME. Most fellowships have both 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 a variety of 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. In fact, ACGME began to realize that the creation of 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 web site 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.

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 to be a 5-year "grandfathering" period during which active clinical informaticians who were also ABMS-certified physicians could apply to be deemed board

eligible and to sit for the examination. Thereafter a formal fellowship in clinical informatics would be required to achieve board eligibility, and those fellowships would need to be reviewed and accredited by the ACGME, as is the case for all residencies and fellowships.

The details of the subsequent process are not important for this discussion, but suffice it to say that there is a mandatory year-long review during which all the other boards in ABMS are required to review and 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 promptly began to garner support from the other boards. With broad informal support from their constituent boards, the leadership of the ABMS agreed in late 2010 to begin its own internal review of the proposal. Their Committee on Certification (COCERT) was required to meet at least twice to review and discuss the proposal before they could forward their recommendation to the full board of ABMS.

The COCERT meetings in 2011 were crucial elements in the approval process, because the members of that committee were 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 to 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 that was debated at both meetings of the committee, was whether clinical informatics was sufficiently "clinical", since the work was viewed by some as being 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 period of study 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. Each of these subspecialties had a direct relationship to one primary board (e.g., cardiology, gastroenterology, forensic pathology, hematology). The certificates were each issued by their primary board.

In the early 1970s there was flurry of activity as internal medicine created six new subspecialties, pediatrics three, and obstetrics & gynecology three. Each of these newly created subspecialties also had a direct relationship to only one primary board even though several subspecialties had analogs with other boards (e.g., nephrology under internal medicine and pediatric nephrology under pediatrics). In total the decade of the 1970s saw 19 subspecialties approved by ABMS.

The 1980s 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. During this decade ABMS also produced 21 new subspecialty certificates.

When a subspecialty is associated with only one primary board, the lines of responsibility are very clear. That board sets the policies, develops and administers the examination, and issues the certificate. With a subspecialty area that has common training standards but involves fellows from more than one board, and with more than one board issuing a certificate, the process became more complex. 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 subcertification 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 that would be 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 certificates were approved by ABMS 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 has seen ABMS approve 12 new subspecialty certificates. Among those subcertificates is clinical informatics. As we have described, this subcertificate 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 is 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 as well as to 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 content expertise to create the formal examination, they asked AMIA for nominees who could sit on the question-development committee. As mentioned, the ABPath had submitted a request to ABMS 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 as well as several subspecialty examinations, had ample internal expertise regarding the steps to be taken, including providing access to psychometric specialists who could guide the logistics and testing of exam questions.

Once ABMS gave approval to ABPM to issue subcertification 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. During the entire development process the AMIA leaders involved kept continuous contact with ACGME to assure that they were well aware of the process that 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, on the basis of 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 the construction of 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.

During the construction and approval of the necessary ACGME documents, another interesting issue surfaced. Although ABPM is the administrative primary board within the ABMS structure, with ABPath as co-sponsor, the intent of the fellowship training process was to avoid limiting sponsorship of fellowship programs exclusively to departments of preventive medicine or pathology. It was always envisioned that many other primary specialties would be interested in sponsoring fellowship programs and therefore local medical school and teaching hospital departments from a wide variety of 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. The reaction to this list was immediate as several of the larger primary specialties, such as internal medicine, pediatrics, and family medicine were not included. The ACGME understood the issue and worked with AMIA's graduate medical education leaders to raise the issue with the leaders of the missing primary specialties. AMIA leadership coordinated a series of conversations between the informatics faculty in the appropriate primary specialties and the leadership of the target RRCs to explain the concern and to seek their support for allowing their RRCs to be involved in the accreditation process. A primary concern from the RRC leaders was the lack of expertise in clinical informatics among their RRC members. It was also clear that the interest of individual primary specialties at the local departmental level is often not available to the leadership of such national organizations. As a result of this process the program requirements for clinical informatics, approved in 2014, allow for sponsorship by departments of nine primary specialties (anesthesiology, diagnostic radiology, emergency medicine, family medicine, internal medicine, medical genetics, pathology, pediatrics and preventive medicine).

The RRC leaders' discomfort was greatly mitigated by the presence of the Clinical Informatics Review Committee (CIRC) that had been approved and appointed by the ACGME. 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 RRC responsible for the decision. That group of reviewers continues to function as initial reviewers of all incoming applications for the accreditation of clinical informatics fellowships by ACGME.

Initial Development of Fellowship Programs

When the application to ABMS was submitted by ABPM, it contained a list of fellowship programs currently in existence (many of which were offering graduate degrees and had trained post-residency physicians) and a projection of programs that would likely emerge in the initial years after approval by the ABMS and ACGME. That list was a combination of fellowship programs that looked somewhat

like the proposed ACGME fellowships and others that had many years of experience and funding but were blends of degree and certificate programs. A good number 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, were reviewed by CIRC and recommendations were sent to the appropriate RRCs. In late 2014 the first set of ACGME-accredited fellowship programs in clinical informatics was approved [10].

Career Options for Clinical Informaticians

Career options as well as job opportunities are expanding rapidly for trained and experienced clinical informaticians, particularly within healthcare delivery systems. As previously noted, the most likely title for an experienced clinical informatician is *Chief Medical Information Officer* (CMIO). 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) as well as 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., electronic health records, data exchanges, and data repositories, as well as systems to address clinical performance, such as quality and safety. When the notion of a CMIO was first introduced, these positions had tended to report to the Chief Financial Officer (CFO) or the CIO and had focused more on information technology as infrastructure rather than as a strategic asset. The role, with its new reporting structure, has evolved to be a strategic as well as 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 personal attributes, experience, and aspirations, some clinical informaticians are beginning to find themselves pursued for the 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.

As the numbers of trained clinical informaticians increase in the future, it is also possible that all major departments and/or 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 in the U.S. includes Chief Health Informatics Officers (CHIOs) within many of its medical centers, who

represent a variety of 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, as well as research, while engaging patients, community resources, and other relevant entities both near and far.

A recent movement among a number of 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). The fact that ABPM also deals specifically with the care of populations makes this newly emerging position a good fit with the ABPM and its administrative oversight of the clinical informatics subspecialty and design of the board examination.

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. For those interested in health policy, a few positions also become available as staff to Congressional representatives, to health committees in Congress, or in the White House. Today, these opportunities may best be described as emerging, but 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 to address employee or customer health issues, but 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, electronic health record (EHR) vendors are beginning to hire such individuals to serve both internal as well as externally facing positions, both for ongoing relationship management, product development and, in some instances, marketing.

Current Challenges for Clinical Informatics

Addressing the Training of Clinical Informaticians

Because the clinical informatics subspecialty is new (2 years old at this writing), and only the first few formal fellowships have been created and accredited by ACGME, many details and concerns remain to be worked out or specified. A relatively large number of individuals took the examination during its first two offerings

(approaching 1000 physicians), essentially all of whom were board-eligible under the 5-year "grandfathering" process that allows people to sit for the exam based on experience in the subspecialty rather than formal fellowship training. This approach to eligibility will be permitted through the exam offered in the autumn of 2017. Thereafter, all individuals sitting for their certification examination will need to have completed an ACGME-accredited fellowship in clinical informatics. Given the likely small number of fellowships and trainees in place by 2018, we can expect a significant reduction in the number of clinical informatics subspecialists certified yearly when the 5-year grace period is over. It is ironic, however, that the demand for such individuals is likely to have increased substantially by that time. It will accordingly be important for health care institutions and academic programs to increase their capacity in the production of clinical informaticians.

Early steps in the creation of fellowships suggests 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 partner with one of the nine primary specialty programs through which the ACGME accreditation process will be carried out by the RRCs. Complex relationships and partnerships will 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 the way in which they evaluate the clinical informatics fellowships. Will there be uniformity in expectations across the specialties, deferring to the CIRC review, or will fellowships evolve to take on an emphasis related to the specialty group with which they are partnering [11]? As this volume emphasizes, clinical informatics is viewed as a broad and integrative discipline. Unintended evolution of sub-subspecialty programs (e.g., *anesthesia informatics*, *pediatric informatics*, *radiology informatics*) would run counter to the intentions of AMIA, ABPM, and ABMS when they approved the subspecialty. 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.

The early fellowship programs can attest that perhaps their greatest hurdle has been funding the fellowship positions that they offer. 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 are in a position to self-fund incremental fellowship positions, and it is politically difficult to reprogram existing fellowship training funds from another subspecialty in order to support clinical informatics fellowship slots. While many observers hope that there will be new federal funding to support such training positions, health systems and training programs will likely need to be innovative in how they fund 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 creates start-up challenges for institutions that may 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 we can anticipate substantial needs for new faculty at many institutions that would like to offer fellowships. Accreditation of their program will clearly require that they have the required local expertise. Given the potential shortage of board-certified subspecialists, especially starting in 2018, this could 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 dizzying 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 [12]. Employers looking at this landscape have a difficult time identifying the training and skill base represented by each option [12]. ABMS certification in clinical informatics is, of course, intended to help with this problem. By establishing an official subspecialty, ABMS and ABPM have sought to 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 of the ACGME-accredited training programs will take several years and physicians holding that certificate will not fill every position. What has been put in place is a credible training and certification system based on a public core content of skills and knowledge.

In addition to the "supply" concern just outlined, there are questions regarding demand. Physicians in the informatics community have been decrying the lack of informatics content in the medical school curriculum for some time [13, 14]. 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 with respect to 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 a number of issues relating to MOC, including costs, relevance to actual competence on the job, and current professional practice profiles, among others. Since clinical informatics is such a new entrant to formal recognition as a subspecialty, further discussion of this issue will not be discussed here except to acknowledge that it will be an important issue for AMIA and ABMS in the years ahead. 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 based upon their individual 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, there are major pedagogical, administrative, and political aspects that will need to be accommodated before such new approaches will be adopted for both specialty education and MOC.

Interprofessional Certification

The 2003 IOM *Health Professions Education: A Bridge to Quality* report identified five core competencies for future health professionals [6]. These included working in interprofessional teams, continuously improving quality, practicing evidence-based care, putting patients (and populations) at the center of care, and utilizing informatics. By 2009, an Interprofessional Education Collaborative (IEC) was created by six national education associations of schools of the health professions, including allopathic and osteopathic medicine, dentistry, nursing, pharmacy, and public health [15]. The IEC aims to encourage constituent efforts in substantive interprofessional learning experiences to foster team-based care of individuals and populations. While substantial progress has been made in the first four competency areas, informatics has until recently remained a challenge for them.

While the ABMS board certification in clinical informatics was taking shape, AMIA took seriously its commitment to consider additional certification efforts in applied informatics, including the interprofessional certification originally envisioned in 2005. AMIA's Academic Forum created a task force to examine the issue and they submitted a report that defined criteria for future work. Further, leaders in nursing informatics had concluded that its entry-level informatics certification was perhaps too basic and that an *advanced* clinical informatics interprofessional certification from AMIA would both improve nursing informatics and foster continuing advancement of informatics in a team context.

In 2014, at the spring meeting of AMIA Board of Directors, two actions were taken. First, creation of an Advanced Interprofessional Informatics Certification (AIIC) should begin in earnest. Further, AMIA engaged Detmer to lead this development activity. The goal would be to gain the commitment of other health professional educational organizations to support creation of an interprofessional educational task force working under the aegis of AMIA, aimed at assuring that a rigorous parallel but largely equivalent informatics examination for all other members of the healthcare team would become available. Over the summer and fall, Detmer met with leaders of the IEC, the American Association of Colleges of Nursing (AACN), the American Academy of Osteopathy (AAO), the American Association of Colleges of Pharmacy (AACP), the Association of Schools and Programs in Public Health (ASPPH), the Radiological Society of North America (RSNA), the American Dental Education Association (ADEA), and the Academy of Nutrition and Dietetics (AND). IEC's leadership supported the concept and the component organizations agreed to participate through a process coordinated by AMIA's leadership. By December 2014, the group had met twice and work was

progressing rapidly to create an updated core content as well as a credible entity to offer accredited training and certification. The goal is to address the certification needs of computer-science and physician clinical informaticians within AMIA who do not meet the ABMS certification requirements, as well as individuals in nursing (AACN), osteopathy (AOA), dentistry (ADEA), pharmacy (AACP), public health (ASPPH), nutrition and dietetics (AND), and for non-physician radiology and imaging informaticians (RSNA). AMIA intends to assure that the first examination is offered in 2016 or 2017. There is genuine international interest in this examination and AMIA plans to foster a global dimension as well.

The evolution of interprofessional informatics certification options, coupled with the current and growing interest in team-based care, suggests that the nascent physician-oriented training programs in clinical informatics have an opportunity to work with colleagues in the other health professions to make these programs interprofessional. This offers multiple advantages beyond the obvious pedagogic gains. Great financial efficiencies present themselves. Furthermore, having interprofessional teams of informatics learners engaging real issues within their institutions can serve as a genuine value-added feature to help to offset the costs of these programs. Sharing faculty is also beneficial since, as we stressed earlier, clinical informatics faculty are in relatively short supply.

Population and Global Health

The original core content for the ABMS-focused examination tended to emphasize questions regarding the implementation of EHRs, although ABPM's original interest in proposing the subspecialty was motivated in part by their view that preventive medicine and public health were important components of the clinical informatics discipline and needed to be part of the training of clinical informatics fellows. In the wake of the 2009 HITECH legislation, which underwrote the costs of implementing meaningful use of EHRs throughout the nation's health system, we are likely to continue to see an emphasis on the traditional problematic informatics issues of interoperability, data exchange, and decision support. But we know that such clinical data systems have also made it feasible to examine, both post-hoc and in real time, the performance of both clinicians and health care units as well as patient-care dimensions relating to quality, cost and safety. This has given rise to much greater interest in the health status and health system performance regarding both care and disease prevention across a variety of populations. Data analytics for strategic planning, value-based payments, care for special populations, and a host of research questions is now emerging as an increasingly important part of the clinical informatics discipline. It is likely that the board examinations will evolve to meet the changing needs of a learning health care system. Indeed, the benefits of an "army" of well-trained clinical informaticians who work interprofessionally to offer ongoing support and integration of information using HIT, improving the care and health of both individuals and populations,

could prove to be pivotal to a sustainable healthcare system and to healthier individuals and communities. The chasm between clinical medicine and public health should finally be bridged if not obliterated.

Formal specialty certification systems for physicians has been generally a primary focus in Canada, Great Britain, Australia and the United States. This has changed dramatically in the last 10 years. As physicians from other countries have sought training in US graduate medical education programs, they were exposed to this system. This led to an interest in many other countries to develop certification and program accreditation systems using the pattern established in the US. The policies of ABMS boards have always restricted certification to physicians who successfully complete ACGME accredited training and hold a valid license in the United States or Canada. Although there have been informal discussions, there has not been a strong interest in expanding certification to physicians practicing outside the United States or Canada. What has evolved is a continuing series of discussions between national organizations in the United States and their counterparts in other countries. To this point these discussions have not produced formal agreements but the fact they continue is evidence of an unfilled need.

There are many challenges to the export of the United States model for training and certification, such as the implied requirements for fiscal resources from both the individual physician and the national organizations. The physician reimbursement model in most less economically developed countries makes the support for an extensive training and certification system difficult. The same financial issue faces many national organizations and governments. There are also the cultural differences that create barriers. Formal testing following a clearly defined training process is not part of the culture in many countries. Coupled with the costs, the interest has been high but the adoption slow.

Concluding Remarks

The details of the clinical informatics certification process we have outlined in this chapter 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 both 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 inclusiveness and openness – not to be politically correct but because it clearly makes sense for the health of our people and the future of our world.

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Chapter 2
The U.S. Health System

Hannah L. Maxey, Connor W. Norwood, and Leisha L. Osburn

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 provides a system level context for the field of 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 policy making

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Core Content

The following core competencies are covered in this chapter:

- 1.2. The Health System
  - 1.2.1. Determinants of individual and population health
  - 1.2.2. Primary domains, organizational structures, cultures, and processes
    - 1.2.2.1. Health care delivery
    - 1.2.2.2. Public health
    - 1.2.2.3. Clinical research
    - 1.2.2.4. Education of health professionals
    - 1.2.2.5. Personal health
  - 1.2.5. Health Economics and financing
  - 1.2.6. Forces shaping health care delivery
  - 1.2.7. Institute of Medicine quality components
    - 1.2.7.1. Safety
    - 1.2.7.2. Effectiveness
    - 1.2.7.3. Efficiency
    - 1.2.7.4. Patient-centeredness
    - 1.2.7.5. Timeliness
    - 1.2.7.6. Equity

Case Vignette

A 48 year old, Caucasian male presents in the emergency department of a level I trauma hospital in a major metropolitan area. He is complaining of flu-like symptoms. The patient reports his personal and health insurance related registration information to a patient access representative in a triage room while waiting to be seen. The patient has never been to this hospital before, but the representative is able to find his electronic medical record (EMR) in their electronic health record (EHR) system, because he has been seen at the critical access hospital near his house, which is in the same network. She opens the administrative section of his EMR to verify and update the previous information. At this time she has the patient sign a consent for treatment form. After she types the patient's updated information into the computer, she logs out and explains that she needs to step out for a moment to make copies of the signed form, ID and insurance cards that the patient provided. Shortly, she re-enters the room with a barcoded wristband for the patient. She returns the patient's ID and insurance cards, and a copy of the consent, which now has a label imprinted with a barcode and the patient's name, date of birth (DOB) and unique identifier number. Then, as she looks at the wristband, she asks the patient to verify his name and birthdate. Satisfied, she places the wristband on the patient, puts extra patient labels next to the computer, and leaves again. Soon a nurse enters the room.

She 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 nausea, vomiting and a headache since the day before, that have all gotten much worse, quickly. The nurse is prompted to ask the patient whether he has been travelling recently as she enters these symptoms into the EMR. The patient shares that in fact, he just returned from Nigeria last week. As the nurse enters this into the computer, she is prompted to ask a series of questions specific to exactly where he travelled and why, and whether others that he was around were sick. He shares that he was travelling for pleasure and he was not aware of anyone being sick that he was around. The nurse then takes his temperature by pointing an infrared thermometer at his forehead. She comments that he has a fever and asks if he has noticed this earlier. He says no. She enters his temperature into the EMR and stares at the screen for a few moments. Her patient has just been flagged as potentially having a deadly and highly contagious disease. She calmly tells the man that based upon his symptoms, they will be implementing some special precautions as they perform more tests to see what might be wrong. She lets him know that she will be back shortly with the doctor.

The patient is moved into a special isolation room where he is hooked up to a variety of monitors to track his vital signs, and the doctor suits up to perform a complete assessment. The doctor notes that the patient also has a stiff neck and as his headache has grown worse, he has begun complaining about the lights being on in his room. After finishing his exam, the doctor documents his new findings 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, a spinal tap and a few other tests. He then looks at the choices of pain medications listed in the order set and chooses one for now and a stronger dose, if needed. He leaves the rest of the orders as they are written for the nurses to follow in their daily care of the patient. He thinks of how good it is that they now have these standardized Order Sets created, so that they know they are delivering consistent, evidence-based medicine.

As the doctor is finishing up, the nurse hears the pneumatic tube station signal a delivery. She finds the pain medication ordered for the patient, and sent up from the inpatient pharmacy. She suits up and enters the room, letting the patient know she has pain medication for him. She picks up the barcode scanner that has been placed in a sealed wrapping and dedicated to stay in his isolation room, and scans the barcode on the patient's wrist ID. She then scans the barcode label on the medication sent up from the pharmacy. Then she scans the barcode on the patient's wristband, and gives him the medication. It doesn't take long for him to relax and drift off to sleep.

Early the next morning, the inpatient lab calls the charge nurse and pages the patient's physician. The patient is negative for Ebola, positive for meningococcal meningitis. Isolation protocols are downgraded slightly and the appropriate treatment protocol is initiated. The patient seems less responsive than on the previous day.

In the background, the National Electronic Disease Surveillance System (NEDSS) is activated, and the State Health Department is informed that the patient has a "noti-

fiable" 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.

Late in the afternoon, the patient becomes unresponsive and a neurology consultation is placed. The neurologist orders an MRI. After it is completed that evening, the neurologist reviews the images and the interpretation of the neuroradiologist remotely, from her home. She then places an order for continuous video EEG monitoring, with real-time viewing of the patient and brainwave data (Neurotelemetry) for the next 24–48 h. A nurse brings the video EEG machine into the room and begins talking with a neurodiagnostic specialist (neuro tech) who is remotely connected to the machine from their home office. The nurse glues small recording leads to many places on the patient's head, using a special template that shows where they should go. She then performs various types of stimulation on the patient while the neuro tech watches the brainwaves. The neuro tech lets the nurse know there were no significant events, and they will call her after the remote neurologist reads the initial brainwave recordings. She leaves the EEG machine on so that the neuro tech can continuously monitor the patient's brain activity.

By midnight, the nurse has received a couple of routine calls from the neuro tech, just to update her and let her know that no significant brainwave events have occurred. Then around 1:00 a.m. she receives another call from the neuro tech saying that they have just paged the on-call neurologist to confirm subclinical seizures from the brainwave recordings. Soon, the neurologist calls the nurse, to confirm that the patient is having seizures and to be connected to the physician caring for the patient. The nurse puts him in touch with the physician and a treatment protocol for seizures is initiated. The nurse communicates with the neuro tech through the night to titrate the patient's medications until the seizures are decreasing in frequency.

By the next day, the seizures appear to be under control and the patient is somewhat responsive again. The patient continues to improve and the brainwave monitoring is discontinued late the second day. The rest of the patient's stay in unremarkable. He improves steadily and he is eventually discharged to home.

As the nurse is preparing him to be discharged, she goes over a set of post-discharge instructions with him. Then, she asks him if he is familiar with the patient personal health portal that is available for him within the EHR. He is not sure, so she shows him how to set up his account, and get logged in, then she goes over how to send secure messages to his caregivers, look at past lab results, radiographs, and other diagnostic tests. She also shows him how to review and download summaries of his clinic visits and hospital stays if he needs them for future doctor visits out-of-network or for other reasons. She reminds him that as a part of his follow-up instructions he is to schedule an appointment with his primary care provider in clinic in 2 weeks. She shows him a scheduling tool in the portal where he can do this on-line if he would like. She also lets him know now that he is signed up for the portal, 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 Health Information Exchange (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 the 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 domains of the health system. Health information has a specific and important role in each of these, as do 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 the field of clinical informatics. This chapter will examine the various domains of the health system and serve as a foundation to understanding the role of clinical informatics in this intricate and complex system. We begin by considering the concept of health as an individual and population characteristic in order to provide a frame of reference for studying the health system.

Health

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. In reality, health is a much broader concept. The widely accepted World Health Organization (WHO) definition, established in 1946, describes health as 'a state of complete physical, mental, and social well-being and not merely the absence of disease.' A myriad of factors play a role in health. Contributing factors are commonly referred to as the 'determinants of health,' and generally include (1) social environment, (2) physical environment, (3) genetics, (4) medical care, and (5) behavior. Health may be conceptualized as a state that results from 'exposure' to multiple determinants [1].

The determinants of health do not exist within a vacuum, they are intertwined and interdependent. Genetics are the foundation of human health. Genes are responsible for basic level of health at birth and determine risk for certain diseases [2]. Beyond genetics, however, individual and environmental factors also have a large influence on human health. Poverty, for example, is a social factor commonly associated with health and also related to 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 access health care 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.

Individual Versus Population

Health may be measured at the individual and population levels. Individuals exist within populations, and their unique characteristics are woven into the fabric of the population. Whereas individuals have a unique set of characteristics contributing to their health, populations are comprised of groups of individuals which generally share some defining characteristics, demographic, geographic, or social. Population health then is a reflection of the health of individuals within a defined group.

Health information is used to evaluate and monitor trends in individual and population health. At the individual level, health information generally summarizes as a set of characteristics or outcomes relating to health. At the population level, health information includes the distribution of characteristics and outcomes within a specific group [3].

Individual health information has been part of health care delivery from its start, as a tool for practitioners to document and monitor the patient health. Historically, data were documented 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 own health. New and emerging technologies empower individuals to collect and monitor their health. These technologies and their role in personal health are explored later in the chapter.

Population health information has also been recorded for many years. The earliest population health information includes mortality records and recordings of major epidemics that occurred throughout history. The 'Bill of Mortality' from 1665 depicted in Fig. 2.1 demonstrates how early data on cause of death were recorded and reported. The first documented recording of population health data to monitor trends in health and disease to determine the source or causation were done by the British physician John Snow. 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, removal of the water pump handle to the contaminated drinking water supply, were successful in stopping the cholera epidemic [4].

John Snow is widely considered to be the father of modern epidemiology [4]. **Epidemiology**, *the branch of medicine concerned with the incidence, distribution, and possible control of disease and factors relating to health, is a science based upon the analyses of population health data.* As we explore later, population health data are critical to the public health system, but they also play an important role in modern health care delivery, where individual patient health information is now aggregated within large health care organizations/systems for clinical decision sup-

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 Mouldfallen	14	Scurvy	105
				Shingles and Swine Pox	2
Canker and Thrush	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. 2.1 Bill of mortality from 1665. The 'Bill of Mortality' from 1665 demonstrates how early data on cause of death were recorded and reported

port and quality improvement and between systems through Health Information Exchanges (HIE). Such high resolution health information on populations provides new perspectives on health and its determinants. Ultimately, these data have an important role in transforming the United States health system.

The Right to Health

Health is not only a human characteristic; enjoyment of the highest attainable standard of health is also considered a fundamental human right [5]. In international human rights laws, the 'right to health' includes assuring access to health care, as well as addressing the underlying determinants of health. A large amount of resources are required to ensure this right. Many countries, including the United States, grapple with assuring the health of its population.

Although the United States expenditures for health are significantly higher than other developed countries, it ranks poorly in commonly reported population health indicators, such as life expectancy at birth [6]. Comparative country-level data are available through the Organization for Economic Co-operation and Development (OECD). OECD is a global organization focused on promoting policies that improve the economic and social well-being of people around the world. Country-level data

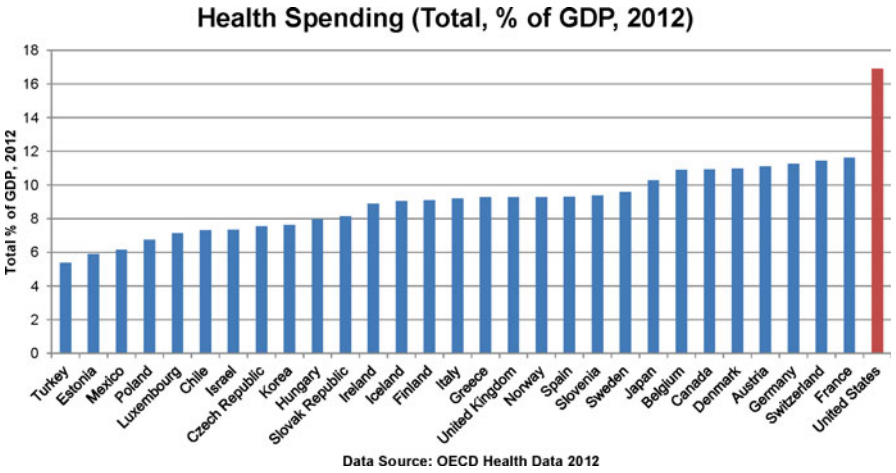

Fig. 2.2 Health spending among OECD (Organization for Economic Co-operation and Development) countries. This figure shows the United States' health care spending relative to other OECD countries (Data source: OECD Health Data 2012)

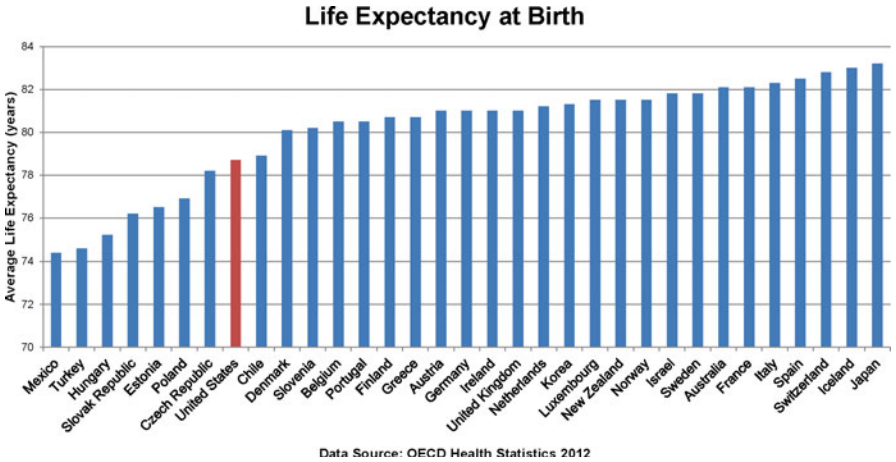

Fig. 2.3 Life expectancy at birth for OECD (Organization for Economic Co-operation and Development) countries. This figure shows the United States' life expectancy relative to other OECD countries (Data source: OECD Health Statistics 2012)

from OECD on life expectancy at birth (See Fig. 2.2) and percent of GPD associated with health care expenditures (See Fig. 2.3) for 32 developed countries are alarming. In 2012, the United States expended an estimated 16.9 % of its GDP on health care, and reported a life expectancy of 78.8 years from birth. That same year, average GDP expenditures for health care among the other OECD countries were 9.3 %, and average life expectancy at birth was 80.2 years.

OECD data suggest that higher health care spending has not led to better health for America's population. The structure and organization of the United States health

system, or rather the lack thereof, is a major contributor to the high cost and poorer health outcomes of Americans.

Summary

Health is a defining human characteristic and a basic human right. Many factors interact and influence health, including genetics, social and physical environments, medical care, and behavior. The 'right to health' is almost universally recognized. 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 disease focused health system.

Health information is used to assess the health of individuals and population within the health system and drive activities within the system. At the individual level, patient health information has historically been collected and analyzed as a part of patient care. At the population level, health information is collected and analyzed to determine distribution and patterns of disease, and to 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 next sections of this chapter review the major domains of the U.S. health system and explores the flow of data throughout it.

The United States Health System

From the 'mile-high' view, a **Health System** may be *described as sum of organizations, institutions, and resources focused on health*. 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 the field of clinical informatics. A basic understand of this system and its key domains is required to appreciate the role and flow of data within and throughout the health system. We explore each major 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* [7]. The United States has the most expensive, highly complex system of health care delivery 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 the delivery of health care services to patients. At the organizational level, providers include vast array of organizations and services. Acute care hospitals, primary care physician offices, dental offices, rehabilitation facilities, home health services, tele-medicine, 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 major component of health care providers. This workforce includes licensed health professions such as physicians, nurses, dentists, therapists, and many other health professionals. In addition to the professionals traditionally thought of as "health care providers," many others professionals support the delivery of health care services. Community health workers, for example, are increasingly being used to support health care delivery and build additional capacity or manage care and care transitions, especially among vulnerable populations [8]. In addition, practitioners in clinical informatics may also be considered a provider as they play a critical role in health care delivery process. This is especially true as newer health care delivery models which rely heavily on clinical information technologies, such as tele-medicine, are more widely utilized.

As the point of intersection between medical sciences and health care delivery, the healthcare workforce has a large role in the health care system. This workforce oversees the collection and recording of patient health information and leverages it to inform patient care. 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 to be a payer* within the health care delivery system.

Health insurance is the foundation of the 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 major losses to the payer*. This is typically accomplished by setting insurance premiums concordant with a patients, 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 cost of health care services out of pocket. This system of health care financing is unique to the United States, represents a major source of inefficiency, and is a threat to equity within the system. Understanding how this system evolved is important.

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 as an incentive to offset the cost of health care [9]. Employer-based health insurance expanded throughout the latter half of the twentieth century and became a major recruiting incentive for employers. During this same time period, incredible advancements in medical science were also being made. Advancements led to the development of technologies and treatments for many conditions that were previously untreatable and/or incurable. 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 as an effort to increase patient awareness regarding the cost of health care.

The advent of health insurance and availability of new health services acted to increase 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 of heath care in the United States largely determines who has access to health care and who does not [10]. **Access** *refers to the ability of an individual to obtain health care services when needed* [7]. Individuals typically must be able to finance health care through one of the following mechanisms in order 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 own private funds
4. They must be able to pay for services privately [7].

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. Unfortunately, health care providers are not evenly distributed across the population.

Health care financing has a large influence on the supply and distribution of health care services. Health care providers are clustered in metropolitan areas with high population densities in which greater 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 large role in shaping 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 major form of reimbursement to health care providers. FFS payments are issued to providers retrospectively after the service is provided. Advanced and specialty health care services requiring greater expertise and more resources were reimbursed at higher FFS rates while primary health care services focused on disease prevention and health promotion were reimbursed at lower rates. Under FFS reimbursement, health care providers are incentivized to increase the volume of specialty services. Over time, the culture favoring high cost specialty services became embedded into the fabric of health care delivery in the United States.

Health Care Delivery: Suppliers

Healthcare suppliers are *organizations which provide resources to the health care delivery system*, such as pharmaceutical companies and medical equipment manufactures. 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 supply services such as biohazardous waste disposal companies, medical laboratory courier, and health information technology companies are also included in this category. Basically, any industry or organization that provides goods, materials, or services which directly or indirectly support health care delivery are considered suppliers.

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 to balance the objectives of enhancing quality, expanding access, and controlling costs* [11]. Currently, the majority of regulation occurs within the various sectors (providers, supplier, and payers) through governmental and private agencies that develop and oversee guideline and policies around cost, access, and quality. Table 2.1 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 of the healthcare delivery sectors although their primary responsibility may lay within one of the three sectors. Although a large number of entities are engaged in regulation, their efforts are not currently coordinated. Ensuring access to high quality, low cost care in the United States requires system level and

Table 2.1 Summary of key regulators within various sectors of health care delivery

Sector of healthcare delivery	Scope and purpose of regulation	Examples	Role of regulators	Examples of regulators
Provider	Direct delivery or facilitating delivery of health services. 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) National Committee for
Payer	Financing health care services.	Medicare Medicaid Private insurers Self-pay	Regulate 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

coordinated regulation. Unfortunately, previous efforts to implement health planning at the system level have failed.

At the system level, **health planning** processes, where the *government develops a plan to align and distribute health care resources with the intention of achieving desired health outcomes* [7]. Through health planning efforts, there have been several regulation initiatives that aimed to ensure an equitable supply and distribution of health care throughout the United States. In 1974, the federal Health Planning and Resource Development Act was enacted, which provided incentives and penalties that would encourage states to adopt certificate-of-need (CON) legislation [12]. A CON is a control exercised by a government planning agency over expansion of medical facilities [7]. CON statutes were enacted through adoption of policies at the state level. These statutes required that health care facilities receive approval for expansion of existing, or building of new, health care facilities. The approval of CONs was largely based on demonstrated need for additional services or supply within specific communities. In 1986, the Health Planning and Resource Development Act was repealed as the federal government moved away from health planning.

More recently, as a result of implementation of the Affordable Care Act (ACA), community health needs assessments (CHNA) and implementation strategies are

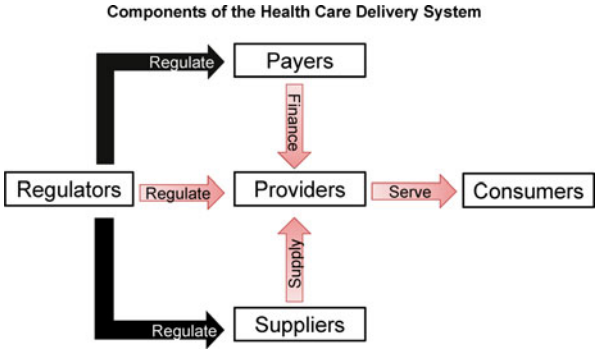

Fig. 2.4 Components of the United State health care delivery system. This figure identifies the relationship between the four major components of the health care delivery system: Payer Providers, Regulators, and Supplies

now required of tax-exempt hospitals much like CONs prior to 1986. CHNAs help to ensure that hospitals and other health care facilities have the information required 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 important component of community health needs assessments as 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 largely responsible for patient safety and health system quality and efficiency. Unfortunately, health care delivery and its regulation is disorganized and fragmented between and within the various sectors. Figure 2.4 illustrates how the sectors are regulated and work together within the delivery system to finance, supply, and serve the health care needs of consumers.

Forces Shaping Health Care Delivery

Over the years, health professionals have recognized the need to improve the quality of the health system while increasing access and reducing costs. However, the complexity of the health system 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" [13]. As a result population health and health outcomes in the United States have been largely 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" [13]. IOM's identifies six aims of quality components necessary for improvement of the health system in the report, which are summarized in Table 2.2.

In order for the United States health system to make substantial improvements the system must be safe, effective, patient-centered, timely, efficient, and equitable. Therefore, these fundamental quality components are significant forces shaping health care delivery today.

Table 2.2 Summary of Institute of Medicines (IOM) six aims of quality components

Institute of Medicine: Six aims of quality components [13]	
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

A Culture Change

As illustrated throughout this chapter, the Health System is made up of several sectors that all play a fundamental role in health care delivery and ultimately determine the system's ability to provide affordable, high quality care to everyone. Therefore, a fundamental redesign of the health system that aims to improve the six quality components identified by the Institute of Medicine must be supported by a commitment to change from all sectors of the health system: Providers, Payers, Suppliers and Regulators.

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 their impact on population health. The culture within the system is currently moving away from one that is focused on diagnosis and treatment and now emphasizes the importance of patient-centered and managed care, which is able to promote disease prevention and population health. Figure 2.5 illustrates the change in culture within the health system by demonstrating how health professionals have begun to shift their understanding of a few fundamental concepts in health care.

Public Health Systems

Public health plays a large role in heath, but is generally lesser understood than health care delivery. Whereas the health care delivery systems, 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' [14], public health focuses on prevention and health promotion, and is

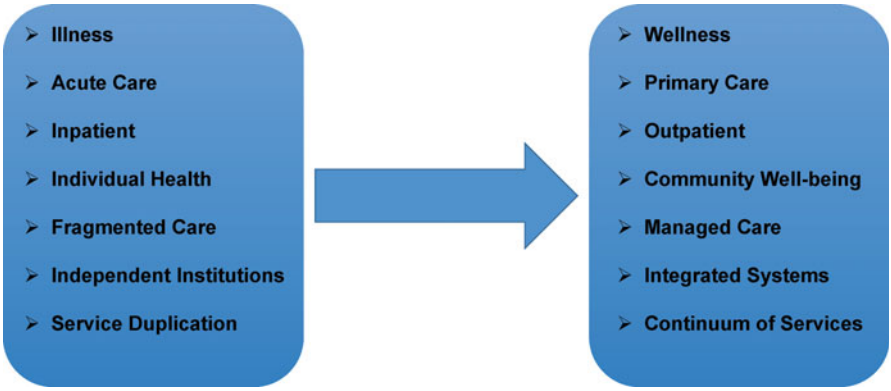

Fig. 2.5 A shift in thinking and culture: moving health care delivery from treating acute conditions to prevention and health promotion. This figure illustrates the change in culture within the health system by demonstrating how health professionals have begun to shift their understanding of a few fundamental concepts in health care

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 [15]. However, it is important to note that in other countries the activities of public health are carried out by a Ministry of Health that also oversees health care administration.

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 [16]. Monitoring, or assessing, population health is one of the primary functions of the public health system. The system of monitoring population health is commonly referred to as public health surveillance and is often referred to as the cornerstone of public health practice [17].

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 health care utilization and have been widely used for public health surveillance because they are relatively inexpensive and available in electronic formats [18]. 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 samples of the population to determine health status as well as 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 drive public health policies which contribute to the environment where health care delivery occurs. However, as data are integrated across the health systems clinical information is becoming increasingly important and will likely play a large role in public health decision making, as described in the vignette.

Clinical Research

Clinical research is the domain of the health system 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 [19]. 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 informaticians are responsible for ensuring that EHR systems and other health information technologies enable clinicians, allied health professionals, and organizations to provide the best possible care to patients. Currently clinical organizations predominantly use two methods for providing front line staff in a health system with access to the latest evidence from clinical research. First, organizations provide frontline staff with direct access to scholarly journals and scientific publications. Users can access resources from the U.S. National Library of Medicine (NLM), such as MEDLINE or PubMed, which search for available evidence across a wide range of publications. Alternatively, EHR systems can include "infobuttons" that enable frontline staff to directly link to relevant evidence when browsing a patient's chart [20]. For example, a primary care physician might desire more information about a medication prescribed by a specialist because he or she does not typically prescribe it. The infobutton in the EHR would directly link the PCP out 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). With CDS, the EHR system could remind the clinician to perform a task considered a "best practice" in a given context. 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 should have their glycosylated hemoglobin tested once every 12 months. Additional information on research and evidence-based guidelines as well as their implementation through CDS can be found in Chaps. 5 and 6 of this book.

Personal Health

Although public health is primarily concerned with improving and maintaining the health of families, communities, and entire populations, its success is largely dependent on personal health. Personal health may be best described through *The Six Dimensions of Wellness Model* developed in 1976 by Bill Hettler, co-founder of the National Wellness Institute (NWI). This model explains personal health as a function of six domains of health: Occupational, Physical, Social, Intellectual, Spiritual, and Emotional Health [21].

Occupational Health – *recognizes the personal satisfaction and enrichment in one's life through work and its impact on overall personal health and wellness*
Physical Health – *recognizes the importance of the overall physical condition of one's body and its impact on overall personal health and wellness*
Social Health – *recognizes the interdependence between others as well as nature and its impact on overall personal health and wellness*
Intellectual Health – *recognizes one's creative stimulating mental activities and their contributions to overall personal health and wellness*
Spiritual – *recognizes how the search for meaning and purpose in the human experience impacts overall personal health and wellness*
Emotional – *recognizes awareness and acceptance of one's feelings and its influence on overall personal health and wellness*

The United States healthcare system has historically been focused on physical disease, but it is important to understand that health at the individual level is not simply the absence of disease. In fact, the major strength of *The Six Dimensions of Wellness Model* is its understanding and emphasis of the interconnectedness of each dimension of personal health and how they play key roles in achieving and maintaining health and wellness [21]. In order for individuals to achieve high levels of overall health and wellness they must actively work to improve or maintain health in all six domains.

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 his or her own health and care* [22]. One important factor that influences a patient's ability to manage his or her personal 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 personal health*. PHRs contain various types of 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* [23].

In recent years, these data have become more accessible to individuals in large part due to the advances in information technology and clinical informatics as well as the emergence of mobile health (mHealth). The World Health Organization (WHO) defines mHealth as "an area of electronic health and is medical or public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal data assistants (PDAs), and other wireless devices [24]. With the advances in clinical informatics and mobile technology which have facilitated the rise of mHealth, people are able to collect vast amounts of personal health data on a daily basis such as blood pressure, body temperature, glucose levels, and heart rates. Personal health data may not only be valuable to treatment decisions related to personal health, but can many times be aggregated at the community or population level and leveraged to enhance and inform clinical research that is so vital to the advancement of medicine and public health.

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

Understanding the Flow of Data

In the vignette in Part I, there were obvious examples of how the flow of data through the electronic medical record and within the electronic health system were critical to the care and treatment of the patient during the hospital stay. The vignette also revealed the many other ways that the electronic flow of data is now utilized to maximize multiple aspects of healthcare delivery related to efficiency, quality, and even public health. When the patient's registration information was already on file in the EHR because he had visited another in-network 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 confirmed 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 the delivery of standardized practices and evidence-based medicine, 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 introduction of the disease into the community. To understand the true depth of the complexity efficiency and impact of electronic data flow in a fully integrated health system today, see Fig. 2.6, which illustrates the flow of data for the patient vignette detailed in Part I. While examining the illustration in Fig. 2.6, keep in mind that this complexity is the domain of the clinical informatician as he/she is generally tasked with sorting out information flows and implementing systems to improve care using redesigned health care delivery workflows.

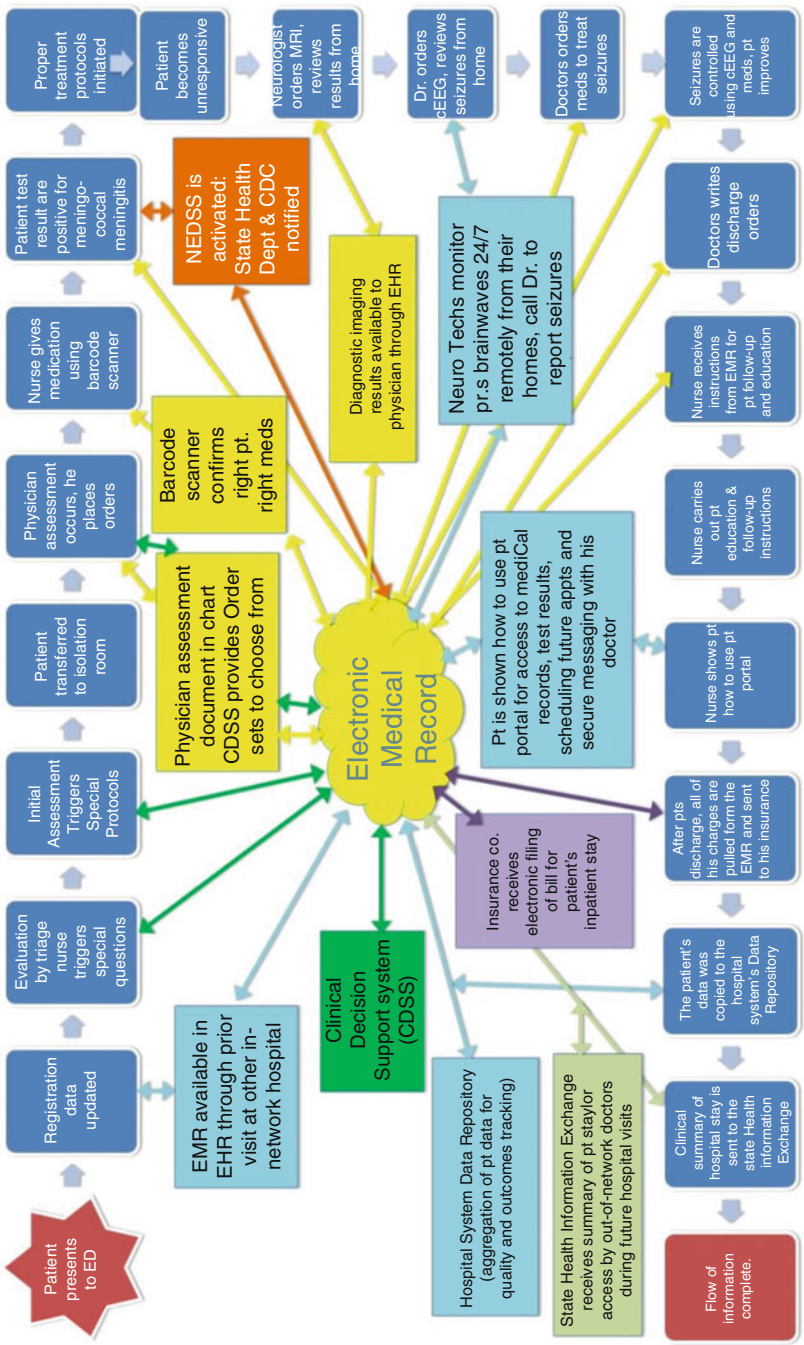

Fig. 2.6 Flow of data and information within the health system. This figure shows the flow of patient data and information within the health system by tracking the data from the beginning of a patient visit. The figure also shows that electronic medical records and clinical informatics is at the center of this complex process

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 on-line, 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 own 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 that they serve.

Emerging Trends in Clinical Informatics: An Effort to Improve Quality

The United States Census Bureau reported in 2011 that 48.6 million Americans, or 15.7 %, did not have health coverage [25]. As a result, health reform has been a hot topic in the United States and was perhaps the most debated issue in both the 2008 and 2012 Presidential elections. In 2000, the World Health Organization (WHO) released the World Health Report, which ranked the U.S. Healthcare System 37th in the world due to its overall performance (15th) and overall health expenditure per capita (1st) [26]. On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (ACA) into law. The purpose of the ACA legislation is to assure that all Americans have access to affordable health insurance. However, with the new legislation, health organizations as well as the system have had to adapt to new policies and regulations. As a result of the implementation of ACA, and the move to a value-based health system, several trends have emerged.

ACA & Accountable Care Organizations

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 are effective in delivering care more efficiently. An **ACO** *is a network of doctors and hospitals that share financial and medical responsibility for providing coordinated care to patients in hopes of limiting unnecessary spending* [27]. In order for ACOs to be effective in providing health care efficiently and improving 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 are ideal for utilization by ACOs and Patient-Centered Medical Homes. Similar to ACOs, **The Patient-Centered Medical Home** *is a care delivery model aimed at providing 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.

Learning Health System and Electronic Health Records

Another trend that has emerged in recent years is the development and implementation of **electronic health records** (**EHR**) which are "*digital versions of a patient's paper chart. EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users*" [28]. With the adoption and use of EHR systems, it is now possible to learn or infer patterns of evidence from the vast amounts of information captured during routine clinical care. This observation led the Institute of Medicine to propose the notion of a Learning Health System in which health care providers not only seek to provide care in accordance with established clinical guidelines based on evidence from clinical research but also in accordance with evidence they infer from their EHR system [29]. Because clinical informaticians are chiefly responsible for the implementation and use of health information technologies within their organization, they are responsible for ensuring that the EHR not only captures data that can inform care delivery processes but that actionable insights are found and applied. This activity is generally referred to as analytics or business intelligence.

The aggregation of patient data through the use of electronic health records has also allowed for an evolution of research into areas of study that were not previously possible. Now scientists can look at EHR level data to track historic data on disease outcomes with branching factors of complications and treatment decisions.

Researchers have begun to tie genomic data and social determinants of health into this equation as well. This use of "Big Data" is aimed at the goal of allowing a care provider or even a patient to input all of the known variables of the patient and then be shown the odds of the various most likely outcomes given specific treatment and life choices.

Chapter Summary

As the U.S. Health System aims to improve overall population health by improving the effectiveness of and efficiency of the system, clinical informatics has and will continue to play an integral role on the path to a coordinated health system that is effective in improving health outcomes by delivering high quality and affordable health care to 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 shift 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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Chapter 3
Clinical Informatics Policy and Regulations

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Learning Objectives

- Describe the policy development process for Health Information Technology (HIT), including the role of public and private sector agencies and organizations
- Become familiar with the major federal legislation that provides legal and regulatory frameworks for HIT
- Identify at least three policy challenges that will affect practicing clinical informaticians in the future

Core Content

- Fundamental knowledge of the organization and regulatory authority of federal and state executive branch agencies that influence the practice of clinical informatics
- Familiarity with key provisions of the main legislation that affects clinical informatics practice, including the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical

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Health (HITECH) Act, the Patient Protection and Affordable Care Act (ACA), and the Food and Drug Administration Safety and Innovation Act (FDASIA)
- Understanding of the role of private sector organizations, including professional organizations, in the policy development process

Case Vignette

A 52 year-old man presents to establish a new primary care relationship with Dr. Carol Jones. The vital signs data collected by the medical practice assistant using an electronic blood pressure monitor reveal that his blood pressure is 155/105, and his weight is 190; the computer calculates that his body mass index is 31. The practice assistant also notes that he is currently a smoker. The patient tells Dr. Jones that he is generally healthy, but he's had more trouble keeping up at work, and that he's been urinating a lot. Physical examination is normal except for the hypertension, which is apparently new.

The concept of '**meaningful use**' was established to help ensure that providers would not only adopt electronic health records, but would use them in ways that would make care better. The electronic health record (EHR) in this instance performed several tasks that might have been overlooked in a paper world—the vital signs were electronically uploaded to the EHR with no need for data entry, and the body mass index (BMI) was automatically calculated.

When Dr. Jones logs on to the secure provider portal from home that evening, there is an auto-alert in her inbox indicating that the patient's labs are ready for review and that the blood sugar is high. The next day, Dr. Jones asks her nurse to send a secure message to the patient to set up an appointment so she can explain that he has diabetes, and when the appointment takes place, she refers him to several online materials available through the health education department to provide diet and physical activity suggestions. While the patient is still in the exam room, with only a couple of clicks, Dr. Jones will generate an appointment summary letter explaining the rest of the labs to the patient, which the patient will be able to view on his personal health record (PHR). He'll also be able to track his blood sugars and his blood pressure in his PHR, and see if he is meeting his recommended targets. Because of the newly diagnosed diabetes, his name will automatically be added to the provider and practice's diabetes registry, which will help ensure that even if he misses follow-up appointments, someone will check in with him.

The adoption of EHR systems has encouraged the development of clinical decision support, helps multiple health professionals work with the same clinical information to coordinate care, and helps engage patients in their own care. It has also promoted the flow of clinical information for population health monitoring and reporting, such as maintaining registries. Taken together, all of these technology-enabled steps should help engage the individual patient, improve the quality of care he gets, and at the same time help providers manage the myriad of tasks they need to juggle more efficiently and ensure that the whole team is involved in caring for him.

Introduction

This chapter is important to the practice of clinical informatics because health information technology (HIT) policy has had major effects on the adoption, content and use of HIT in routine care, and it is likely to have downstream effects for the foreseeable future.

The chapter begins with an overview of the public policy process in the United States and the governmental, legal, and regulatory environment for HIT. It then describes the role of public-private collaborations and private-sector organizations in driving the policy process and helping to implement health information infrastructure improvements and organizational changes that will accelerate the adoption and meaningful use of HIT in a learning health system.

The chapter highlights the major governing pieces of legislation that are fundamental to the understanding of decision-making and implementation of public and private sector policies that govern the way HIT functions within delivery systems: the Health Insurance Portability and Accountability Act (HIPAA) (1996), the Health Information Technology for Economic and Clinical Health (HITECH) Act (2009); The Patient Protection and Affordable Care Act (ACA, 2009); and the Food and Drug Administration Safety and Innovation Act (FDASIA, or FDA Safety and Improvement Act, 2012). The chapter closes with a look forward to some key policy issues that will be particularly important to practicing informaticians and the health systems in which they practice over the next several years, and that may influence their becoming involved in the policy process.

Fundamentals of the Policy Process in the United States

One of the core functions of government is to act in the public interest to protect health and safety [1]. Government policies, or public policies, are positions, statements, and courses of action that reflect the government's goals and values and that may appear in the context of legislation, regulations, budgets and program priorities, written statements, speeches, executive orders, and in other ways.

In the United States, the Constitution does not explicitly grant the federal government authority over health. The states have the majority of statutory responsibility for health, insurance regulation (including medical liability), professional licensure and credentialing, and other activities [2]. The tensions and gaps between federal and state authority for health are inherent in the design of the US system of government and are re-negotiated and re-interpreted with most new laws and regulations, particularly when new responsibilities, authority, and new agencies are created by law.

In recent years, the balance of powers has been seen clearly with the variability of state responses to the Affordable Care Act (ACA). For example, by law, states are expected to exercise enforcement authority over health insurance marketplace reform or notify the Centers for Medicare and Medicare Services (CMS) that they

lack the authority or ability to enforce these reforms. In the latter cases, CMS will work out a collaborative arrangement with the states [3]. Because the policy and political climates vary so much across the states, this approach to shared federal-state responsibility can range from cooperative to contentious and may or may not reach public awareness or become the subject of public debate.

The U.S. Constitution is based on a separation of powers, meaning that Congress has the authority to make laws; the President is commander in chief and head of the executive branch of government, with the responsibility for administering and enforcing the laws; and the judicial branch or courts interpret the laws. This chapter focuses on the legislative and executive branches.

Organization and Authority of Congress

The U.S. Congress consists of the Senate, whose 100 members serve 6-year terms, and the House of Representatives, whose 435 members serve for 2-year terms. Each branch does its legislative work through committees and subcommittees, whose chairs have the most influence in the legislative process. The most influential committees are those that deal with appropriations, and some subcommittees have special oversight responsibilities for programs and issues that cut across committee jurisdictions.

In its purest form, the legislative process begins when a "lawmaker" or individual member introduces a bill, with as many co-sponsors as possible. Whenever a bill is introduced in either the House or Senate, it is first sent to the committee of jurisdiction for consideration, which can then send it to a subcommittee, hold public hearings, "mark up" or rewrite the bill. The committee then votes on whether to send the bill to the floor for debate and further consideration. If the bill reaches the floor for a vote and is passed, it then passes to the other chamber, which develops and votes on a similar bill. The two versions are reconciled in conference and another vote is held. When the conference version is passed in both chambers, it goes to the President for signature or veto.

The Senate has 21 standing committees, and the most important for health care and public health are Finance; Health, Education, Labor and Pensions (HELP); and Appropriations. In the House, there are 20 standing committees, and the key for health issues are Ways and Means; Energy and Commerce; and Appropriations. The Senate Finance and House Ways and Means Committees have jurisdiction over Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), and Senate and House Appropriations Committees have authority for agencies in the Department of Health and Human Services (HHS), including the 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), the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Office of the Secretary (OS).

Congressional members and staff often have or develop individual expertise in health issues, but because of the complexity of the health sector and the absence or lag time in getting relevant information from the field, they often seek advice and information from other credible sources, such as reports from the Government Accountability Office (GAO), the Institute of Medicine (IOM), the Congressional Research Service (CRS), and professional as well as trade associations such as the American Medical Informatics Association (AMIA) Health Information and Management Systems Society (HIMSS), and College of Health Information Executives (CHIME). The information provided by professional experts such as those from these organizations to Hill staff and members can provide valuable background and context for policy issues as they are playing out around the country.

Organization and Authority of the Federal Executive Branch

The President heads the executive branch of government, which administers and implements laws by developing budgets, regulations, and programmatic guidelines and also oversees programs and provides regulatory oversight as specified by law. The executive branch is organized into 15 Cabinet-level departments, including the Department of Health and Human Services (HHS), whose FY 2015 budget totals $1 trillion in outlays [4].

HHS is the principal department for protecting the health of all Americans, and it is organized into 8 agencies or operating divisions. Virtually every one has responsibilities that affect or interface with informatics.

The **Agency for Healthcare Research and Quality** (AHRQ) has provided guidance and technical assistance for planning, implementing, and evaluating HIT since 2004, when it began providing funding for implementation projects to improve patient safety and population health [5]. Over the past decade, AHRQ created a variety of toolkits to assist and support health systems and the clinical community in developing decision support tools [6]. AHRQ continues to fund HIT research to improve the design and deployment of HIT systems, and has probably been the leading funder of applied evaluations.

The **Centers for Disease Control and Prevention** (**CDC**) provides funding to states through cooperative agreements that support information infrastructure development and data collection for heath promotion, disease prevention, and emergency preparedness, including biosurveillance and environmental health. CDC has been the federal focal point for public health informatics and sponsors regular convenings for public health informaticians to share information and tools for public and population health planning, research, and reporting [7].

The **Centers for Medicare and Medicaid Services** (**CMS**) is the regulatory and payment agency for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). CMS also oversees the Medicare and Medicaid incentive programs for the adoption and meaningful use of EHRs, in collaboration with the Office of the National Coordinator for HIT (ONC).

The **Food and Drug Administration** (**FDA**) protects the public health by assuring the safety and security of human and veterinary drugs as well as food safety. The FDA Safety and Innovation Act (FDASIA), which will be covered further below, expanded the FDA's authority to include mobile medical applications [8].

The **Health Resources and Services Administration** (**HRSA**) provides support and technical assistance for safety net providers, such as Federally Qualified Health Centers, rural hospitals, and critical access hospitals, to implement HIT systems and health information exchanges [9].

The **Indian Health Service** (**IHS**) provides funding and technical assistance to improve the quality, safety, and efficiency of health information systems used in providing health care and services for 1.9 million American Indians and Alaska Natives (AI/AN) [10]. IHS maintains a database of best practices (evidence-based practices) in AI/AN communities, schools, work sites, and health centers, clinics, and hospitals [11]. IHS uses an Electronic Health Record (EHR) derived from the VHA VISTA EHR code base and has developed a comprehensive suite of software applications to help meet meaningful use and quality reporting requirements [12].

The National Institutes of Health (**NIH**) [13] is the single largest funder of biomedical research, and the **National Library of Medicine** (**NLM**), the world's largest medical library, produces electronic information that is searched by millions of people (e.g. MEDLINE, PubMed) and also has the lead federal responsibility for developing clinical terminology standards for HIT. NLM also has been a leading source of support for the field of informatics through fellowships at NLM and sponsored university-based training programs [14]. One of many free NLM information resources is MedlinePlus Connect, which allows health organizations and HIT providers to link electronic record (EHR) systems and patient portals to MedlinePlus, which has hundreds of health topic pages aimed at consumers [15].

The **Substance Abuse and Mental Health Services Administration** (**SAMHSA**) supports programs for the promotion of mental health and the treatment and prevention of substance use disorders and mental illness, also known as behavioral health conditions. To help ensure that behavioral health and physical health services share information while ensuring patient confidentiality, SAMHSA and HRSA collaborate to use HIT to support care coordination among networks of providers, patients, and payers.

The **Office of the National Coordinator for HIT** (**ONC**). Located administratively in the Office of the Secretary of HHS, ONC is charged with coordinating nationwide efforts to implement and use HIT to exchange electronic health information [16]. ONC was created in 2004 by a Presidential Executive Order and was codified (mandated legislatively) in the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009. ONC is responsible for coordinating HIT activities within the executive branch, making sure that the federal HIT programs are meeting the objectives of the strategic plan to create a nationwide HIT infrastructure, and reporting on progress being made in public and private sectors.

The **Office for Civil Rights** (**OCR**). Located administratively in the Office of the Secretary of HHS, OCR enforces HIPAA and civil rights laws to "protect fundamental

rights of nondiscrimination and privacy." OCR is the principal drafter and compliance enforcer of the HIPAA rules meant to protect individually identifiable health information, including the Privacy, Security and Breach Notification rules.

Other Key Federal Agencies for HIT

Outside of HHS, the **Veterans Health Administration** (**VHA**), part of the **U.S. Department of Veterans Affairs** (**VA**), is not only a major provider of health services for veterans and the largest integrated healthcare system in the US, but also an early adopter of EHRs and consumer web portals to facilitate patient access to clinical records. VistA, the Veterans Health Information Systems Technology Architecture, provides an integrated inpatient and outpatient EHR for patients at the VA and allows nationwide access through all VA facilities [17].

The **National Institute for Standards and Technology** (**NIST**) was created by Congress in 1901 to develop a measurement infrastructure, beginning with standards in the physical sciences. Now located within the Department of Commerce, NIST has evolved to include global communication networks and other technologies and includes a health and standards testing program that collaborates with ONC to help improve health care delivery through HIT [18].

The **President's Council of Advisors on Science and Technology** (**PCAST**), administered by the Office of Science and Technology Policy in the White House, is an advisory panel appointed by the President that expands the range of science and technology advice available through the executive branch. Members are selected from academic and research institutions, industry, and non-governmental organizations and have expertise in many areas of science and technology innovation. A 2010 PCAST report on HIT called for an acceleration of efforts to build a digital infrastructure for healthcare [19] and PCAST reports in 2014 called for the use of a systems engineering approach to address healthcare cost and quality challenges [20] and analyzed the technical aspects of big data and privacy [21].

The **Federal Trade Commission** (**FTC**) was created by Congress in 1914 to protect consumers by stopping unfair, deceptive, or fraudulent practices in the marketplace and promoting competition by ensuring free and open markets. In February 2010, FTC began enforcing its Health Breach Notification Rule for web-based businesses that are not covered by HIPAA.

Role of the Private Sector in Policy Development

Independent advisory bodies have always played a vital role in health policy development. Since 1949, the **National Committee on Vital and Health Statistics** (**NCVHS**) has served as a statutory advisory body to the Secretary of HHS on health information policy, making policy recommendations on a variety of topics affecting

health information infrastructure and informatics, including data access and quality, standards, privacy and confidentiality, and population health [22].

In 1970, the National Academy of Sciences founded the **Institute of Medicine** (**IOM**) to provide independent advice to Congress and the executive branch on issues related to health and science policy. Over the years, IOM committees have been convened to issue reports on health care coverage and access, health services research priorities, health care quality, patient safety, the role of HIT in health system transformation, public and population health, and many other subjects. IOM studies are sometimes Congressionally mandated or requested, or may also be requested and funded by federal agencies or private organizations [23]. Their influence on health policy development in both public and private sectors has been very substantial.

The **Patient-Centered Outcomes Research Institute** (**PCORI**) is a nonprofit, nongovernmental organization created by the Affordable Care Act to fund comparative effectiveness research (CER) and disseminate findings widely to policy-makers, practitioners, and the general public. PCORI seeks to improve clinical outcomes by filling evidence gaps about what works in clinical practice and by engaging consumers in developing research questions that will answer their questions about treatment options. The emphasis on patient-centered research outcomes (PCOR) is a departure from previous priorities driven by the biomedical research community and is helping to build an information infrastructure for working with electronic health record (EHR) data that can be readily shared with patients and consumers.

Health care represents the largest sector for federal lobbying, accounting for $549 million in calendar year 2013 [24] and there are approximately 8 registered lobbyists for each member of Congress [25]. But individual members of national organizations such as AMIA, HIMSS, the American Hospital Association (AHA), the American Medical Association (AMA), the American College of Physicians (ACP), and many others also can be influential in the policy development process by meeting with Congressional members and staff to provide technical background, sharing real-world experiences about how legislation and regulations are being implemented, and being available to advise on legislative language, speeches, hearings, constituent meetings, and other activities.

The Policy Environment for Clinical Informatics

For practicing informaticians, it is vitally important to be familiar with influential and policy-relevant pieces of legislation. In this section, we will discuss the Health Insurance Portability and Accountability Act (HIPAA), HITECH (Health Information Technology for Economic and Clinical Health Act), the Patient Protection and Affordable Care Act (ACA), and the Food and Drug Administration Safety and Innovation Act (FDASIA). We include a timeline of key legislative and regulatory events associated with these laws to put them in context (Table 3.1).

Table 3.1 Timeline of key legislative and regulatory events

August 1996	Health Insurance Portability and Accountability Act (HIPAA) requires development of standards for electronic exchange of health information under administrative simplification provisions
December 2000	HIPAA Privacy Rule sets national standards to protect individually identifiable personal health information used by health plans, health care clearinghouses, and health care providers (covered entities)
August 2002	HIPAA Privacy Rule is modified and finalized, with a compliance date of April 2003 for most entities
February 2003	HIPAA Security Rule establishes national standards to protect the confidentiality, integrity, and security of electronic personal health information
April 2004	Presidential Executive Order creates Office of the National Coordinator for HIT (ONC) in the Office of the HHS Secretary and calls for widespread use of HIT within 10 years
February 2009	Congress passes the Health Information Technology for Economic and Clinical Health (HITECH) as part of the American Reinvestment and Recovery Act of 2009 (ARRA), outlining an incentive program for adopting electronic health records known as meaningful use and creating a HIT Policy Committee and an HIT Standards Committee to advise ONC
March 2011	ONC releases a 5-year strategic plan for HIT to increase adoption of EHRs, promote health information exchange, and promote individual access to health information
July 2012	Congress passes the Food and Drug Administration Safety and Innovation Act (FDASIA), stimulating medical device innovation while expanding the agency's authority to regulate medical devices
January 2013	HHS releases an "omnibus" Rule that makes changes to HIPAA Privacy, Security and Enforcement Rules as required by the HITECH statute.

From HIPAA to HITECH: What Every Informatician Should Know About Privacy Regulations Governing Health Information

In 1996 Congress passed the Health Insurance Portability and Accountability Act (HIPAA), a remnant of the Clinton health reform effort that was intended to protect ongoing health insurance coverage for workers who change or lose jobs. Title II of HIPAA, known as Administrative Simplification, required the establishment of national standards for electronic health care transactions and development of national identifiers for providers, health insurance plans, and employers. Broadly, the idea was to facilitate the transition of the U.S. health care system from antiquated paper records and communications systems to an efficient electronic information environment by establishing standards for the use and exchange of health care information.

But even as it committed to advancing electronic health information technologies, Congress was concerned about the privacy and security of health records and so the HIPAA law called for passage of national health information privacy legislation within 36 months, with the proviso that the Secretary of Health and Human Services (HHS) would promulgate health privacy standards if Congress failed to

act. And thus in the period from 1999 through 2002 the HIPAA Privacy Rule was developed by HHS. Since that time, HIPAA has been updated once, in the HITECH Act of 2009.

What Should Every Informatician Know About HIPAA Today – and What Developments Might We Expect in the Future?

The Basics of the Privacy Rule: HIPAA 1 – From 2002 to 2009

The Privacy Rule Provides rights to individuals (patients) and mechanisms for the exercise of those rights, while imposing obligations on covered entities to protect the privacy of individually identifiable health information and to facilitate the individual's rights.

Who Is Covered by the Rule?

Covered Entities: Provisions of the rule apply to covered entities: health plans, health care clearinghouses, and "health care providers who transmit health information in electronic form in connection with any transaction referred to in Section 1173(a)(1)." (Transactions include: health claims or encounter information – enrollment and disenrollment – eligibility – payment and remittance advice – premium payments – 1st report of injury – claim status – referral certification and authorization)

What Is Covered?

Health Information: any information created or received by a health care provider that "relates to the past, present or future physical or mental health or condition of an individual", the provision of care, or payment for care.

Individually Identifiable Health Information: a subset of health information, including demographic information, that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Protected health information: means individually identifiable health information that is transmitted or maintained electronically, or transmitted or maintained in any other form or medium.

When May a Covered Entity Use or Disclose Protected Health Information (PHI)?

Without a specific consent for "treatment, payment and health care operations" (but subject to "minimum necessary" limitation and "notice" must be provided.)

With certain exceptions, *all other uses/disclosures require an authorization* signed by the individual. (Exceptions to authorization include: when required by law; for public health; to avert serious threats to health or safety; for health oversight; for law enforcement; and for research, subject to various conditions.)

What About Business Associates?

Business Associates "perform or assist in the performance of" a function or activity involving the use or disclosure of individually identifiable health information *on behalf of* a covered entity, under a written contract that cannot permit the business associate to make any uses/disclosures that the covered entity could not make. BAs "work for" CEs on activities related to "treatment, payment and health care operations." They are not directly subject to the jurisdiction of HHS, but are contractually 'regulated through' the covered entity.

Points to Remember

Within the HIPAA Privacy Rule, always think about:

- *Who the Rule covers* – providers, health plans, claims clearinghouses;
- *What the Rule covers* – protected health information (PHI);
- *Who is doing what, for whom, under what condition* – covered entities, business associates on behalf of covered entities, others (under certain exceptions: e.g., public health authorities, researchers under limited circumstances.)

Under the Privacy Rule, consider in every instance under what authority PHI is used or disclosed:

- *Without consent* – for "treatment, payment, health care operations" of the covered entity, subject to minimum necessary limitation and Notice must be provided to the individual;
- *To a business associate performing activities on behalf of a covered entity, by contract*, which cannot permit any uses or disclosures that the covered entity would not be permitted;
- *With an individual authorization,* (e.g., for the release or transfer of records, for the use or disclosure of PHI for research, etc.)*;*
- *Under a waiver granted by an IRB or Privacy Board;*
- *To a person subject to the jurisdiction of the FDA,* (e.g., for the reporting of adverse events to a pharmaceutical company) – but not for commercial purposes;
- *And for certain public health, health oversight and law enforcement purposes.*

These six pathways constitute the entirety of methods by which PHI can be used or disclosed between and among covered entities and business associates, and the ways in which a covered entity or business associate can disclose PHI to an entity

that is not subject to HIPAA per se, such as a pharmaceutical company collecting clinical trial data as permitted by an individual's signed authorization.

What Happens If a Covered Entity Fails to Comply with HIPAA Requirements?

The covered entity could be subject to civil penalties of $100 per violation for failure to comply with standards, and up to $50,000 fine for wrongful disclosure of individually identifiable health information. The covered entity will be unable to use or disclose individually identifiable health information lawfully.

HIPAA in the HITECH Era: 2009 to the Present

In 2009 President Obama signed into law the American Recovery and Reinvestment Act (ARRA) a $787 billion package of "shovel ready" projects intended to stimulate an economy in deep recession. Included in ARRA was the HITECH Act, which provided for between $25 and $36 billion in incentive payments for the adoption of electronic health record (EHR) system that included functionalities sufficient to demonstrate "meaningful use." HITECH also included a series of provisions that were intended to strengthen the privacy and security requirements of HIPAA, and to broaden the reach of the rules.

Who Is Covered Under HITECH?

- Covered Entities (CEs)
- Business Associates (BAs) – not just by contract now, but directly subject to the jurisdiction of HHS in regard to the requirements (and penalties) of the HIPAA Security Rule and relevant provisions of the Privacy Rule. This expanded jurisdiction over business associates specifically included entities that transmit or process data on behalf of CEs, like RHIOs, E-Prescribing Gateways and cloud providers.
- Personal Health Record (PHR) vendors, in relation to new breach reporting obligations.

The Largest New Requirement is Breach Reporting – So What's a Breach?

- A breach is "unauthorized acquisition, access, use, or disclosure" of PHI which compromises security or privacy, except –
- when the person could not have reasonably retained the PHI
- is to an employee acting in good faith and under the scope of his/her employment
- is an inadvertent disclosure made by an authorized person and occurs within the facility

And the PHI is not further acquired, accessed, used, disclosed, etc.

What Happens in the Event of a Breach?

In the event that a CE discovers a breach, it shall "notify each individual whose unsecured PHI has been, or is reasonably believed by the CE to have been, accessed, acquired or disclosed as a result of such breach:"

- Without unreasonable delay and in no case later than 60 calendar days;
- In writing, by US mail or electronically (and, in certain cases, via broadcast media, web posting, etc.);
- Notify the Secretary of HHS, either immediately (if more than 500 persons involved) or annually;
- (And similar requirements apply to PHR vendors, who will notify individuals and the Federal Trade Commission).

And What Must the Notification to an Individual Include?

- What happened, including the date of the breach and the date of its discovery;
- The type of PHI involved;
- Steps individuals should take to protect their privacy and/or identity;
- What the CE is doing to investigate, mitigate and protect against future breaches;
- Contact procedures for questions and additional information.

What Is the Cost of Breach Reporting to the Covered Entity, Business Associate or PHR Vendor?

The total costs of a breach incident – including preparing notices to individuals, providing identity theft monitoring service, legal costs, etc. – have been estimated at up to $200 per individual whose PHI was breached. This does not include the loss of consumer trust and institutional reputation incurred by the covered entity, business associate or PHR vendor, nor fines of up to $1.5 million per year that can be levied by HHS.

What Are Some of the Other New Obligations and Requirements HITECH Put in Place?

- CEs must, on request of the individual, provide an accounting of non-oral disclosures made for purposes of treatment, payment or health care operations for a period of 3 years [this rule has not been finalized, and is not enforced by HHS at this time];

- CEs must, on request, restrict disclosure of PHI to a health plan for purposes of payment or health care operations, if the individual self-pays for a service;
- In making uses or disclosures for payment or health care operations, CEs must use a 'limited data set', to the extent practicable;
- If a CE or BA receives direct or indirect remuneration for communications with an individual this is Marketing and requires an authorization, except for communications relating to a drug or biologic currently being prescribed.

Changes Made by HITECH Regarding Enforcement and Penalties

- Business Associates are directly subject to Security and applicable Privacy provisions;
- Criminal penalties can be enforced against individuals, not just CEs and their employees;
- Civil monetary penalties (CMPs) must be pursued by HHS in cases in which a covered entity or business associate shows "willful neglect" of the rules;
- CMPs are increased from $100 per violation with an annual maximum of $25,000 to up to $50,000 per violation and an annual maximum of $1.5 million.

Under HIPAA and HITECH

- PHI can be used and disclosed only as permitted.
- A limited data set that excludes 16 direct identifiers and is disclosed with a data use agreement for research, public health or health care operations is still considered PHI for the purposes of breach reporting.
- The only methods for rendering unsecured PHI "unusable, unreadable or indecipherable" and therefore not subject to breach reporting requirements are *encryption* and *destruction*.
- "Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information" – *and therefore is not subject to the requirements of the HIPAA Privacy or Security Rules.* The two acceptable methodologies of de-identification are the Safe Harbor in which 18 identifiers are removed or the Statistician's Certification in which the risk of re-identification is determined to be "very small."

Meaningful Use (HITECH) and the Affordable Care Act (ACA)

Before 2004, the U.S. did not have HIT coordination at the national level. That changed with the appointment of David Brailer by President George W. Bush and the establishment of the Office of the National Coordinator by Presidential Executive Order.

Later, in 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed to encourage hospitals and outpatient providers to both adopt electronic health records, and use them in meaningful ways. National coordination was linked with grant programs and payment incentives, under the assumption that this would result in enhanced trust would enable providers who had been "on the fence" about EHR adoption to move forward.

A key to this was the new concept of "**meaningful use**." The idea was to try to ensure that providers would not simply adopt electronic health records, but that they also would use them in ways that would improve the safety and quality of healthcare, and reduce its costs. This was linked with the "escalator concept," the idea being that providers would get on the escalator and continue up it, to higher levels of adoption and better care delivery. Meaningful use has three stages. To qualify for Stage 1, providers simply needed to adopt EHRs that were certified. For Stage 2, providers had to begin to implement advanced care processes linked with clinical decision support. The hope with Stage 3 is that providers will be able to go all the way to demonstrating improved outcomes.

Although they were enacted over a year apart, today the HITECH Act is closely linked with the Affordable Care Act, which is intended to begin payment reform and includes the notion that providers will be accountable for the costs of the care they deliver. As part of HITECH, two HIT committees were formed—the HIT Policy and Standards committees. The concept of meaningful use was developed by the Health Information Technology Policy Committee, which then sent its recommendations to ONC. ONC refined them and worked with CMS to convert these recommendations into regulations that would result in payment for providers who qualified. The Standards Committee has been asked to identify standards for all the main types of clinical data, and this has largely been accomplished, which will make it much easier for vendors to move forward. Examples include LOINC (Logical Observation Identifiers Names and Codes) for laboratory results and SNOMED (Systematized Nomenclature of Medicine-Clinical Terms) for problems. The work of both the HIT Policy and Standards Committees has been completely in the open.

Stage 1 of Meaningful Use has been quite successful, in that around 80% of hospitals and eligible providers in the outpatient setting qualified. Attestation rates, however, have been much lower to date for Stage 2, and it is unclear how much these will rise over time [26, 27]. The final criteria for Stage 3 were released early in 2015. Vendors and providers have generally felt that the criteria to be met have been too difficult, while payers and patient groups have pushed for more stringent criteria. To qualify, providers have to meet all the criteria, which has involved doing a number of things that they would not have done as quickly as they did them because of the incentives involved.

Many have been concerned that the need to meet the criteria has diverted attention from their own quality and efficiency improvement agendas. While the program appears to have gotten a high proportion of providers to adopt, it is probably too early to assess the impact of the meaningful use criteria on the quality, safety and efficiency of healthcare, though these have been the main target of the policy.

Federal Drug Administration Safety and Innovation Act (FDASIA)

Signed into law in 2012, the Federal Drug Administration Safety and Innovation Act (FDASIA) gives the FDA authority to continue to collect user fees from the biomedical industry, as well as to regulate medical software. The Secretary of Health and Human Services asked the Health Information Technology (HIT) Policy Committee to convene a stakeholder group to help provide input into the development of a framework for regulating software. This was done through ONC, FDA, and the Federal Communication Commission. The workgroup was asked to put forward a risk-based regulatory framework, including how healthcare IT systems could be stratified in terms of risk, and recommendations about how the regulatory requirements currently in place should be adapted. The tri-agencies then took these suggestions and released a full report in the spring of 2014 [28].

Key findings of the report were that electronic health records were felt to be relatively low-risk, so that full FDA regulation would not be helpful, and could stifle innovation. Nonetheless, it was clear that HIT does create new risks. One of the main recommendations of the report was that it would be helpful to create a new HIT Safety Center, and a federal contract has been let to provide input around what the mandate of and goals for such a center might be.

Emerging Trends

The regulatory framework for assuring the privacy and security of an individual's health information will continue to evolve. The circle of HIPAA coverage is expanding from covered entities during the first era to business associates and PHR vendors post-HITECH. Protected health information (PHI) is beginning to become less contextually determined; e.g., "PHR identifiable health information" does not need to be created, managed, or held by a CE or BA, but can be held by the person or by another party.

While in the early days of HIPAA there were promises that "there will never be HIPAA police" and that HHS would always look to educate covered entities and business associates about how to follow the rules, the post-HITECH era has seen a marked shift to compliance enforcement, supported by the imposition of fines and penalties for non-compliance. In another development, the Federal Trade Commission (FTC) is increasingly asserting oversight of the privacy and security of health information as a consumer protection issue, which sometimes means that those covered by HIPAA will also be subject to enforcement actions by the FTC.

We foresee many public discussions about big data, interoperability, mobile devices and user-generated data. HIPAA does not apply to health data collected, accessed, used and/or disclosed by non-covered entities, such as websites and consumer-facing devices and apps. At the same time, it is not clear how the FDA

and/or other regulators should regulate HIT hardware and software [29]. Clinical informaticians may be asked to form opinions and offer public comment on whether a new regulatory framework should extend HIPAA-like protections (and obligations on app developers and mobile companies) to such "nonhealth" data.

For example, future informaticians will need to decide whether HIPAA's de-identification methodologies (Safe Harbor and "statistician certification") are adequate in an era of big data. They will need to evaluate the potential risks of re-identification of data, and decide what protections would prevent harm to individuals while maintaining the workflow of clinical research and quality reporting.

Once the HITECH adoption incentives are gone, we don't yet know what array of incentives, mandates, standards, etc. will be needed to improve the interoperability of health data systems across sites of care, payment systems, methods of data collection, etc. There is a tremendous gap between the generators of clinical research data and clinical care data, and also between the original generators of data and those who reuse the data for research and reporting. Currently, there are few opportunities for these spheres to interact and inform each other. Similarly, there are too many examples of healthcare systems developing their own standards when interoperability would be far better served by their using existing standards and specifications. However, as long as healthcare systems see themselves primarily as competitors and as owners of proprietary data, the incentives for data-sharing will continue to be limited.

We encourage clinical informaticians to engage in the coming policy debate on these issues through AMIA and other professional associations, as well as through governance discussions in your own institutions. The debate will be far more productive when practicing informaticians bring real-world evidence to the discussion.

Summary

The adoption and use of HIT in the U.S. has been influenced by a complex set of factors in both public and private sectors. These include geographic variations in technology infrastructure investments; variations in provider experiences and attitudes toward information technology; the complexity of communicating the regulatory environment governing information-sharing under HIPAA; market forces, particularly competition among providers and lack of alignment of financial incentives for providers to invest in Health IT; variations in legal interpretations of HIPAA across institutions; general lack of familiarity among clinical practitioners with the policy process and the regulatory environment in which they practice; and siloes, and even some competition, among the federal entities whose authorities span Health IT.

The recent implementation of meaningful use has had a profound impact on the adoption of HIT in the U.S., and it has also had major effects on what features electronic health records contain. The vendors have been so busy with responding to the requirements of meaningful use that they have been less responsive to the requests of their users. Whether or not this policy will have the desired long-term impact on health

care quality and costs is uncertain, but it has had a huge impact on clinical informatics. Similarly, the extent to which information technology is regulated in the future by the government – and the culture and approach of the different federal regulatory agencies (e.g., CMS, FDA, FTC) is likely to have a major impact on how HIT develops.

At the highest conceptual level, and at the operational level within individual healthcare delivery systems, the HIT enterprise requires ongoing and continuous collaboration and cooperation between public and private sectors. We hope that this chapter has helped to illuminate the reasons why all clinical informaticians will benefit from a working knowledge of the policy process and regulatory environment, including the key federal and private-sector agencies and organizations that engage with each other to drive HIT implementation and use.

Questions for Discussion

1. The Medicare and Medicaid EHR Incentive program provides financial incentives for the meaningful use of certified EHR technology to improve patient care. Payers and patient groups have generally pushed for more stringent meaningful use criteria, while providers and vendors have generally felt that the criteria were too difficult. Why did stakeholders disagree about the speed of implementing and adopting EHRs?
2. The Office of the National Coordinator is charged with coordinating HIT within the executive branch and reporting on progress in the public and private sectors. How do you think the role of ONC will change in the new post-HITECH ecosystem, after the financial incentives for adoption of EHRs are gone?
3. What is the role of professional organizations, particularly the American Medical Informatics Association (AMIA), in policy development and implementation?
4. The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. Is the Privacy Rule adequate to protect the privacy of personal health information?
5. The FDA has the authority to regulate medical software and will focus on medical device Health IT functionality, but not on platforms or product names. Is this a reasonable regulatory approach?

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Part II
Clinical Decision Making/Care Process Improvement

Chapter 4
Clinical Decision-Making

Stephen M. Downs and Lydia K. Johns

Learning Objectives

1. Describe the basic concepts and main schools of probability.
2. Use Bayes Theorem to estimate probabilities in an environment prone to changing circumstances.
3. Recognize potential biases and heuristics in probability and decision analysis.
4. Analyze possible courses of action and outcomes with decision trees.
5. Apply axioms of expected utility theory to determine best options.
6. Assess patient outcomes using cost-effectiveness analysis and QALY.
7. Identify advanced decision-modeling techniques used in CDSS.
8. Explain the relationship between decision science and clinical informatics.
9. Understand real world contexts for clinical decision analysis and CDSS.

Core Content

The following core competencies are covered in this chapter:

Clinical Decision Support

- The nature and cognitive aspects of human decision making
  - General
  - Medical

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- Decision science
  - Decision analysis
  - Probability theory
  - Utility and preference assessment
  - Cost effectiveness analysis
  - Test characteristics (e.g., sensitivity, specificity, predictive value)
- Legal, ethical, and regulatory issues

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 (streptococcal) throat? What questions and physical examination findings will you rely on to help narrow down the differential diagnosis? Are there any other 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 has the potential to 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 limitations of the human brain, and so 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]. However, by the 1960s

a growing body of psychological research showed that human decision-making could (and usually did) deviate from the idealized model, [2] and from there, decision analysis was born [3].

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 [4]. What is a probability? It is a number between zero and one that represents 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 "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 [5]. In addition to zero and one representing certainty, these include that the probability of A *and* B is equal to the probability of A times the probability of B:

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

if A and B are *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 role 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 [6]. The classical school refers to the early concepts of probability. These apply 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 classical interpretation of probability, one that can be derived from an understanding of 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 gets 50 % and tails gets 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've seen) as long as there is consensus about the underlying mechanisms. However, they require knowledge of elementary events and are strongly model bound.

The more modern school of probability, taught 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 [7]. This conceptualization assumes the existence of some underlying "true" probability of the outcome and 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 estimation of the probability.

It can be seen that 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. So estimating the probability of success of the first landing of a probe on mars could not be done in a strictly frequentist way. The experiment can't be repeated multiple times. Frequentist probabilities are never exact because infinite replication is not possible.

The third school of probability is the subjectivist school. Subjectivist probabilities require neither data nor formal analysis, but in fact, the subjective probability school subsumes the other schools philosophically. In fact, subjective probabilities are the most commonly estimated and used by far. 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 [6].

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'd 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 not only because they are the most commonly used, but because their necessity is inescapable in clinical practice and in formal decision modeling. Consider the physician who sees a patient with a sore throat. According to the Centor criteria, [8, 9] the probability this patient has a streptococcal pharyngitis can be estimated by adding points for the patient's age and symptoms:

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. But if we learn that two other members of the household have had positive strep throat cultures or observe that the patient has a scarletiniform 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. There are no patients or circumstances that 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, and almost never are there clinical studies that provide 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]. 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 issues of discrimination and social justice, and also 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, despite the fact that quick reflection will reveal that the population of bank tellers active in the feminist movement is a strict subset of all bank tellers. Therefore it is at least as likely that Linda is a bank teller as that she is a bank teller and is 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 antinuclear 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. Similar to the representativeness heuristic, availability refers to the estimation of 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 the massive press this condition receives. While, in fact, over ten times more women die each year from cardiovascular disease than from breast cancer.

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. According to surveys, Americans are nearly as worried about Ebola as they are about catching the flu. At the time of this writing, exactly one person in the US has 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 hear 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

Table 4.1 Classic 2-by-2 contingency table

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

infection has an elevated white blood count or a pedestrian judges the volume of traffic before endeavoring to cross the street), but we often do it badly. Test yourself.

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 % [10]. In fact, 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 4.1).

The table depicts 10,000 hypothetical patients. In the columns, we see that one in 1000, 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 nine 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:

$$PPV = \frac{Prevalence \times Sensitivity}{Prevalence \times Sensitivity + \left(1 - Prevalence\right) \times \left(1 - Specificity\right)} \tag{4.1}$$

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

$$p\left(D|T\right) = \frac{p\left(D\right) \times p\left(T \mid D\right)}{p\left(D\right) \times p\left(T \mid D\right) + p\left(\neg D\right) \times p\left(T \mid \neg D\right)} \tag{4.2}$$

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 $p(T \mid \neg D)$ is the probability of a positive test given not disease (1-*specificity*).

This is Bayes' formula, attributed posthumously to reverend Bayes in 1763 [11]. A more compact version of Bayes' formula can be derived by dividing formula (4.1) above, by the equivalent formula for calculating the *negative predictive value* as follows:

$$\frac{PPV}{1-NPV} = \frac{\left[\dfrac{Prevalence \times Sensitivity}{Prevalence \times Sensitivity + (1-Prevalence) \times (1-Specificity)}\right]}{\left[\dfrac{(1-Prevalence) \times (1-Specificity)}{Prevalence \times Sensitivity + (1-Prevalence) \times (1-Specificity)}\right]} \tag{4.3}$$

Formula (4.3) reduces to

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

The term $\dfrac{Prevalence}{1-Prevalence}$ is referred to as the *odds* of disease; it is the probability divided by one minus the probability. The term $\dfrac{Sensitivity}{1-Specificity}$ is known as the *positive likelihood ratio* (LR^+). The term $\dfrac{PPV}{1-NPV}$ 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 is calculated in the same way, using the *negative likelihood ratio* (LR^-), which is given by $\dfrac{1 - Sensitivity}{Specificity}$.

This is known as the *likelihood ratio* form of Bayes' formula [12]. With practice, it can become relatively easy to use this formula to estimate posterior probabilities in one's head. 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 probabilities that are very low, the odds is approximately equal to the probability.) The *positive*

Table 4.2 Sample collection of likelihood ratios (LR) for a hypothetical decision support system

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

Each LR describes the relationship between evidence (symptoms, findings, test results) and a given diagnosis. (See text)

likelihood ratio is the *sensitivity* divided by 1 minus *specificity* or .9/.1 = 9. The *posterior odds* is 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 as we saw with the 2-by-2 table above.

The likelihood ratio form of Bayes' formula 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 catalogue of positive and negative *likelihood ratios* for the evidence to be considered (Table 4.2).

A diagnostic program could evaluate the likelihood of a diagnosis with a prevalence of 2 % in a patient who has symptom A, exam finding B and negative test C, but for whom the results of test D are unknown as follows:

$$\text{Odds}_{\text{prior}} := \text{Prevalence} / 1 - \text{Prevalence} = 0.02 / 0.98 = 0.0204$$

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

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

Such a diagnostic program, with a sufficient knowledge base of LRs, 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. In fact, this assumption is rarely precisely true. However, it is often close enough that the algorithm works. This approach has been successfully employed in a number of decision support systems [13].

So far, we have only considered Bayes' formula for the binary case in which two hypotheses are being considered, i.e. that patient has the disease or the patient does not have the disease. In fact, 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

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

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 likelihood ratio form, with an adequate knowledge base of condition probabilities, complex diagnostic problems can be addressed.

Decision Science

Decision analysis is a method for choosing a course of action under conditions of uncertainty. For the purposes of decision analysis, 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,
3. Preferences for the different outcomes that are possible.

A decision also involves an irreversible commitment of resources (no "do-overs"). Decision analysis 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, which we will discuss 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 that represents 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 that 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, then 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

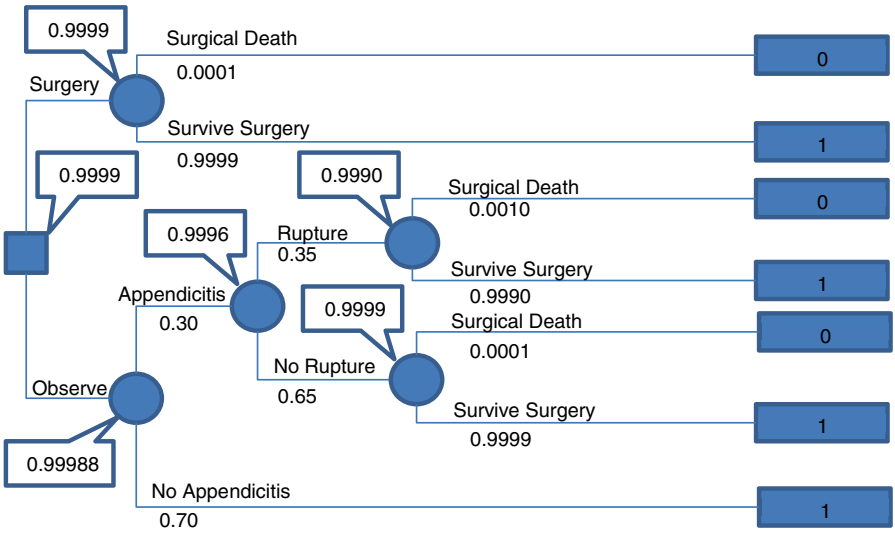

Fig. 4.1 The appendicitis decision tree. As described in the text, this decision tree illustrates the three main types of nodes in a decision tree: *square decision nodes*, *round chance nodes*, and *terminal nodes* at the end of each path

35 % chance that her appendix will rupture. In that case, she will have to have 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 4.1 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 that are 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 of the branches 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 10,000). 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 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. 4.1. These nodes hold numeric representations of the values the decision maker places 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 theoretic basis for assigning more precise values to outcomes is discussed in the Expected Utility Theory section below.

Following the tree from left to right, if the decision maker decides on the surgery option, we have said there is a 9999 chance in 10,000 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 does rupture, 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. 4.1 are shown as bubbles. 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, $(1\times0.9999)+(0\times0.0001)=0.9999$. The value of the *Rupture* node is $(1\times0.9990)+(0\times0.001)=0.9990$. The value of the *Appendicitis* node is $(0.35\times0.9990)+(0.65\times0.9999)=0.9996$. Finally, the value of the *Observe* node is $(0.30\times0.9996)+(0.70\times1)=0.99988$. 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 on sensitivity analysis below. A second concern might be that our utilities, 1 for survival and 0 for death, may be 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 on 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. 4.2. Between the *Surgery* and *Observation* nodes, we have inserted a *Test* node. We have modeled a test with 70 % sensitivity and 80 % specificity. 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, and the *Test Negative* branch has the same structure as the *Observe* branch, under the assumption that that is how 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 $p\left(T^{+}|D\right)\times p\left(D\right)+p\left(T^{+}\mid\neg D\right)\times p\left(D\right)$, the denominator of Bayes' theorem.

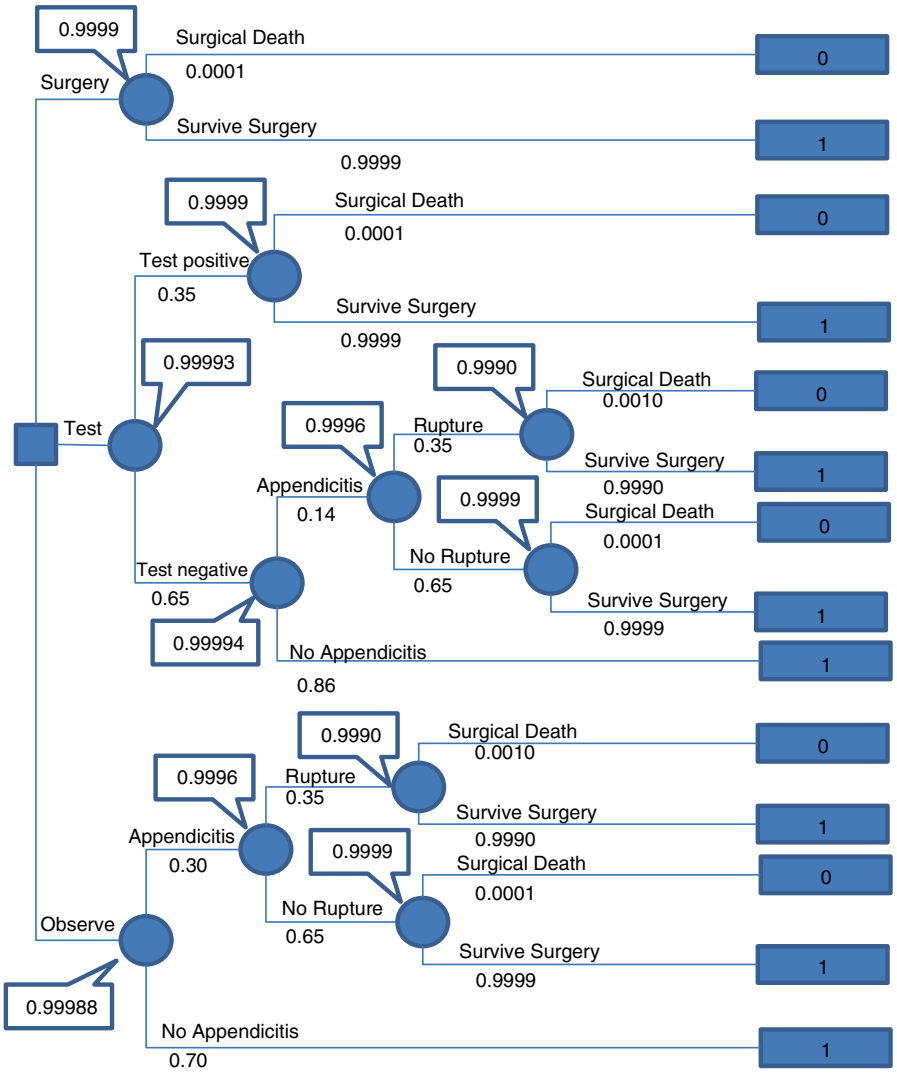

Fig. 4.2 The appendicitis decision tree with a "test" node. As described in the text, this version of the appendicitis decision tree includes the option of obtaining a test to decide how to treat the patient

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.

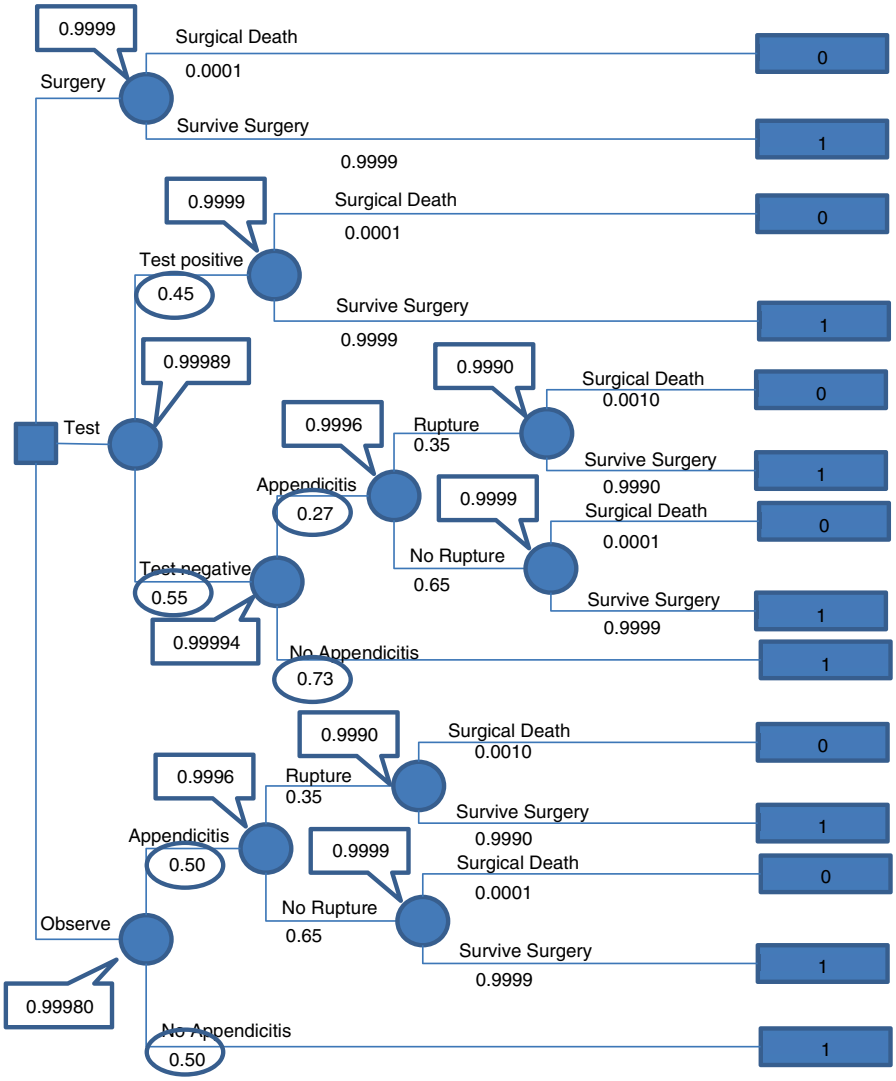

Fig. 4.3 The appendicitis decision tree with the prior probability of appendicitis increased to 50 %, illustrating that which option is best changes as the parameters in the decision model change. The circled probabilities are those that change as the prior probability of appendicitis is increased

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. 4.3. 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*.

To understand why this is so, consider the six probabilities that have changed, circled in Fig. 4.3. The probability of a positive test has gone up to 45 % and the probability of a negative test has gone down to 55 %. More important, the probability of appendicitis given a negative test (the false negative rate) has gone up 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 4.4 shows a one-way sensitivity analysis of the probability of appendicitis. The x-axis shows the probability 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. The points where the lines cross are known as thresholds and they represent the points where the best decision changes. 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. Figure 4.4 has dotted lines projecting the thresholds on to a "threshold bar" at the bottom [14]. This bar represents a kind of decision rule suggesting which option is best given the estimated risk of appendicitis.

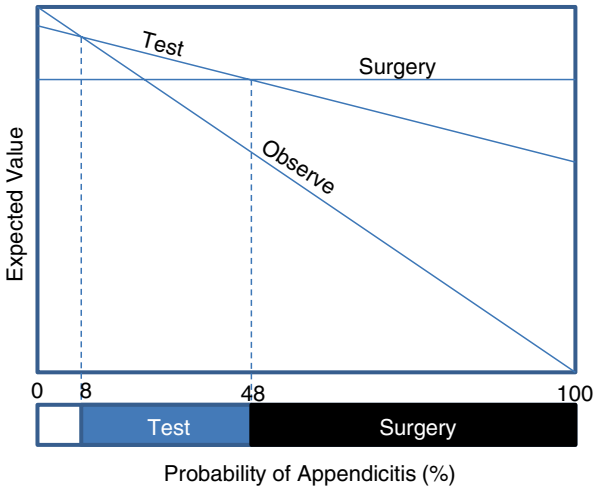

Fig. 4.4 One way sensitivity analysis of the prior probability of appendicitis. The x-axis shows the probability of appendicitis. The y-axis shows the expected value of each decision option as the probability increases. Points where the lines cross are known as thresholds

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, survival after spending a night in observation with no surgery is certainly better than having a ruptured appendix, requiring emergency surgery and resulting in peritonitis although both may 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 is greater than the $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 that is 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 [15]. 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 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, $\lim_{n\to\infty}\sum\left(\frac{1}{2^n}\right)\times 2^n$, 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 on which to make 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.

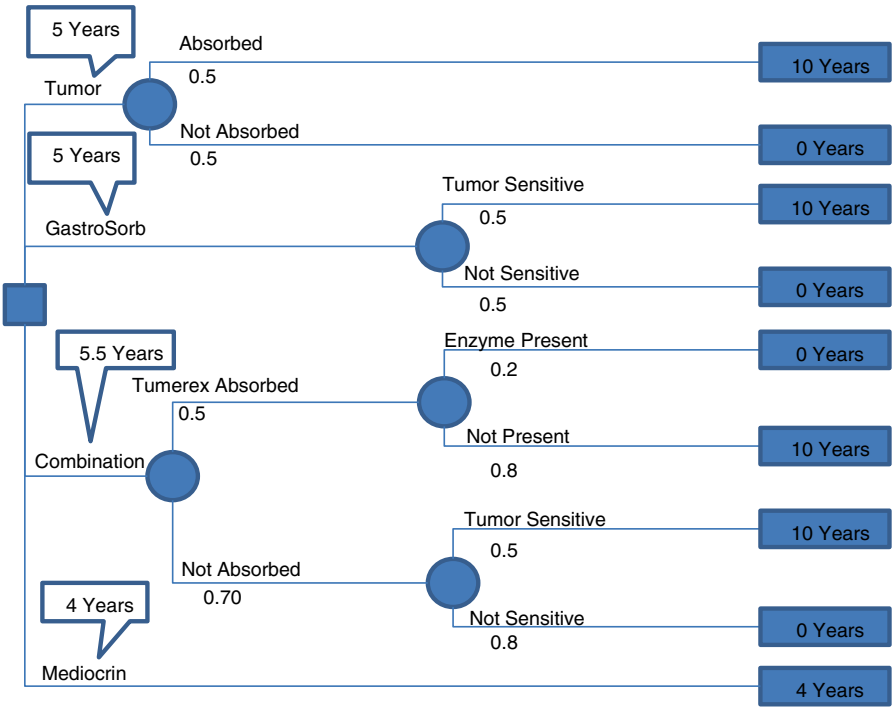

Fig. 4.5 Decision tree illustrating the choice of treatments for the *clinical epidemioma*. The combination treatment appears to offer the highest expected survival. However, application of the axioms of expected utility theory shows that this may not be the best choice (see text)

Raiffa and Howard have developed more intuitive versions of this proof [16]. What follows is adapted from Howard's.

The axioms of expected utility theory, as framed by Howard are: (1) orderability, (2) transitivity, (3) monotonicity, (4) decomposability, (5) continuity and substitutability [17]. 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 4.5 illustrates the choice of treatments of 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** means simply 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 years, 4 years, 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.

To show how these can be applied to the CE tree in Fig. 4.5, let's consider just the *Combination* branch. The decomposability axiom says that by multiplying and adding, we 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.

Now, comparing the *Combination* and *Mediocrin* branches, we are comparing two gambles with the outcomes 10 years 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. 4.6). 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

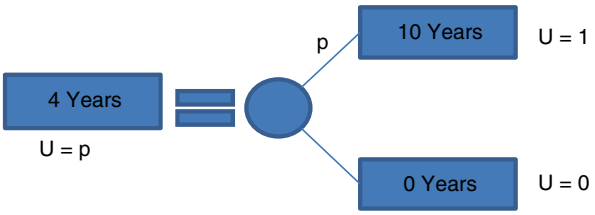

Fig. 4.6 The standard gamble. The relative utility values for outcomes in a decision analysis are calculated in threes. A forced choice is set up between a gamble, consisting of a probability, p, of the most preferred outcome and probability, 1-p, of the least preferred outcome, or a certainty of the 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

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. 4.6, 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 on which to choose alternatives. If these utility values are plotted as a function of the outcomes, the result is typically a curve like that shown in Fig. 4.7. 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].

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

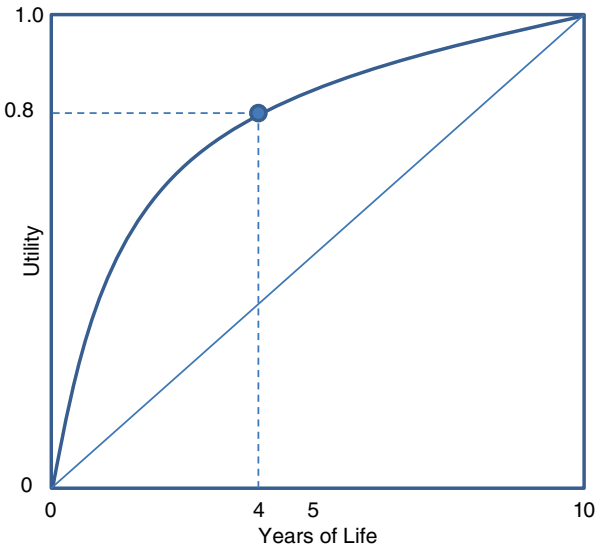

Fig. 4.7 Utility curve on years of life. The *curve* shows one decision maker's utilities on remaining years of life as a function of years of life. The figure highlights the that the utility of 4 years of life, U(4 years) is 0.8 on a scale where U(0 years) = 0 and U(10 years) = 1. The curve is bowed up and to the left (*concave up*), indicating the decision maker is risk averse

pose a cognitive burden, other methods have been developed. The most important of these is the time trade-off (TTO) [18]. 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 a duration of time in a chronic, less than ideal health state. For example, living with total blindness for 20 years. He is then asked how many of those 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 ten 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 [19]. Additionally, the TTO assumes 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 [20]. QALY is a multi-attribute utility model, meaning that it takes separate measures of health outcomes and combines

them to form one utility measure [21]. 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 [22, 23]. 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 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 as well as 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. When the health outcome is a utility, we use the more specific term, cost-utility analysis. To illustrate, below (Fig. 4.8) 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 effectiveness of the vaccine. 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 is 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 4.3.

To construct Table 4.3, 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

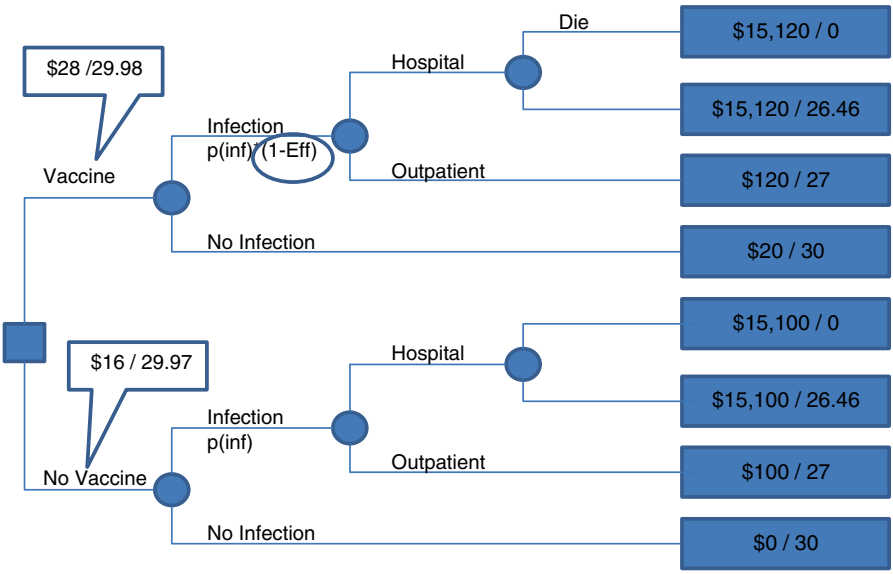

Fig. 4.8 A decision tree for conducting a cost-effectiveness analysis. The terminal nodes show a value and a cost term. The tree is solved once, calculating the expected value of each option, and a second time, calculating the expected cost of each option. The difference in cost between two options divided by the difference in value is the incremental cost-effectiveness (See Table 4.3)

Table 4.3 Table showing the calculation of incremental cost-effectiveness

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

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

entered next, followed by the incremental effect, the difference in effect from 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. *Cost-effectiveness analysis 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.

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

$50,000 are often considered cost effective. ICERs are especially useful for comparing alternative health interventions in order to achieve the most efficient use of healthcare dollars [24].

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," which accounts for all costs and health outcomes, but it must be acknowledged that no one has a societal perspective [20].

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 decision analysis, 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.

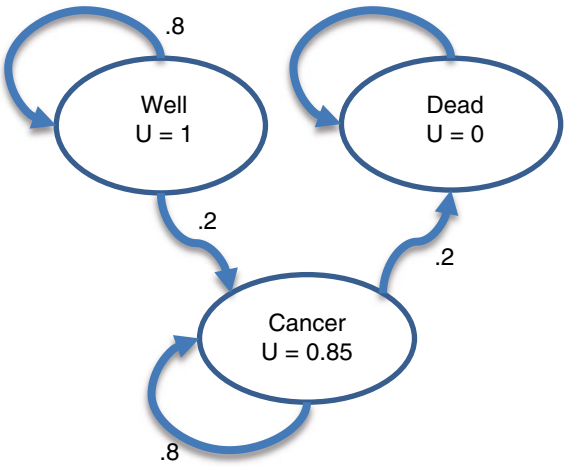

Fig. 4.9 A simple Markov model. The Markov model shows three health states, *well*, *cancer*, and *dead*. Arcs (*arrows*) between the health states represent the probability of transitioning from one health state to the next during a *Markov cycle* (for example, a year). Utility is accumulated for each cycle (see Table 4.4)

Table 4.4 Showing the accumulation of expected utilities (as quality adjusted life years) during two cycles of a Markov model

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

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

Markov models provide a more compact method for evaluating such models. Figure 4.9 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 that 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 in order 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 4.4 shows how utilities, in the form of QALYs accumulate with the first two cycle of the model.

At the initiation of the cycle we determined that 90 % of patients were in remission (the well state) and 10 % had residual 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 who were in the *Well* state in cycle 1 and retained 80 % of those who were 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 who were 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 is an alternative to a decision tree that emphasizes the probabilistic relationships among variables. 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 4.10 illustrates a rather generic 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 that will be 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 decision to treat or observe combined with the presence or absence of disease determines the value. The bubbles in Fig. 4.10 show the contents of each of the nodes.

Influence diagrams are especially 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 (aka Bayes net or belief network). In fact, 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 for everything from detection of credit card fraud to complex diagnostic decision support [25, 26].

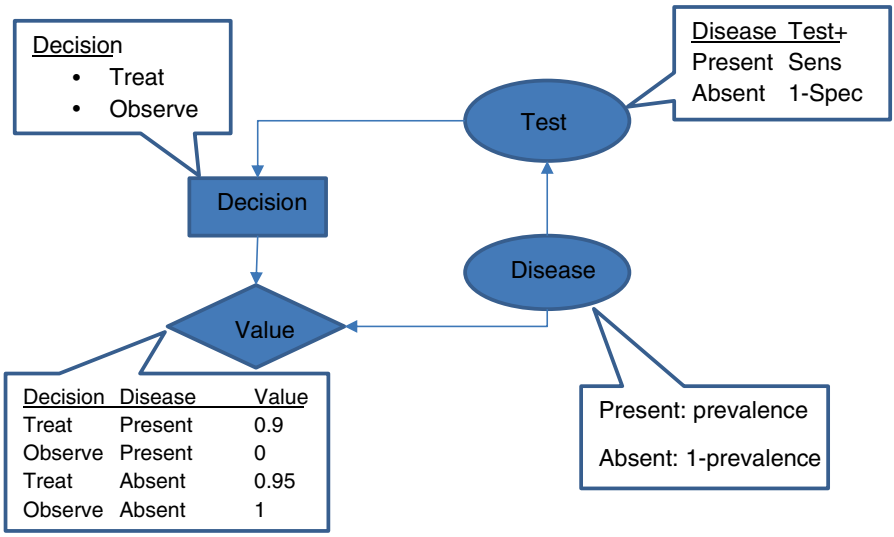

Fig. 4.10 A simple influence diagram. The diagram shows the three types of nodes found in an influence diagram: *round chance nodes*, a *square decision node*, and a *diamond value node*. The contents of each node are shown. An influence diagram with only chance nodes is known as a Bayesian belief network (or belief net)

The Role of Decision Sciences in Clinical Informatics

Medicine is an information intensive business that is 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, if used correctly, they have the potential, 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 encoded in your systems. Models of complex Bayesian inference can help guide computer based clinical decision support. Even day-to-day decision making about IT purchases, investments and distributions can be informed by more careful analysis of decisions made under uncertainty.

Regulatory, Legal, and Ethical Issues

The advances in the way the medical community utilizes decisional support encourage efficiency in the process, and as a result, promoting widespread usage of CDSS has been on the agenda of the federal government for several years. In 2009, Congress passed the Health Information Technology for Economic and Clinical

Health (HITECH) Act, which provides monetary incentives to health professionals and hospitals that adopt and effectively use electronic medical records. The HITECH Act also established the Office of the National Coordinator for Health Information Technology (ONC), a division of the U.S. Department of Health and Human Services, which is specifically designed to promote and regulate various types of health information technology. Federal standardization and regulation of CDSS programs is overseen by the ONC. The ONC heads a certification program that ensures health IT initiatives and products meet specific standards of "technological capability, functionality, and security" required by the Department of Health and Human Services [27]. The Food and Drug Administration has indicated plans to establish its own set of minimum standards required for CDSS, however as of Spring 2015 it had not yet published its final report on the subject [28].

CDSS started receiving governmental oversight because while its use and capabilities are advancing, there remain causes for concern. One major remaining fear is that CDSS will eliminate subjectivity in the diagnostic and treatment process. A system dependent on CDSS could potentially jeopardize two of the four basic tenets of medical ethics: autonomy and beneficence. Physicians have an obligation to provide the best care for each individual patient. Obviously, CDSS has the same goal, but there are always anomalies. While new technology may improve an overall standard of patient care, it will not necessarily improve the care of each individual. Patients could potentially present any number of unforeseen restrictions for which the CDSS is not prepared. Maybe they don't have transportation to a suggested specialist, or maybe religious beliefs restrict certain procedures. Maybe they present with a rare case that the system is not prepared for. While informatics has the capacity for many models and matrices of situations, so does human life. Thus, the CDSS may overlook options that would be best for this specific patient, because they may not be best for the average patient within the same parameters.

These limitations may also present legal challenges for physicians. If a system fails to alert the physician to an important warning sign or diagnosis, and something happens to the patient, it could be considered medical malpractice, leaving the physician liable. This may be especially true for younger physicians, who lack the experience to consider unique presentations. Thus, the CDSS runs the risk of reducing the physician's autonomy as well as the patient's. Ultimately, there remains a concern that physicians may allow decision support to become decision authority, forgoing the human element necessary for a successful physician-patient relationship.

Additional risks may occur for the physician over the long-term. A diagnostic system may show signs of chronic respiratory illness, but does it suggest an underlying immunodeficiency? If it does not, should the physician be considered negligent for not investigating the patient's problems further than the CDSS could? Likewise, how should the physician be held accountable for a diagnostic or treatment error committed because he did not understand the CDSS as well as he should have, and over- or underestimated the system's capabilities? This is a significant risk, due to the nature of clinical decision support systems. There is always a possibility that the system will not provide as much support as the health care provider expects or needs, but also that it provides an overabundance of support, suggesting

too many false positives. Referred to as "alert fatigue," the fear is that physicians will stop taking alerts seriously if a system provides too many alerts. This is particularly risky for drug interaction alerts, because current systems include thousands of possible interactions, many of which may be harmless in reality. As a result, the physician ignores drug interaction alerts all together, neglecting to recognize an alert for an interaction that is potentially dangerous to the patient [29, 30].

While there are concerns for flaws in the systems, there are also the risks of user-errors. Physicians may choose not to address all of the results from a particular system, because of alert fatigue, lack of time in the patient's appointment, or maybe he or she only glances at the first few prompts and ignores those at the bottom. There is evidence that it is a common practice for physicians to override automated warnings from CDSS. Whether flaws are human or technological, CDSS is not without its risks, and physicians can often be risk-averse because of a fear of malpractice litigation [29].

Adding to the liability of physicians and institutions, manufacturers and vendors of the systems attempt to shield themselves from such risks in multiple ways. First, they protect themselves by inserting a "hold harmless" clause into the contract, which restricts a physician or practice from reporting faulty systems, and places the liability for such flaws with the physician or institution [30, 31].

Despite the shield the hold harmless clause creates, vendors remain cautious in their CDSS programming. Vendors fear failing to warn of certain health risks would be more costly—in litigation—than over-warning, and so the systems are designed to deliver any possible warnings that may arise for the patient, running the risk of a great deal of false positives for the physician—and the patient. This is also very expensive for the medical institution and patients or their insurance carriers, because if the system suggests an expensive diagnostic test or procedure, the physician or medical group runs risk of negligence if they do not follow through. And so a vicious cycle is born.

Safety, Quality, and Unintended Consequences

The section above provided examples of some concerns about the safety and quality of CDSS: some issues with the systems and some with their users. Alert fatigue, in particular, is a notable risk. Errors in CDSS can be caused by any number of sources, from faulty Internet connections to program policies that do not correspond to a patient's reality. These errors can be very dangerous, because, for instance, if it is an error in the software, it could affect potentially thousands of patients, and because these system errors are very likely to adversely affect patient outcomes [32]. However, while errors can occur, and patient safety is a priority, studies on the quality of CDSS programs have shown them to be quite effective. In one systematic review, 62 out of 97 CDSS improved practitioner performance. These CDSS included a variety of system types, including diagnostic programs, reminder systems, drug prescribing programs and disease management systems [33]. Although evidence of improved patient outcomes has been less obvious in the literature, with many studies calling for further

investigation, from a societal perspective, the outcomes have often been excellent. Especially because, despite a lack of information or proof of improved patient outcomes in some investigations, many studies have found improved patient *care*, with fewer practitioner errors and omissions [32, 34, 35]. For instance, one major CDSS benefit to patient safety is that when designed well, the system should enable the physician to catch hidden issues like medicine interactions that would not have been inherently obvious to them otherwise. The key to these results is a well-developed CDSS, which is used effectively by healthcare practitioners [36]. In particular, use of QALY and Bayesian inferences can focus the CDSS capabilities, in order to improve the probability of favorable patient outcomes. A July 2013 ONC report points out that CDSS is especially useful in offering best practice clinical guidelines for practitioners to follow, particularly for delivery of preventive care such as routine screenings and immunizations. Wright, Sittig, et al, in their 2009 article, suggest that certification—proving standards and meeting certain requirements—would greatly improve the quality of CDSS [36]. Since then, the HITECH Act created the ONC, which functions to ensure those standards exist. The July 2013 ONC report outlined goals, objectives, and strategies for how to improve health IT patient safety. Two key elements of the plan were to emphasize Meaningful Use and the Health IT certification program, two initiatives that provide oversight and accountability for CDSS, in an effort to provide the safest and highest quality patient care technology can offer [37].

Chapter Summary

In the clinical setting, you will often be faced with 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 tools of decision analysis 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 is capable of processing much more information at a much faster speed than one physician, CDSS can be invaluable in providing an efficient and effective medical practice.

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

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Chapter 5
Evidence Based Health Care

P. Jon White and Edwin Lomotan

Learning Objectives

After reading this chapter individuals will be able to:

- List types of clinical research studies
- Apply grading criteria to clinical evidence
- Define characteristics of high quality clinical guidelines
- Name several sources of clinical evidence
- Identify and evaluate evidence for appropriate application to clinical information systems

Core Content

- Evidence sources
- Evidence grading
- Clinical guidelines

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Case Vignette

At 7 AM, the coffee and muffins were set out for a meeting of the Electronic Health Record Committee for your hospital. Over the past 2 years, you and your colleagues have been working hard to implement your new clinical information system. Today's agenda was to start working on new order sets for the emergency department.

The work of this committee has been challenging, and today is no exception. By 7:15, the group has reached a standoff over whether to include a CT scan or an MRI in a prepopulated order set to rule out a skull fracture. Local standards of care are at odds with national guidelines, and there is disagreement between guidelines from different specialty societies on the appropriate diagnostic approach. Somebody mentions that a large randomized controlled trial on nasal bone fractures was published just last week in a leading national journal, complicating the discussion. At a tense moment, your colleagues turn to you and say, "Well, you're the clinical information specialist here. What do you think we should do?"

Introduction

Why do people trust clinicians with their lives? That's a deceptively simple question with a complex answer, but one important reason is the scientific validity of the care that clinicians provide. Most people want care that is grounded in fact, guided by experience, and personalized for them. This is the core precept of evidence based health care. Put another way, we expect our clinicians to use the best available science as they practice their art on us.

One of the key roles of the clinical informatician is to transform knowledge into improved care and outcomes through clinical information tools, systems and practices. While detailed experiences in the design of rigorous clinical trials or the methodology of literature review is not necessary to fulfill this responsibility, a solid understanding of the evidentiary basis of clinical knowledge is essential. This foundation includes knowledge of sources of evidence applicable to health care, grading of evidence, characteristics of high quality clinical guidelines, and the ability to apply that knowledge to improve patient care, enhance outcomes and strengthen the clinician-patient relationship.

Evidence Based Health Care

The scientific method has endured the test of time to transform our understanding of the universe and most areas of human concern. This is certainly true for health sciences, where clinical research has become a pillar of our health care system that informs and guides millions of literally life-and-death decisions every day. In recent decades, the use of research results for decision-making has grown in sophistication

and broad use. So much so, in fact, that the term "evidence based health care" has come to embody a specific set of concepts. For the purposes of this chapter, *evidence based health care* applies the best available research results when making decisions about health care [1]. The term "evidence" is fundamental to the ensuing material, and therefore bears early attention. In the context of evidence based health care, *evidence* means 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 an important inspiration for the use of evidence. Without additional qualifiers such 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. A widely used and well-respected explanation of quality comes from the Institute of Medicine, 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 Studies

The design of a clinical research study can vary based on many factors, including the state of knowledge about a given subject, resources available, and characteristics of a condition or treatment. There are a variety of valid design approaches to clinical research studies, and several types are described here.

Randomized Controlled Trials

Randomized controlled trials (RCTs) compare one intervention, medication or treatment with other interventions by randomly assigning participants to two or more study groups [3]. One of the groups is not subject to the interventions, or one of the medications or treatments is often a placebo or inactive medicine, and is considered the "control". Because of the rigorous way these studies are conducted, RCT results are usually considered to be the most valid and reliable type of evidence. However, they are by no means the only kind.

Observational Studies

In *observational research*, a population of individuals is observed or studied, and certain variables such as outcomes are measured. In contrast to RCTs, no attempt is made to affect the outcome, so there is no direct intervention on the subjects [4]. While randomization of subjects as in RCTs is desirable for statistical purposes,

sometimes randomization is not ethical or practical. Examples of observational study design include cohort studies, case control studies and cross-sectional studies.

Cohort studies prospectively assign subjects to a group (or groups), and follow those subjects over time. The group is called a "cohort". Subsequent evaluation looks for subjects with a certain condition or who receive a particular intervention and compares them with subjects who are not affected by the condition or intervention [5]. Cohort studies have some statistical and logistical advantages over other studies, but may be affected by confounding variables and lack of randomization.

Case control studies retrospectively match subjects with a given condition or intervention with subjects without that condition or intervention [6]. They are useful to establish initial evidence about a hypothesis, but the data are less reliable than prospective study designs due to the retrospective nature of the data collected. Case control studies are also less desirable for evaluating diagnostic tests, as the diagnosis of each subject is already known and sensitivity and specificity cannot be determined.

Cross-sectional studies are a type of observational study design that gathers data about subjects at a particular point in time, and are useful for determining information such as the prevalence of a condition in a selected population.

Case Reports

Case reports are detailed descriptions of individual clinical situations. They are a time-honored tradition in the clinical literature, and represent the "first line" of evidence. Although they have obvious and significant limitations in statistical power and rigor, they describe new and interesting findings or ideas that can advance our understanding of medicine and health. In a cumulative effect, several case studies that indicate similar observations can prompt more powerfully designed studies such as those detailed above.

Other Study Designs

The *epidemiological study* designs described above represent commonly accepted types of evidence. There are many other types of useful research, including surveys and human factors studies. Please see Chap. 7 for more detailed descriptions of these.

Grading of Evidence

When evaluating evidence for use in health care, a reliable method of grading allows the clinical informatician to make valid comparisons between study results. Although the rigor of different study designs is described above, factors affecting

individual studies can increase or decrease the value of a given set of findings for the actual delivery of health care. There have been many historical approaches to evidence evaluation. While this is understandable, differing approaches complicate the subsequent task of incorporating graded evidence into practice. To improve consistency across clinical recommendations the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group has been existence since 2000 and has developed a widely used approach to rating quality of evidence and strength of recommendations [7]. The approach is transparent and well structured, and applicable across a broad spectrum of clinical questions.

When trying to address a clinical question by finding high quality evidence, individual research findings are reviewed and rated. In the GRADE approach, RCTs are initially rated as high or medium quality, while observational studies are initially rated low or very low quality. Factors subsequently affecting the rating of evidence include risk of bias, inconsistency, indirectness, imprecision, publication bias, large effect, dose–response curve, and effect of confounding factors [8].

Strengths of Recommendation

After grading the evidence, sometimes a recommendation is made for or against a particular intervention. It is useful to indicate how strongly that recommendation can be made based on the supporting evidence, what benefits and risks may be associated with that intervention, and to what populations that recommendation applies. This allows the patient and clinician to judge the potential benefits against any potential downside, and allows the clinical informatician to supply useful information for decision making in their information tools and systems.

Often the evidence, even when high grade, does not indicate that a particular intervention should or should not be recommended. In such cases the recommendation may be "unclear" or "indeterminate". An alternate situation occurs when there is not enough evidence to indicate a statistically significant benefit. In such cases, there is no recommendation and it is stated that there is insufficient evidence to make are recommendation. The United States Preventative Services Task Force, or USPSTF, provides a useful example of a clear system indicating strength of recommendation.

Systematic Reviews and Meta-analysis

It is surpassingly rare that a single study can definitively determine the most effective intervention for a particular condition or a given outcome. Therefore, approaches are needed to combine results from different studies and come to agreement as a community on standards of practice. Systematic reviews of the literature are "research about previously conducted research". While results of individual trials form the foundation of clinical evidence, they can be limited by factors such as study

population size or selection bias. Greater statistical significance can be achieved by evaluating the effects of an intervention across many studies conducted by different researchers at different times and places. High quality systematic reviews construct rigorous, answerable questions and conduct a comprehensive survey of medical literature to identify all relevant studies for that set of questions. Candidate studies are then evaluated and graded, and the findings of the assembled studies are assessed as a whole for net effect. Meta-analysis is the statistical technique used to combine the findings of a good systematic review, and is a highly rigorous form of study that is considered to be perhaps the most valid form of evidence. It assesses the included studies for heterogeneity and addresses the robustness of the findings [9].

Clinical Guidelines

Clinical guidelines are an important resource clinicians and patients, and are used by health care organizations to develop recommendations for health care delivery. Clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [10]. Guidelines are frequently based on a robust systematic review, and can represent an evidence based consensus from an authoritative group of subject matter experts, professional organizations or large care delivery systems. Guidelines can also be quite sweeping in scope, encompassing many different levels of evidence and recommendations in an effort to comprehensively address a particular clinical condition.

Quality Measurement

Quality measurement is an important matter in twenty-first century health care, as quality measures are increasingly used for reimbursement, licensing and accreditation of providers and organizations, and to inform health care consumers. Consequently, it is desirable to develop quality measures based on high quality evidence, where individual opinion about what is "quality" is a less divisive factor. Organizations such as the National Quality Forum and the National Committee for Quality Assurance have developed robust stakeholder consensus on quality measurement by incorporating consideration of the evidence base for approved quality measures.

Evidence Sources

Research Literature

Conducting research studies is the first step in evidence generation. The next step is peer review and publication of study results in clinical journals. Peer review is an important control on the limitations inherent in the perspectives of a given

individual researcher or group. When conducted appropriately and consistently, peer review provides objective evaluation of a proposed publication by multiple experts. It is a valuable approach that can weed out low quality studies, reduce duplicative publications, improve proposed findings, and aid editors in selecting the most significant submission for limited journal space.

Pubmed Central

The set of scientific publications that constitute the peer-reviewed literature is astounding in scope and volume. Each year hundreds of thousands of new studies are published, meaning any individual would have to read thousands of studies every day to remain "current". Evaluation of this body of evidence would not be humanly possible without cataloging and search engine resources. The most well-known example is PubMed Central, which is a free full-text searchable archive of biomedical and life sciences journal literature by the U.S. National Institutes of Health's National Library of Medicine [11]. PubMed Central contains over 24 million records of published studies from as far back as the early nineteenth century, and is updated on a daily basis.

Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is an operating division of the United States Department of Health and Human Services [12]. The mission of AHRQ is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. AHRQ has several important programs and resources that support evidence based health care.

The Evidence-based Practice Center (EPC) Program at AHRQ reviews all relevant scientific literature on a wide spectrum of clinical and health services topics to produce various kinds of evidence reports. The Centers are established at institutions in the United States and Canada. Although systematic reviews conducted by the EPCs are largely focused on clinical topics, it is of particular interest to clinical informaticians that the EPCs have produced several reports on health IT topics such as clinical decision support and health information exchange [13]. The National Guideline Clearinghouse (NGC) is an AHRQ initiative that provides access to objective, detailed information on clinical practice guidelines to further their dissemination, implementation and use [14]. Originally created in partnership with the American Medical Association and the American Association of Health Plans, the NGC is a carefully curated compilation of evidence-based guidelines. The John M. Eisenberg Center for Clinical Decisions and Communications Science translates systematic reviews

and other evidence reports into plain language summaries and tools which can be used by consumers, clinicians and policymakers to make decisions about health care [15].

Cochrane Collaboration

Another important source of evidence is the Cochrane Collaboration. The Collaboration is an international independent distributed network of researchers and other interested health care stakeholders [16]. The collaborators conduct systematic reviews and meta-analysis on a broad range of topics, and are widely recognized for their excellence in methodology.

Emerging Trends

The approaches for evidence based health care described above are well elucidated and accepted by most stakeholders, but they are by no means static. The recent expansion of digital information systems in health care has fuelled intense interest and activity in new and innovative approaches to evidence development and use. The analysis of extremely large sets of data generated from clinical, biomedical, genomic, environmental and other sources is a subject of intense interest and great promise (see Chap. 8). Innovative approaches to the digital data infrastructure for research and relevant new methodological approaches to research have been developed through the early years of the twenty-first century and are gaining momentum as widespread use of electronic health records and other health information systems grows. Clinical recommendations based on evidence are also adapting to the digital health care trend by increased precision in the writing, specification and codification of the recommendation, allowing more replicable implementation of those recommendations in clinical decision support and computerized order entry applications. All three of these rapidly advancing areas relevant to clinical informatics are envisioned to support a robust *Learning Health System* [17] in which evolving evidence based health care innovations can be disseminated and translated into routine clinical practice in just a couple years or few months rather than the traditional 17 years estimated in early studies [18].

Summary

The use of high quality scientific evidence about health care is a key reason for public trust in our clinicians. Application of the scientific method to the development of clinical evidence has resulted in a variety of study designs, including randomized controlled trials, observational studies, and case studies. The findings of these studies can be graded, synthesized into systematic reviews and clinical

guidelines, and quantitatively evaluated to produce recommendations of varying strength. Understanding of this body of evidence generation and evaluation is of great importance to the practicing clinical informaticist, who uses that evidence to guide implementation of information tools and systems. The development of evidence continues to change and develop in new and exciting ways, as the digital health information infrastructure evolves.

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Chapter 6
Clinical Decision Support

Karandeep Singh and Adam Wright

Learning Objectives

- Recognize the systems that influenced the development of modern clinical decision support systems
- Describe the types of clinical decision support
- Summarize the best practices for implementing and maintaining decision support interventions
- Differentiate the phases of the knowledge life cycle
- Appraise the legal issues surrounding CDS systems
- Describe the unintended consequences of clinical decision support

Core Content

2.1 Clinical Decision Support

2.1.1 The nature and cognitive aspects of human decision making

2.1.1.1 General
2.1.1.2 Medical

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2.1.3 Application of clinical decision support

2.1.3.1 Types of decision support (e.g., alerts, reminders, prompts)
2.1.3.2 Users of decision support (including clinicians and patients)
2.1.3.3 Implementing, evaluating, and maintaining decision support tools

2.1.4 Transformation of knowledge into clinical decision support tools

2.1.4.1 Knowledge generation
2.1.4.2 Knowledge acquisition
2.1.4.3 Knowledge modeling
2.1.4.4 Knowledge representation
2.1.4.5 Knowledge management and maintenance

2.1.5 Legal, ethical, and regulatory issues
2.1.6 Quality and safety issues
2.1.7 Supporting decisions for populations of patients

Key Terms

- Alert fatigue: a term used to described the symptom of too many decision support alerts being shown to a provider in the course of clinical care, often resulting in critical alerts being ignored
- Clinical decision support (CDS): software that provides clinicians, patients, or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health
- Computerized physician order entry (CPOE): software used by clinicians to enter patient-related orders electronically
- Electronic health record (EHR): software used by clinicians to view patient records electronically
- Learned intermediary standard: a legal standard that deflects blame away from computerized systems that are used by a clinician because clinicians have expert knowledge and are ultimately responsible for making decisions about patient care
- Service-oriented CDS: "service" refers to the concept of software-as-a-service, where relevant patient information is passed to a third party that in turn provides clinical decision support-based recommendations back to the user

Case Vignette

In 1973, Clement McDonald of the Regenstrief Institute in Indiana developed the Regenstrief Medical Record System (RMRS), an electronic health record (EHR) and clinical decision support (CDS) system that used a large body of rules to make suggestions about care. While physicians using the system performed better than

those not using it, turning the system off immediately brought the performance of the physicians using the system back to the their prior baseline.

Why do you think physicians using clinical decision support performed better? Why did their performance drop to pre-CDS levels once the system was turned off? What types of CDS do you use in your everyday life as a clinician? What are the key ingredients to make a CDS intervention succeed from the standpoint of physicians using it and the patients benefiting from it?

Introduction

Clinical decision support (CDS) is broadly defined as software that "[provides] clinicians, patients or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health" [1]. A substantial body of evidence exists to suggest that decision support systems can be extremely effective [2–5]. A systematic review of 100 studies found that CDS systems improved practitioner performance in 64 % of the studies assessing this outcome, including 4 of 10 diagnostic systems, 16 of 21 reminder systems, 23 of 37 disease management systems, and 19 of 29 drug dosing or prescribing systems [5].

Because the term CDS applies to several different types of software tools, CDS systems can be categorized in several different ways [6], such as the following:

- Clinical purpose: systems may assist clinicians with diagnosis or treatment
- Mechanism of intervention: systems may make passive suggestions or may actively interrupt the workflow in order to communicate information
- Method of reasoning: CDS systems may rely on logic arising from hard-coded rules, chaining of rules, or on probabilistic reasoning
- Software architecture: CDS systems may operate as "standalone" applications that require direct user input or may be integrated in an electronic health record system. CDS rules may be run locally on the user's machine, semi-remotely in the context of a broader execution engine, or in the cloud.

In this chapter, we will classify systems based on their clinical intent and highlight differences between various systems. We will also review mechanisms of intervention, elements of a successful CDS intervention, the knowledge life cycle, legal concerns, and quality and safety concerns surrounding CDS.

Medical Decision Making

Among all the tasks that clinicians face, medical decision making is among the most challenging. To make the right diagnosis, a clinician must first actually consider that diagnosis among the list of all possible diagnoses. Second, a clinician must determine which questions, physical exam findings, laboratories, or imaging will best narrow this

list as far as possible while taking into the account the costs and risks of the tests as well as the consequences of a missed diagnosis. Third, a clinician must offer the best possible therapy, taking into account national clinical guidelines and local drug formularies. And finally, clinicians must accomplish all of the above tasks without committing grave medical errors such as drug-drug interactions and life-threatening allergic reactions.

Diagnostic Decision Support

Leeds Abdominal Pain System

One of the earliest examples of diagnostic CDS systems is the University of Leeds abdominal pain system developed in 1971 by F. T. de Dombal to classify causes of acute abdominal pain [7, 8]. Acute abdominal pain is typically caused a limited set of clinical disorders, and timely diagnosis is essential to determine whether a patient needs to be managed surgically or if medical therapy will suffice. The Leeds system was derived from an analysis of 42 clinical attributes of 600 patients who had confirmed diagnoses of appendicitis, diverticulitis, perforated peptic ulcer, nonspecific abdominal pain, cholecystitis, small bowel obstruction, or pancreatitis. The final database consisted of approximately 25,000 observations linking a clinical attribute to a diagnosis, which formed the basis for establishing Bayesian probabilities for each disease process for a given set of observations. The accuracy of the system was evaluated prospectively on 304 patients in a study where clinicians entered the clinical attributes into the system in real-time but were not shown the system's recommendation. Whereas the admitting diagnosis was correct in only 44.8 % of cases, senior surgeons achieved the correct diagnosis 79.6 % of the time. Remarkably, the Leeds abdominal pain system correctly diagnosed 91.8 % of patients, cutting the error rate in half as compared to the most experienced surgeons. The system was implemented in the emergency room for a brief trial period during which emergency physicians were made aware of the system's diagnosis, and the accuracy of the admitting diagnosis improved by over 20 % along with a 15 % decrease in the number of admissions for abdominal pain [9].

The system's use of Bayesian probabilities is important because in addition to choosing the most likely diagnosis, the system was able to determine a level of certainty for each diagnosis, which is a key piece of information for clinicians to know when incorporating CDS recommendations into their decision making. In addition to being very accurate, the system was on average 84.7 % certain of its diagnoses in the aforementioned prospective study.

Internist-I

Whereas the Leeds abdominal pain system considered a narrow set of diagnosis for a particular chief complaint, the INTERNIST-I system [10] attempted to provide diagnostic decision support across the entire field of internal medicine. Developed by Randolph

Miller, Harry Pople and Jack Myers in the early 1980s, the system's knowledge base contained associations between 3550 clinical findings and 500 diseases. In a validation study of its accuracy in diagnosing 19 clinical cases published in the *New England Journal of Medicine*, its performance matched hospital clinicians but did not match experts. Two key intellectual contribution of the INTERNIST-I system is the way it abstracted the complex field of diagnosis into three concepts (evoking strength, frequency and import) and the interactive manner in the system asks the user follow-up questions in a strategic manner (pursuing, ruling out, and discriminating) to narrow the differential diagnosis.

In the development of INTERNIST-1, each disease-manifestation relationship was assigned values for evoking strength and frequency by clinical experts based on personal experience and a review of the scientific literature. The evoking strength (graded 0–5) refers to the likelihood that a patient with a certain clinical finding has a given disease, with low values assigned to findings that are not specific to the disease and high values assigned to findings considered pathognomic of the disease. Frequency values (graded 1–5) reflect how common that finding is in the disease in question. In aggregate, the evoking strength and frequency values relate the strength of the association between the observed findings and the possible diagnoses for a given patient. INTERNIST-1 also takes into account the fact that not all clinical findings are equally important through assignment of a disease-independent import value (graded 1–5) for each clinical finding. Findings which may occur in health individuals are assigned low values and findings which are definitely abnormal and must be explained by the final diagnosis are assigned high import values.

Unlike prior diagnostic CDS systems, INTERNIST-I was capable of interacting with users to narrow the list of diagnoses by asking a series of follow-up questions and was even able to arrive at multiple diagnoses by evaluating findings not explained by the first diagnosis. In asking the user follow-up questions, the system uses three distinct strategies. If the topmost diagnosis is much more likely than the next best option, the system uses a "pursuing" strategy by asking follow-up questions to pursue and establish the topmost diagnosis. If there are five or more diagnoses that are close in score to the topmost diagnosis, the system uses a "ruling out" strategy by asking questions with the aim of eliminating possible diagnoses. And lastly, if there are less than five options that are all close in score, the system pursues a "discrimination strategy" by asking questions to maximize the spread in score among the diagnoses.

Limitations of the INTERNIST-I system include an inability to take anatomical or temporal information into account as well as its inability to provide the user an explanation for its diagnostic reasoning. While INTERNIST-I was adapted for personal computers in a new product called the QUICK MEDICAL REFERENCE (QMR) in the 1980s [11], neither product is commercially available today.

DXplain

DXplain is a diagnostic CDS system developed at the Massachusetts General Hospital Laboratory of Computer Science that aims to solve some of the deficiencies of the INTERNIST-I system [12]. Initially developed by Octo Barnett in the

1984, the DXplain system uses clinical findings to produce a ranked list of possible diagnoses along with explanations for why each diagnosis should be considered, and it can suggest which further clinical information would be of the highest yield support the presence of a specific disease. The current DXplain knowledge base includes over 2400 diseases and over 5000 clinical findings [13], significantly larger than the INTERNIST-I. In addition to considering the evoking strength, frequency, and manifestation importance that were introduced by INTERNIST-I, DXplain also assigns disease-specific numbers for prevalence and importance, with the latter reflecting that certain diseases carry higher consequences if missed. In a recent evaluation of the accuracy of DXplain on an arbitrary set of cases derived from the *New England Journal of Medicine* and the *Medical Knowledge Self Assessment Program*, DXplain included the correct diagnosis in its top 20 suggestions in half of the cases [14]. A web-based version of DXplain is currently available to institutions (not individuals) through an organizational license.

Therapeutic Decision Support

HELP

The HELP system developed at the LDS Hospital in Salt Lake City, Utah in 1967 was the first CDS system capable of analyzing events in the electronic health record (EHR) and bringing abnormalities to the clinician's attention in the form of alerts with the goal of altering therapeutic plans [15]. HELP was instrumental in demonstrating the ability of CDS to reduce medical errors and save money with high levels of user acceptance. For example, the antibiotic prescribing features were linked to a 58 % reduction in per-patient antibiotic costs and a 30 % decrease in antibiotic-related adverse events [16].

The system was first used in the cardiac catheterization laboratory and cardiac intensive care unit, and its use was subsequently expanded to provide sophisticated clinical decision-support capabilities to a wide variety of clinical areas spanning areas of the hospital and clinical departments. The HELP and HELP2 systems are currently operational in most of Intermountain Health Care's (IHC) 22 hospitals and 200 associated facilities, although they will be switched off as IHC transitions to a Cerner-based EHR by 2016. HELP has served as the substrate for many successful projects in clinical decision support, such as Dean Sittig's COMPAS system for ventilator management [17], a system for blood product ordering developed by Reed Gardner [18, 19], and a well-known antibiotic advising system developed by Scott Evans [20].

Structurally, HELP originally represented each piece of logic and resulting alert in the form of a medical logic module through a novel programming language developed specifically for this purpose known as PAL. In the 1990s, this was replaced by the Arden syntax, which is described in further detail later in the chapter.

MYCIN

The MYCIN system was developed in the early 1970s, and its primary innovation lay in its mechanism of reasoning through the chaining of rules to produce its recommendations, an approach drawn from the field of artificial intelligence. Information about infectious processes is represented in MYCIN through an independent set of "production rules." Each rule consists of an observation along with the inferences that can be drawn if that observation is present. Using MYCIN, a clinician enters what is known about a patient's infectious process. The system chains together these observations to the set of production rules from its knowledge base to arrive at an optimal recommendation for therapy. Early evaluation showed that it suggested acceptable therapy 75 % of the time, and it improved as more rules were added. Because this system bases its reasoning on a series of rules, it has the benefit of built-in explanatory power and ease of maintenance. Since the chaining of rules represents the logic of the recommendation, the system can explain how it arrived at its conclusion as a natural side effect of how its reasoning process is structured. As clinical guidelines are updated, one only has to add, remove, or modify individual rules in order to change the entire logical process.

Mechanisms of Intervention

The use of EHR and CPOE systems has taken tasks previously accomplished using pen and paper successfully into a digital form. However, the isolated use of these two technologies does not demonstrably improve clinical workflow. When clinicians evaluate patients, they must synthesize information from the current visit along with information contained within the electronic health record in order to decide which medications and tests to order, and then they must separately document their decisions in a clinical note and place orders into a CPOE system. Clinical decision support placed at the intersection of EHR and CPOE systems can foster better health processes while simultaneously improving workflow.

There are several ways in which clinical decision support can engage with a clinician when integrated more broadly into an EHR and CPOE system, which include non-interruptive alerts, interruptive alerts and reminders, order sets, templates, and smart forms.

Non-interruptive Alerts

Non-interruptive alerts are often placed on EHR patient chart summary screens to display tasks that are less time-sensitive, such as immunizations and age- and gender-specific screening tests. They may also be used to convey important but

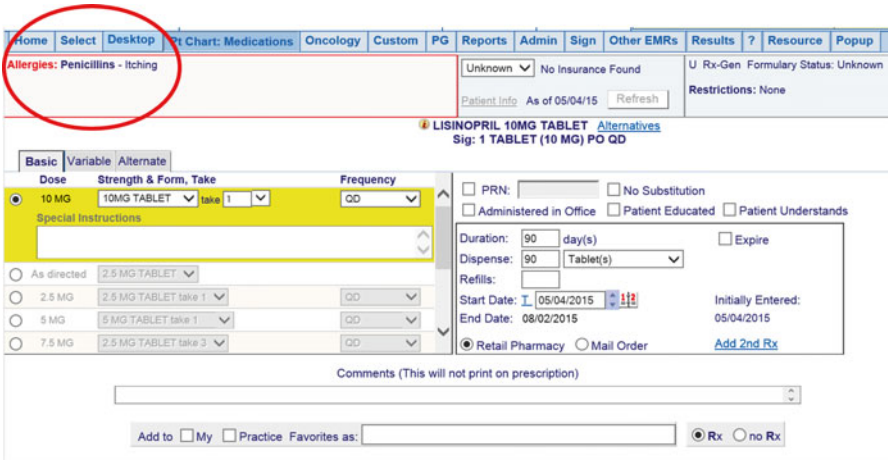

Fig. 6.1 An example of a non-interruptive alert noting an unrelated minor allergy to penicillin when prescribing a blood pressure medication

non-critical information (Fig. 6.1). Their placement ensures that they can be seen by multiple providers for a patient but their non-interruptive nature means that they may be missed unless actively sought out.

Interruptive Alerts and Reminders

Since the introduction of integrated clinical decision support in the HELP system, alerts and reminders have become a commonplace feature of modern commercial electronic health record systems. The terms "alerts" and "reminders" are used interchangeably and refer to prompts that are delivered to the clinician at the point of care to communicate critical information.

In the most basic implementation, a series of logic rules are evaluated by the CDS system in response to a clinical action such as prescribing a medication. If the criteria for a rule is met, a corresponding alert is generated. Contrasted with the Bayesian approaches of some of CDS systems described previously, rule-based CDS systems may be viewed as simplistic in their evaluation of patients. However, this simplicity serves as an advantage because clinician users have no ambiguity about why a particular alert was generated. Such systems have also been shown to be quite effective in improving patient care. In a meta-analysis of randomized controlled trials of physician reminders to improve preventive care, both screening and immunization rates were noted to higher among physicians exposed to CDS [21]. In a systematic review of clinical alerts to improve safe physician prescribing, 23 studies demonstrated a beneficial effect on prescribing practices, five studies demonstrated a positive effect on clinical outcomes, and four studies demonstrated no change in prescribing practices [22].

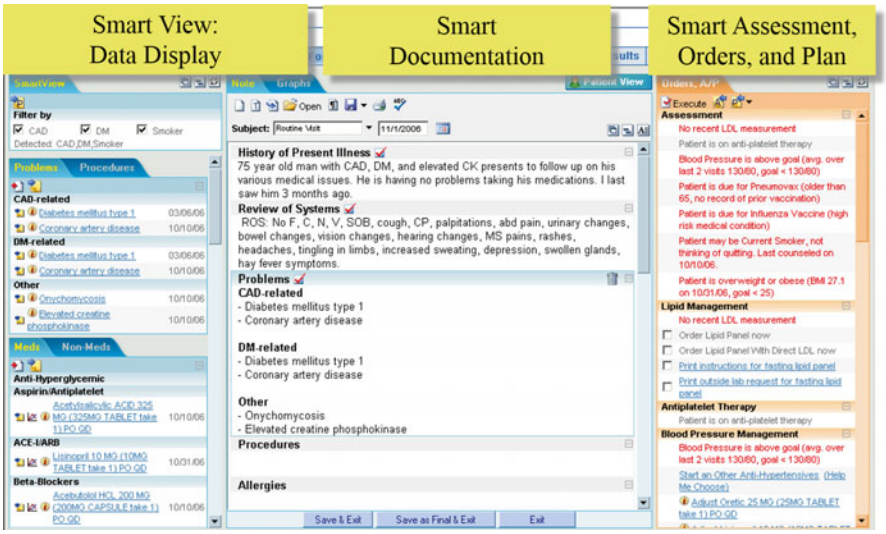

Fig. 6.2 A "smart form." The smart form application displays information in three vertical panels: Smart view (patient summary), visit note editor, and orders assessment/plan

Order Sets, Templates, and Smart Forms

A basic form of workflow facilitation using CDS lies in the use of order sets, which allows clinicians to view and act on a given set of orders for a particular condition. Such order sets are commonly used to encourage actions that may otherwise be forgotten, such as to prescribe medications to prevent deep vein thromboses in patients admitted to the hospital. Order sets may be specific to a disorder (e.g. congestive heart failure) or to a hospital location (e.g. surgical intensive care unit admission orders).

Smart forms [23] or templates [24] represent a more advanced form of integration, where clinical documentation, the ability to add or remove coded order structured information, and order entry are intrinsically linked and displayed on the same screen. Smart forms (Fig. 6.2) differ from traditional CDS systems in the following ways:

1. Decision support is not interruptive in nature but rather is in the form of suggested orders and presented at a place and time in a user's work-flow, i.e., while they are gathering information and writing their note, which may make the decision support more acceptable.
2. The documentation function allows the user to document a typical outpatient visit note in a patient with multiple medical problems, some of which may be supported by decision support and some may not be. This obviates the need for a separate CDSS application.
3. The Smart Form is designed to provide decision support for multiple problems simultaneously and to allow for future expansion to additional acute and chronic conditions.

Implementing, Evaluating, and Maintaining Decision Support Tools

"Five Rights" of CDS

While clinical decision support systems have tremendous potential to improve individual patient care and population health, their positive impact can be severely blunted if not implemented in a way that respects the desires and needs of its users. The "five rights" of CDS [25] is a framework for a successful implementation that includes:

1. The **right information**
2. To the **right person**
3. In the **right intervention format**
4. Through the **right channel**
5. At the **right time** in workflow

The information presented to the user should be evidence-based (refer to Chap. 5). The user should have a clear understanding about the source of the information, whether it is a national guideline, a performance measure, or a hospital policy. If the information is derived from a guideline, the guideline's strength of evidence may also be helpful information to the user. The information should be presented to the right user. For example, if a medication dose requires adjustment, this alert should be presented to the prescribing physician and not to the nurse caring for the patient. As has been discussed earlier, CDS exists in many different formats, including standalone diagnostic and therapeutic systems, interruptive and non-interruptive alerts, order sets, and smart forms. Users may prefer different formats depending on the type of problem that a proposed CDS intervention is meant to address. With an increasingly connected world, there are more ways than ever before to communicate information with physicians, such as through the electronic health record, through secure e-mail, paging, text-messaging, or through a smartphone application. The information must be delivered through a channel that best matches the urgency and privacy of the information with the location of the user receiving the alert. Finally, CDS interventions in many instances interrupt workflow to seek input from the user. When such workflow interruption is required, presenting information at the right time can affect just how much disruption occurs. For example, prompting a clinician about a drug-drug interaction when he or she first searches for the order for the second drug rather than waiting until the clinician has already chosen a dose and is about to finalize the order can make a big difference in how the clinician perceives the interaction with the CDS system.

Best Practices for CDS

If the "Five Rights" of clinical decision support are the road to a successful implementation of a CDS intervention, the "Ten Commandments for Effective Clinical Decision Support" proposed by David Bates and colleagues [26] is the map outlining how to get there.

The "Ten Commandments" highlight key factors in implementing, evaluating, and maintaining decision support tools:

1. **Speed is everything**. The time it takes users to navigate a CDS system is the primary determinant of user satisfaction. Sub-second screen transitions should be the goal when designing a CDS intervention.
2. **Anticipate needs and deliver in real time**. CDS systems should strive to present key bits of pertinent information to the clinician to make decision-making easier, such as displaying the potassium level when ordering a medication that may raise or lower it. CDS systems should also anticipate "latent needs" of clinicians and suggest corollary orders, such as checking medication levels when ordering a medication that requires monitoring.
3. **Fit into the user's workflow**. Clinicians are unlikely to consider even excellent recommendations when they are not presented at the right time in a user's workflow.
4. **Little things can make a big difference**. The presentation of information is as important as the content. Offering clinicians the ability to enter free text diagnoses greatly reduces the entry of coded information, which may have downstream consequences. Presenting alerts that are easy to ignore can nullify their impact. Usability testing can be helpful in finding and correcting unintended consequences.
5. **Recognize that physicians will strongly resist stopping**. Clinicians rarely discontinue an order based on a CDS recommendation, even when ordering redundant tests or prescribing medications without appropriate evidence. If clinician behavior must absolutely be changed due to high costs or limited resources, then coercing clinicians to choose an appropriate indication for an order and allowing overrides only with the approval of a local clinical expert may be effective strategies in preventing inappropriate order entry. Close and ongoing monitoring of such CDS interventions is critical to prevent "gaming" of the system.
6. **Changing direction is easier than stopping**. Changing clinician behavior can be easy when clinicians do not have strong feelings about certain attributes of an order, such as the dosing or route of a medication or the number of views for a particular radiology test. Altering the default selections and suggesting appropriate attributes based on the indication are effective strategies to change direction.
7. **Simple interventions work best**. Guidelines must be condensed to a single screen to be usable at the point of care. Clinicians often give up when working through complex CDS interventions.
8. **Ask for additional information only when you really need it**. The likelihood of success in implementing a computerized guideline is often inversely proportional to the number of extra data elements needed. Getting buy-in from clinicians to enter unnecessary information particularly when the risks to the patient are low may threaten the success of the intervention.
9. **Monitor impact**, **get feedback**, **and respond**. When action-oriented alerts are presented to a clinician, there should be a reasonable chance that they are acted upon. Alerts that are rarely acted upon should be closely evaluated to determine

why they are being ignored – in many cases the reason may be medically appropriate and not originally anticipated. Making corrections to the content and severity level of clinical alerts and even removing alerts that are not having the intended impact is critical to the ongoing success of CDS systems.

10. **Manage and maintain your knowledge-based systems**. The effort required to monitor and address issues in CDS systems is easily underestimated. In the face of rapid changes in medical knowledge and clinician behavior, knowledge encoded in CDS systems must be continually adjusted, pruned, and corrected. Assigning each subject area of a knowledge-based system to an appropriate clinical expert is a first step towards successful management of the knowledge base.

CDS Capabilities in Commercial EHR

Following the passage of the HITECH Act in 2009, the Office of the National Coordinator for Health Information Technology (ONC) was charged with creating and maintaining a certification program for EHR systems, including CDS systems that are integrated with EHR systems. The ONC Certification Program was established to oversee the certification and testing of EHR products. As part of the program, commercial CDS systems are tested by the ONC-Authorized Testing and Certification Bodies (ATCBs), with approved programs are recognized as "certified EHR technology" by the ONC and added to the Certified Health IT Product List, which is a comprehensive listing of certified systems. Currently there are six ATCBs, including the Certification Commission for Health Information Technology (CCHIT). Despite being the first and a model for ATCBs, CCHIT ceased operations in December 2014.

In 2009, researchers carried out an independent analysis of CDS capabilities among nine EHR systems that were CCHIT-certified and among the best-selling of the commercial systems. The authors found that "six of the nine reviewed systems offered all the applicable event-driven, action-oriented, real-time clinical decision support triggers required for initiating clinical decision support interventions. Five of the nine systems could access all the patient-specific data items identified as necessary. Six of the nine systems supported all the intervention types identified as necessary to allow clinical information systems to tailor their interventions based on the severity of the clinical situation and the user's workflow. Only one system supported all the offered choices identified as key to allowing physicians to take action directly from within the alert [27]."

Transformation of Knowledge into Clinical Decision Support Tools

Clinical decision support systems need to be managed and maintained to stay relevant in the face of changing practice guidelines, quality standards, and costs. As hospital systems merge and transition towards becoming accountable care

organizations, they are faced with the difficult task of keeping clinical decision support systems in sync, especially when their underlying EHR and CPOE systems and practice standards may not be uniform across the organization. The task of implementing a CDS system is thus broader than programming a series of rules and the resulting alerts. It typically requires organizations to move through a cyclical process to generate and acquire knowledge, to model represent the knowledge in a structured format, and to repeat this process in order to keep the knowledge updated.

Knowledge Generation

An Institute of Medicine report on the development and use of clinical guidelines notes that "clinical practice guidelines may be meticulously developed, sound in content, clearly presented, and widely known, but they are without value if they are not successfully applied" [28]. The very first step towards step towards implementing a CDS intervention is agreeing upon what constitutes relevant medical knowledge to be represented. This knowledge may come in the form of national guidelines, the view of domain experts at the hospital, or a hospital policy committee. Consider the case of the 2014 Ebola outbreak in West Africa, where sporadic cases of Ebola occurred in the U.S. as a result of returning travelers. The U.S. Centers for Disease Control and Prevention released an algorithm [29] to help clinicians determine which individuals required testing for Ebola through a process of knowledge generation.

Knowledge Acquisition

Knowledge acquisition refers to the process of importing knowledge into the CDS system. In this sense, knowledge does not refer to the exact logic but to the general flowchart of decision points and actions that are to be encoded more formally in later steps (see "knowledge modeling and representation" below). For example, in the Ebola algorithm, knowledge acquisition would entail representing the flow chart of symptoms, risk factors, and resulting suspicion level in a digital form. Knowledge acquisition tools exist to facilitate the entry of knowledge in a structured format directly by domain experts. *Protégé* and GEODE are two examples of tools that contain modules to enable entry of knowledge in a structured form.

Knowledge Modeling and Representation

After knowledge has been encoded in a high-level format, it must be represented on a granular level to contain each piece of logic and resulting alert. A variety of efforts have been undertaken to standardize how knowledge is modeled and represented.

Arden Syntax

The foremost among these is the Arden Syntax [30]. The initial version of the Arden Syntax was developed at a 3 day consensus meeting in June of 1989 held at the Arden Homestead in New York from which the standard obtained its name. The standard combined the syntaxes used by the HELP system and the RMRS system. Rules encoded in Arden Syntax are called Medical Logic Modules. The Arden Syntax divides rules into three sections, called the "maintenance", "library" and "knowledge" sections. The maintenance section contains meta-data about the rule, such as who owns it, when it was created, when it was last reviewed or updated, and its validation status. The library section contains meta-data describing the clinical role of the rule, its purpose, an explanation, keywords, and a citation to the original source of the guideline or best practice that the rule encodes. The computable portion of the rule is encoded in the knowledge section. The knowledge section contains subsections called "type", "data", "evoke", "logic", "action" and "urgency". In the current version of Arden Syntax, type is always set to "data-driven" because this is the only mode of decision support offered. The data section is used to read data values, such as recent lab tests, medications lists, or clinical problems from the encompassing clinical system. The evoke section contains one or more triggers that might cause the rule to fire, such as "new potassium value stored". The logic section encodes the rule, generally as a series of if-then statements, and the action section encodes what the rule does when its logic section is satisfied – in general, Arden Syntax has only been used to raise alerts. The urgency section contains a number between 1 and 100 to encode how important that rule is. The guideline used to assign urgencies is implementation dependent and not fully defined in the specification. Arden Syntax has had some limited commercial success. Three clinical system vendors (Eclipsys, McKesson and Siemens), which together represent about a quarter of the overall clinical information system market, offer some support for the Arden Syntax, and a number of vendors, most notably Thomson Micromedex (Denver, CO) and Zynx (Los Angeles, CA) sell Medical Logic Modules.

The Arden syntax has two key limitations: first, it can only be used to encode event-driven, patient-specific rules. For use cases such as drug-drug interaction checking, or panic lab value alerting, this modality is sufficient. However, because Arden Syntax is patient-specific, it cannot be used for population-based decision support (such as a quality-of-care dashboard), and because it is event-driven, it can't be used for point-of-care reference or information retrieval support. The other key limitation relates to vocabulary: Arden Syntax does not define a standard vocabulary for things like lab tests, drugs or procedures. As a result, even if two clinical systems support the Arden Syntax, if they use different clinical terminologies, Arden Syntax rules from one system cannot be used in the other system without modification. For example, if one hospital's clinical system stored a blood test result as "Serum Potassium" and another hospital's clinical system stored the same result as "K+" a human-guided mapping would be needed. To assist in this mapping, Arden Syntax wraps system-specific terminological expressions in curly braces, and automated tools exist to help the implementer disambiguate these bracketed

terms, but human intervention is still required. This problem is so limiting and well-known that it is referred to simply as the "curly braces problem." The Arden Syntax has been revised several times since it was first created in 1989, and its most recent version (version 2.6) has been accepted as a standard by both the American National Standards Institute (ANSI), and Health Level 7 (HL7), a healthcare standards body.

Guideline Interchange Format

Since the creation of Arden Syntax, numerous other standards for representing and sharing decision support content and knowledge have been created. Many of these efforts have stalled, but one effort in particular, the Guideline Interchange Format (GLIF), developed over the past decade, has gained some traction. Unlike Arden Syntax, which is mostly designed for Alerts and Reminders, GLIF focuses on more complex multi-part guidelines, including complex clinical pathways that take place in phases or over time. A general-purpose execution engine for executing GLIF guidelines has been described, but it has not yet been implemented in any commercially available system.

Service-Oriented CDS

Recent efforts have separated the clinical information system and clinical decision support system components of an integrated decision support system, and recombined them by using a standard application programming interface (API). The first effort along this front was the Shareable Active Guideline Environment project (SAGE) [31, 32]. SAGE placed an API in front of the clinical system. A properly designed SAGE rule could interact with any clinical system that supported this SAGE-compliant API. The approach that SAGE took, placing a standardized interface in front of the clinical system, has been termed a Virtual Medical Record (VMR) approach [33]. The principle advantage of this approach is that it solves the vocabulary problem – the SAGE virtual medical record specifies the vocabularies that will be used to access and process the medical record, and to the extent that a clinical system uses different terminologies, it is required to provide a suitable mapping. Like Arden Syntax, SAGE requires a standard guideline format, necessarily constraining the type of decision support that can be implemented in SAGE.

SEBASTIAN [34], a more recent system first described in 2005, has taken the opposite approach from SAGE. It places a standardized interface in front of clinical decision support modules, and makes only limited demands on the clinical system to store data in any particular way. In this model, any clinical system which understands the SEBASTIAN protocol can make queries of centralized decision support services. SEBASTIAN maintains most of the same advantages of something like the Arden syntax, while freeing the user from the restrictions that statically defined knowledge representation formats impose. Moreover, since the modules are located on the Internet, they can be shared by more than one hospital, allowing for greater efficiency.

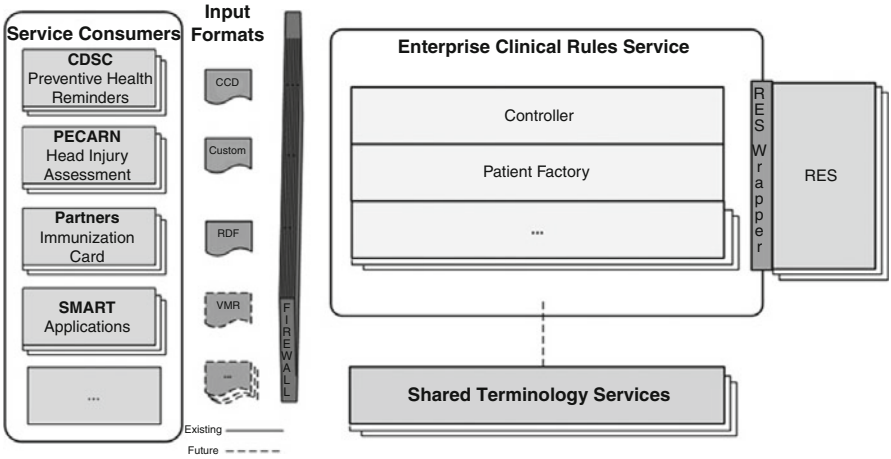

Fig. 6.3 CDS Consortium Enterprise Clinical Rules Service architecture [37]. Service Consumers (*CDSC* clinical decision support consortium, *PECARN* pediatric emergency care applied research network, *SMART* substitutable medical application reference technology), input formats (*CCD* continuity of care document, *RDF* resource description framework, *VMR* virtual medical record), and block architecture of the enterprise clinical rules service (*ECRS*), a modular decision support service. ECRS modules include a controller, a patient factory, which transforms input data into an inference model, a set of shared terminology services for translation and classification, and a back-end rules execution service (*RES*). The RES wrapper abstracts the connection to the RES, allowing different rules engines to serve as the decision processor

Although SEBASTIAN is standardized, each knowledge module is free to require any given set of data, which may create more work for the consumer. When knowledge modules do not ascribe to the same set of vocabulary standards, the responsibility of converting the same data to different encodings ultimately falls on the consumer. SEBASTIAN also requires that a service consumer move patient data to the service, which some hospitals or providers may be reluctant to do. Further, because the amount of patient data needed may potentially be large, performance issues may manifest, although in early testing to this point, performance has been acceptable.

More recently, the necessity to service-enable decision support has been given national attention. In June of 2012, the ONC sponsored a public-private initiative to develop and validate standards to enable CDS at scale, known as the "Health eDecisions Initiative" [35]. Work performed by the initiative led to the creation of the HL7 decision support service (DSS) draft standard, the Virtual Medical Record (vMR) Logical Model draft standard, and accompanying implementation guides.

OpenCDS is the reference implementation of the DSS and vMR standards, utilizing all open-source components to support a framework for service-oriented CDS [36]. The Clinical Decision Support Consortium is another service-oriented CDS project which uses the DSS standard to provide an enterprise clinical rules service (ECRS) that leverages off-the-shelf rules management systems in order to provide consistent, maintainable, and scalable decision support in a variety of settings (Fig. 6.3). An evaluation of the ECRS demonstrated sub-second response times when measured apart from services required to retrieve data and assemble the continuity of care document used as input [37].

Knowledge Maintenance

Maintaining a knowledge base is difficult because it involves a significant degree of time and resources and is a task that is never truly complete. One of the challenges around knowledge maintenance is the manpower required. In a survey of six geographically diverse healthcare systems [38], all of the organizations surveyed had a dedicated, multidisciplinary team of individuals responsible for creating and maintaining clinical knowledge. While portions of the clinical knowledge may be purchased from external sources, the purchased content may need substantial curation prior to implementation, which requires additional human capital. Knowledge may be turned obsolete as new practice standards are adopted. However, among the surveyed organizations, none had the capability to send automatic reminders to review clinical knowledge on a routine schedule, and only one had the ability to send notifications to key stakeholders when clinical guidelines relevant to existing CDS rules were updated.

In a survey of nine EHR vendors [39], all vendors provided healthcare organizations with a "starter set" of clinical content with varying frequencies of updates. Six of the nine vendors implemented, configured, and maintained the clinical content, while the remaining relied on customers to manage the clinical content. While making EHR vendors responsible for clinical content may reduce the overhead of knowledge maintenance for healthcare organizations, the effect of this with regards to the quality and quantity of the clinical knowledge is not known. Service-based CDS also hands off responsibility for knowledge maintenance to a third party and is an emerging model of decision support.

Legal, Ethical, and Regulatory Issues

Liability

As described previously in this chapter, the effectiveness of CDS systems may be markedly limited by "alert fatigue" when clinicians are presented with too many alerts in the course of clinical care. Tailoring alerts to the preferences of clinicians or removing certain alerts altogether are seemingly effective strategies to reduce alert fatigue, but this not routinely done due to fears of liability. Both vendors of CDS systems and physicians worry that they could be exposed to liability if they remove an alert that could have prevented a harmful prescribing error, so providing excess alerts is common to CDS implementations.

Are excess alerts legally needed to minimize liability? Likely not. The two parties at risk of litigation are vendors and users of CDS systems, and each is exposed to different types of risks [40].

Vendors may worry about litigation when CDS systems contain errors or when certain alerts are disabled and lead to bad patient outcomes. However, because most CDS systems behave as services rather than goods, they are held to a standard of negligence rather than strict liability. Making a case for negligence requires the

plaintiff to establish that a party did not take appropriate care or that the party's behavior was not in line with usual practices in the field. This is a fairly high standard of proof that favors defendants. Another principle that protects vendors is the "learned intermediary standard," where learned intermediary refers to the clinician's role as a middleman between the CDS system and the patient. Because clinicians have expert knowledge and are ultimately responsible for making decisions about patient care, errors that occur in the process of providing patient care reflect more on a clinician than they do on a vendor of CDS. As a result, developers of CDS systems have a fair degree of legal protection as long as they take basic steps (e.g. routine quality checks) to minimize the chances of errors in their systems.

Clinicians who use CDS systems may worry that disabling or overriding certain alerts may expose them to litigation, especially if their handling of alerts is documented in the medical record. Legally, CDS systems are fundamentally similar to clinical guidelines and should be approached the same way. While adhering to clinical guidelines may help clinicians avoid liability, acting outside of guidelines does not necessarily subject physicians to liability if the reason was medically appropriate. The same principle applies to CDS systems, where clinicians may override alerts if they can justify their actions on medical grounds.

The FDA Safety and Innovation Act (FDASIA)

On April 7, 2014, the Food and Drug Administration (FDA) issued strategic and regulatory guidance on health information technology (HIT) as part of a workgroup sanctioned by the FDA Safety and Innovation Act (FDASIA). Members of the workgroup included representatives from the FDA, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology. In its report, the workgroup categorized HIT into administrative, health management, and medical devices. One purpose of the categorization was to pair the degrees of regulatory scrutiny with the health risk posed by the technology. While medical device CDS systems do exist, most CDS systems fall into the category of health management software. Since this is considered a low risk group, CDS systems remain largely unregulated by the FDA.

Quality and Safety Issues

While CDS interventions paired with CPOE systems can increase the delivery of appropriate and safe patient care, they contain a list of side effects as well much like other therapeutics. Researchers from Oregon Health and Science University interviewed 19 experts and conducted fieldwork at five hospitals and identified 47 examples of unintended consequences [41]. These unintended consequences were analyzed and found to relate primarily to either the content or the presentation of clinical information.

Content-Related Unintended Consequences

1. **Elimination or shifting of human roles**. In the past, successful order entry often relied on multiple double checks that included clerical staff, pharmacists, and nurses. The advent of CDS systems has in many cases removed or minimized the role of support staff in the order entry process. As a result, inadequate CDS systems may paradoxically increase the ordering of tests inappropriately (e.g. "daily chest x-ray") or allow errors in the ordering of intravenous drips or ventilator settings.
2. **Currency of the CDS content**. Keeping content up to date is made more difficult by the fact that each element of each CDS rule is subject to change over time, either through changes in medical coding, medical practice, or regulatory guidelines. As a result, updating even a single rule can a contentious process.
3. **Wrong or misleading CDS content**. CDS systems can be make misleading recommendations for several reasons. CDS interventions that apply to a large group of patients may quickly result in supply shortages if the recommendation leads to the ordering of tests or medications with insufficient inventories. Presenting the same alerts regardless of a patient's clinical setting or situation may be inappropriate. Patients in the intensive care unit should not be subject to the same set of decision support rules as patients on a general medical ward. Contradictory recommendations can also be severely problematic and frustrating for users. Two CDS rules may make sense individually but end up providing conflicting recommendations to the user.

Presentation-Related Unintended Consequences

1. **Rigidity of systems**. Systems that are not flexible and easily integrated into a clinician's workflow can result in undesirable user behavior. For example, if a CDS system demands numerical entry of information prior to allowing clinicians to proceed, users may insert a "1" simply in order to move to the next screen. If order sets are organized in a way that forces physicians to enter orders in a linear rather than a problem-based order, certain orders may get missed by the clinician due to a higher cognitive load.
2. **Alert fatigue**. While delivering information in response to clinical actions has the benefit of capturing clinicians' attention when they are most engaged with that particular aspect of a patient's care, the overuse of interruptive alerts can blunt their effectiveness, a phenomenon known as "alert fatigue." Alert fatigue can be decreased through the use of non-interruptive alerts, but such alerts may be non-effective in changing physician behavior [42]. However, both implementers and users of CDS systems may favor the use of non-interruptive reminders for non-urgent, low-morbidity clinical scenarios. In an analysis of drug-drug interaction based alerts at a single institution, over a third of all alerts were judged to be of low priority [43].

3. **Sources of potential errors**. Misspellings, inappropriate timing of alerts, and simple mistakes made when updating systems all have the potential to create errors that lead to patients being harmed.

Supporting Decisions for Populations of Patients

Modern CDS systems aim to provide alerts at the point-of-care for individual patients, but several forces are shifting the focus to a population-based approach. Previously, the financial risks for caring for a population of patients lay squarely on the shoulder of insurers. As healthcare organizations transform into accountable care organizations (ACOs), much of the financial risk has begun to shift to the healthcare organizations. ACOs are incentivized to provide care that is cost-effective and directed at the right set of individuals. Concurrently, the implementation of the meaningful use legislation incentivizes developers of EHRs and CDS systems to incorporate population management into their respective systems. Unsurprisingly, providing population management is an active area of growth in CDS.

The first step in managing populations has been the establishment of registries, which allow cohorts of patients to be categorized into groups in order to track quality measures over time. For example, a primary care physician may want to monitor completion of routine preventative tasks for his or her panel of patients with diabetes, asthma, or cardiovascular disease. Population management systems that allow triaging or order entry on a dashboard of several patients are in various stages of development or deployment and have yet to be systematically evaluated.

Many registries are housed in public health agencies. Therefore population health CDS provides an opportunity for clinical and public health organizations to work together in addressing major threats to health and well-being. For example, work at the Regenstrief Institute enables community-based CDS alerts to be pushed out to clinicians when there is a localized outbreak. A CDS alert based on increased cases of *salmonellosis*, for example, might inform front line clinicians about an outbreak and, given the patient's primary diagnosis, suggest an order a laboratory test to determine if the patient may have salmonella [44].

Emerging Trends

Modern CDS systems act solely based upon a coded series of hand-crafted rules to carry out clinical care. Two paradigms are extending CDS systems into the territory of clinical research.

The first such paradigm is the point-of-care clinical trial, which uses EHRs and CDS systems as the infrastructure to conduct clinical research [45]. CDS may be used to enroll eligible patients for a clinical study through a clinical alert delivered to the provider at the point-of-care [46]. CDS can also be used to randomize patients to different arms of a study, with outcomes captured automatically by the EHR.

The second such paradigm is the learning health system [47]. Rather than using CDS to conduct research, the learning health system flips this on its head by conducting research in order to inform CDS. By finding patients that are similar in characteristics to a given patient and examining their outcomes based on what treatments they received, the learning health system generates recommendations that are based on actual experience rather than expert opinion. While still early in development, the learning health system approach may solve the knowledge maintenance problem, as rules will be automatically updated in response to new information entering the EHR, though some degree of manual curation will continue to be required.

Summary

Clinical decision support systems provide a powerful tool through which clinicians can provide safer, cost-effective, and more appropriate care. However, such systems must align themselves with the priorities of their users in order to be effective. Systems require continued monitoring and adjustment to maximize their utility without causing unintended consequences. The underlying knowledge base also needs to be updated to reflect changing medical guidelines and practice. While vendors and users of CDS may be hesitant to tailor CDS systems to users by limiting which alerts are shown due to legal concerns, this concern is largely unfounded.

Questions for Discussion

1. In what ways are the goals of clinical decision support systems aligned with the goals of their users? In what ways are they different?
2. What is alert fatigue and how can it be reduced?
3. What are the legal concerns that vendors may have who develop CDS systems? How about users of CDS?
4. What steps need to be taken for knowledge contained within a newly released clinical guideline to be converted into a clinical decision support intervention?
5. What are some unintended consequences of CDS systems? How can they be avoided or prevented?

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Chapter 7
Clinical Workflow Analysis, Process Redesign, and Quality Improvement

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Learning Objectives

By the end of the chapter, the reader should be able to: (1) apply appropriate tools and techniques for analyzing workflow in a health setting using; (2) appraise the value of process re-engineering and its application to improve health care processes; (3) describe quality improvement tools available for use in clinical settings; (4)

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discuss the role of workflow in clinical decision making, design and implementations of health IT and organizational design.

Core Content

The following core competencies are covered in this chapter:

- Characterize, evaluate, and refine clinical processes
- Understand how business processes influence health care delivery and the flow of data among the major domains of the health system
- Apply methods of workflow analysis
- Appraise quality improvement and re-engineering principles and practices

Key Terms

Workflow analysis, process redesign, quality improvement, lean, six sigma, visualization, qualitative approaches, quantitative approaches

Case Vignette

Background

City Hospital (CH) is a community hospital in the United States. Physicians at the hospital include both employed physicians and physicians in private practice. The majority of hospitalists and primary care physicians are employed, while the majority of specialists are not. In the midst of an EHR implementation, the implementation team is reviewing the clinical workflow with the hope of improving patient safety in conjunction with the EHR deployment. Some units are on the new EHR, some are on old department-specific ones and some are entirely on paper. Each unit has its own processes, partially due to the documentation systems, and partially due to unit-specific culture.

Situation

Mr. Smith's wife drove him to the Emergency Department (ED) of CH in the middle of the night because he was complaining of shortness of breath and arm pain. Upon arrival to the ED, the triage nurse put his information into the registration system,

settled the patient in a room and called the ED physician. The ED physician took a history and physical and documented results in the ED system. The unit clerk was directed to place a consult for a cardiologist. The cardiologist ordered tests and examined Mr. Smith. After initial testing, the cardiologist called the interventional cardiologist at home and they agreed that the patient should go immediately to the interventional cardiology unit for angioplasty and possible stent placement. The interventional cardiologist told the cardiologist he would meet the patient at the unit.

The cardiologist informed the ED staff that the patient was going to the interventional unit immediately. The ED staff nurse called the interventional cardiology unit, but it was after hours and closed. The ED staff nurse then consulted the cardiologist, who called the hospital operator and asked her to call the interventional cardiology unit team on call. This on call team consisted of nurses and scrub techs from the unit who staff the unit during the day. They take turns taking call for emergencies.

Upon arrival, the on call staff called the ED to ask about the patient. After a brief hold, the nurse obtained the patient's last name, identified the patient in the registration system, and started gathering information and inputting it into the interventional cardiology unit system. As she was doing this, the interventional cardiologist and scrub tech arrived. After being briefed by the interventional cardiologist, she called the ED and told them to bring the patient over.

The ED staff printed out information from their chart, put it on the patient's stretcher and transported the patient to the interventional cardiology unit. There upon arrival, the ED and unit staff conferred about Mr. Smith then proceeded to take the patient to the procedure room. Typically, patients are taken to a holding room for an examination beforehand, but this did not occur in the interest of time. Preprocedure documentation was done and a brief history taken.

Mr. Smith was allergic to one of the common medications (unfractionated heparin) given in the interventional cardiology unit. However, this was not known to the staff of the interventional unit. It was documented in the ED, but not in the interventional cardiology system. The patient was given this medication and had an adverse reaction. Ultimately, the interventional cardiologist was not able to complete the procedure and the patient died. The CH administration are in the midst of conducting a detailed analysis of why this occurred and ways that EHR implementation can help prevent future events.

Introduction

The case vignette at the beginning of the chapter presents how workflow and processes can breakdown in a typical clinical setting. What are the places where communication broke down? How can systems and processes accommodate those breakdowns? What kinds of quality improvement efforts would improve processes? Where were there delays in the process? Why did these occur? Answers to these questions are related to workflow and processes, which affect patient outcomes and

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

Process redesign and quality improvement efforts aim to make the delivery of care more effective and efficient by changing the steps in the delivery of care. This chapter begins with a definition of workflow and description of related frameworks. Then we describe tools and techniques to capture, visualize and analyze workflow in health care settings. Afterwards, we discussed several quality improvement approaches to improve quality of care.

What Is Workflow?

Workflow has been examined as a phenomenon and as a concept. Workflow as a phenomenon can be defined as the flow of work through space and time [1]. Workflow as a concept refers to the procedural aspect of a work system [2, 3]. Either way, workflow focuses on temporal properties (e.g. unfolding of work activities over time). Temporal properties are important because they provide tools and information to users at key moments of activities or enable the user to overview the work process. Other than temporal properties activities, actors [4], information [4], other resources (e.g. technology, materials) [5, 6] are important building blocks of workflow. Moreover, organizational infrastructure such as rules, policies, [7] and the external environment [6] are important 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 "hyper complex" when it is compared with other domains [8, 9]. Modeling is an appropriate strategy to make complex systems more comprehendible because of the explanatory power of models [10]. However, it is important that workflow models accurately show the essential components and functions of the work that is under investigation.

Because of the comprehensive scope and complexity of workflow, multilevel perspectives are needed in understanding workflow [3, 11, 12]. One possible multilevel workflow approach can be describing the scope from lower to higher levels. For example, cognitive, individual, organizational and inter-organizational workflow can be the focus of describing the scope of work. Cognitive workflow focuses on the collection of cerebral activities such as sensation, perception, decision-making and response-execution [12]. Individual workflow refers to the collection of physical and mental activities by a single individual (physician, nurse, respiratory therapist etc.). 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 [6, 13]. Inter-organizational workflow occurs when activities to produce a specific output takes place in multiple organizational context. For example, if a patient with a diagnosis of asthma is seen in an ED for a breathing problem, a summary of the visit should be communicated to the patient's primary care office. This is essential to the flow of communication and patient management

when modifying therapy by one set of providers to another. In health care delivery settings, the output or outcome is better health status for patients, lower costs, efficiency of care delivery and patient satisfaction.

Workflow studies are more likely 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, thus enhancing efficiency and generalizability [14]. We will provide a summary of four approaches to workflow that were developed within the informatics community.

Pervasive and Specific Levels of Workflow

Unertl et al. [7] proposes that a model has two levels of workflow, *pervasive* and *specific*. The *pervasive* level includes three components that apply to 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. 7.1).

Workflow as Collection of Individuals' Routines

Malhotra et al. [4] suggested the development of a workflow in care delivery settings by combining routines of individuals (e.g. nurses, residents and attendings). They also discussed the requirement of "a framework to temporally relate and

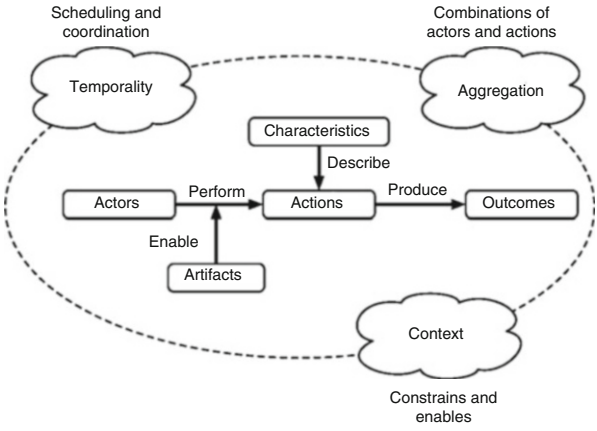

Fig. 7.1 Workflow elements model

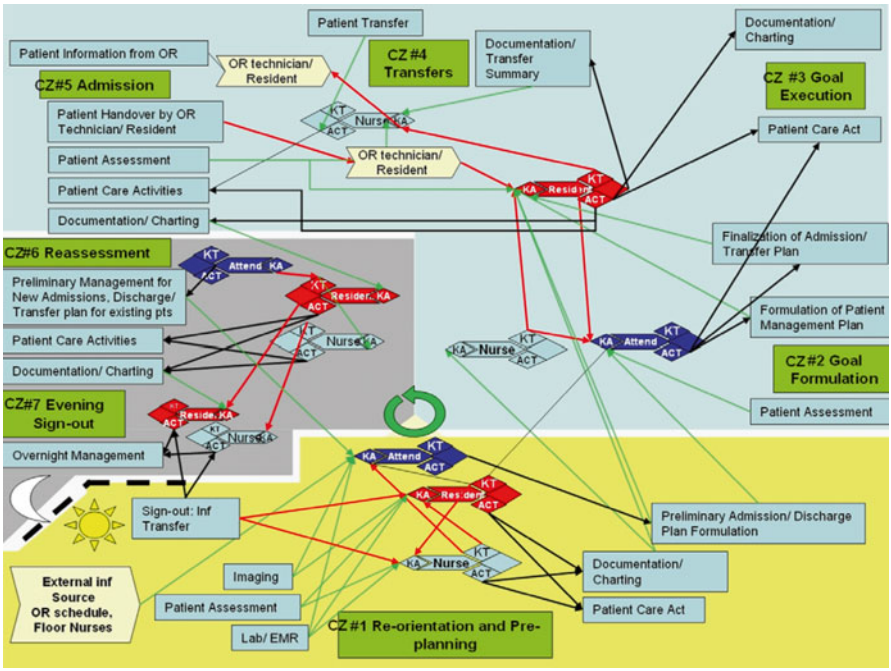

Fig. 7.2 Workflow in an intensive care unit (Reproduced from Malhotra et al. [4] with permission from Academic Press)

identify activities" for representing workflow. For that purpose, they set up conceptual zones (i.e. activity groups) in a way that the zones show the temporal relationship of the activities with each other. In this model, they delineated the workflow into different activities during the day shift and then clustered them based on the critical nature or temporal relevance into seven critical zones (CZ) (Fig. 7.2). This model reflects cognitive, individual and organizational workflows together.

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 [15]. Patient-oriented workflow models provide the "true flow of the work" [16] by including activities performed by multiple individuals and capturing the cooperative nature of health-related work in the care of a patient. In institutional environments, patient-oriented workflow models traditionally capture the work of multiple staff members. Extending patient-oriented workflow to the study of health-related activities in the home and community environment can capture the work of the patient, informal caregivers and "care partners" [17].

Organizational Routines

Organizational Routines framework examines workflow as a set of tasks and associated resources including people, systems and equipment, needed to reach a particular goal [18]. While some workflows are explicitly codified, others are tacit. These tacit workflows are operationalized through routines, or repetitive patterns of action [19]. Routines allow "actors" to know what to expect from others and can help bridge spatial, temporal and professional lines.

Routines can be studied as a whole, in parts or studied in tandem with how they change [20]. Regardless of how routines are studied, they have two different aspects: *ostensive* and *performative* [19]. The *ostensive* aspect of the routine is the "ideal-type", or how the routine should occur. This aspect of a routine can be determined by asking the actor "how do you do x?" or by reviewing policies and procedures. When developing process models, the ostensive aspect of the routine is what is being modeled. Individual performances of the routine might vary from the ostensive routine. The *performative* aspect of the routine [19] outlines how the routine occurs in actual practice i.e. the "real world".

Studying both the ostensive and performative aspects of a routine is necessary to understand workflow because the two aspects may differ. Ostensive routines are a guide for routines in practice. Ostensive and performative aspects of routines can differ for several reasons. Sometimes, there are changes from the norm in the environment or in the patient. Other times, the way that actors conceptualize the routine and the way that it occurs in practice differ [21]. This might occur for a number of reasons including, actors being unaware of each other's role in the routine, the processes being tacit, or because it is difficult to fully describe the routine. Some unintended consequences of these differences include adverse events or inefficiencies [18]. In other cases, the tension between the ideal-type (ostensive) and routine in practice (performative), may lead to organizational change [20].

These four workflow approaches can guide workflow studies. However, each approach has a different focus and purposes. "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 various clinicians' routines intersect with each other. Patient-oriented workflow suggests individual patients (as opposed to clinician) as the foci of workflow. Organizational routines focus on repetitive patterns that allow a care delivery settings accomplish its goals. Researchers and practitioners can choice to utilize any of these four frameworks depending on their needs and objectives.

The comprehensive examination of workflow may require interdisciplinary expertise including industrial engineering, human factors, sociology, psychology and organizational theory, combined with domain knowledge as well as perspectives of stakeholders such as patients. Therefore, a workflow study starts with establishing a team with complementary skills. A missing expertise can lead to incomplete modeling of workflow or incomplete interpretation of it. Xie et al. [22] examined multi-stakeholder collaboration in the redesign of 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 an important role in the collaboration process within the team. Clinicians and hospital management provided their perspective 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 is likely to capture only a small fraction of this complexity. A wide range of methods are useful for capturing workflow data, including qualitative, quantitative, and mixed methods. No single "right" approach to studying workflow exists. Selection of method is dependent on underlying theoretical frameworks, research questions, 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 in nature than study designs using quantitative methods. Qualitative methods are more suited towards generating hypotheses rather than testing them.

Observation, or *naturalistic observation*, is the systematic study of behavior and activities in context. When studying healthcare workflow, context refers to locations where work is occurring, such as an ambulatory clinic, ED, or hospital unit. Subjects for naturalistic observation could include anyone participating in the workflow of interest such as nurses, physicians, patients and their caregivers, administrative staff, and ancillary professionals. During naturalistic observation sessions, a researcher shadows a subject as the subject participates 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 information technology include: paper forms, sticky notes, print-outs from electronic health records (or other technology systems), lists of contact information, and written descriptions of procedures. The heavy use of artifacts can be an indicator of workarounds and gaps between existing technology systems and user needs. **Spatial analysis** involves studying the physical environment in which work is occurring. This method can involve 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 constrains 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 to 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 common 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 type of group interview, with several subjects asked to respond to questions. Group interviews have limitations related to the potential for dominant personalities to steer the discussion without including other perspectives and related to difficulty sharing potentially sensitive information in a group setting. Participatory design workshops could be considered a more active type of group interview, with participants asked to contribute to design of an experience or technology.

An emerging trend in healthcare workflow research (particularly with respect to qualitative methods) is the study of the activities that patients engage in while managing their health. New methods will likely be needed to assist in this type of workflow research outside the boundaries of traditional healthcare contexts. Methods that have shown promise for understanding patient workflow include journals recorded by patients about their health management activities, photo diaries of health related artifacts, and walkthroughs of homes. Significant work is needed to continue refining methods to study patient health management workflow outside of the traditional health care setting.

Quantitative Approaches

While naturalistic observation is considered a qualitative method, structured approaches to observation may be considered a more quantitative method. Early approaches in this regard emerged from industrial settings, through the time-motion study concepts developed by Frederick Winslow Taylor, Frank Gilbreth, and Lillian Gilbreth [23, 24]. The time-motion study approach seeks to quantify the amount of time and effort involved in completing specific work activities, through structured observation involving collection of temporal data. Researchers studying healthcare workflow have adapted these concepts to the study of more complex work in healthcare. Other structured approaches to observation have included structured data collection instruments to quantify the observed behavior [25–27].

Various approaches related to Human Factors Engineering [28] have also proved useful in collecting data about workflow. Approaches such as "think-aloud" protocols [29, 30], have individuals describe each step of their activities. For example, an

individual could describe each part of an electronic health record as they access it and why they are selecting specific functions. Other useful human factors approaches include studying individual and team workflow during scenarios in simulated clinical environments.

Surveys and questionnaires have also shown promise for study of workflow. Several standardized survey instruments including the NASA-TLX [31] and System Engineering Initiative for Patient Safety [32] have demonstrated an understanding of workload and task allocation.

An area of workflow methodology still under development is the use of data extracted from health information technology systems. In theory, information recorded through routine use of technology such as electronic health records and electronic scheduling and registration systems could assist researchers in understanding aspects of clinical workflow. Much work remains however, to further develop and refine software extraction.

Visualizing Workflow

In general, visualization supports researchers and practitioners by providing cognitive support through exploiting advantages of human perception, such as parallel visual processing, and compensating for cognitive deficiencies, such as limited working memory [33]. Specifically, visualizing workflow facilitates examining patterns and variations in practice. In this chapter we will discuss four different visualization techniques.

Process Map/Flow (Process) Charts

Although in this chapter the terms flow (process) chart and process maps will be used interchangeably, there is slight difference in these terms. The actual 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 [34]. The idea of process mapping is not new. It was described in the early 1920s [24] as "*a device for visualizing a process as a means of improving*." Every detail of a process is more or less affected by every other detail; therefore the entire process must be presented in such a form that it can be visualized all at once before any changes are made in any of its subdivisions. In any subdivision of the process under examination, any changes made without due consideration of all the decisions and motions that precede and follow that subdivision will often be found unsuitable to the ultimate plan of operation. 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 correctly and completely mapped.

Creating a process map entails the use of symbols, as shown in Fig. 7.3.

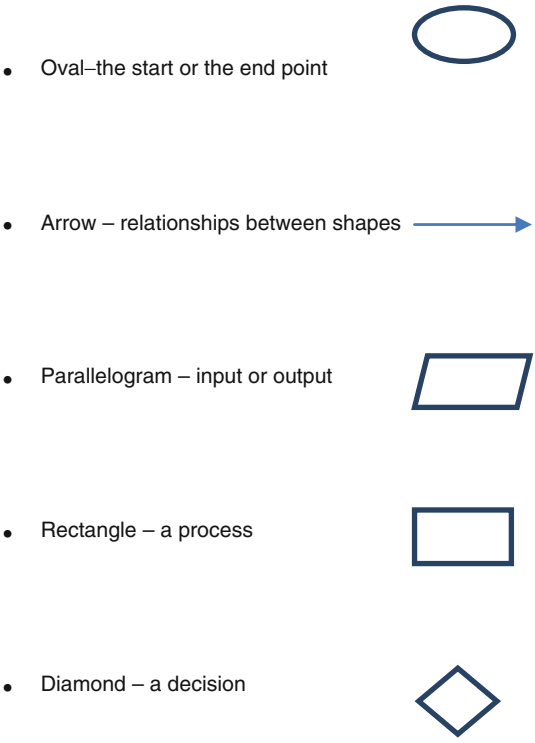

Fig. 7.3 The five basic symbols of a process map

Data Flow Diagrams

A data flow diagram is defined as "a graphical representation of the flow of data through a system." This includes what information is exchanged but it does not show when or in what sequence the information is exchanged. As such the data flow diagram differs from a flowchart diagram. Sharp and McDermott [34] explain that "on a data flow diagram, a data flow line between the steps indicates that data produced by the originating step is used by the receiving step". It is not recommended to merge a data flow diagram and a process map. A merged diagram can become highly complex resulting in a loss of explicit detail visualized in individual diagrams.

Like the process map, creating a data flow diagram involves the use of symbols (**see** Fig. 7.4) [35]:

Spaghetti Diagrams

Spaghetti diagrams (Fig. 7.5) are a visual illustration of the work unit running through a process including the flow sequence of the information. It documents the functional dependencies and responsibilities for each step in the process. The name

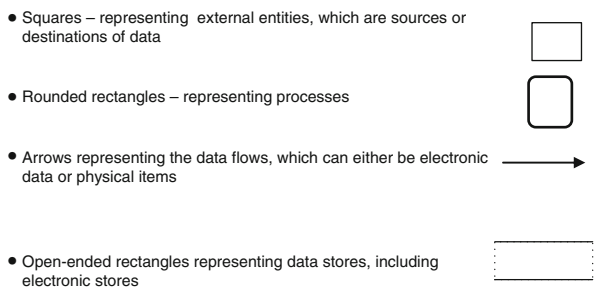

Fig. 7.4 The four major symbols of a data-flow diagram

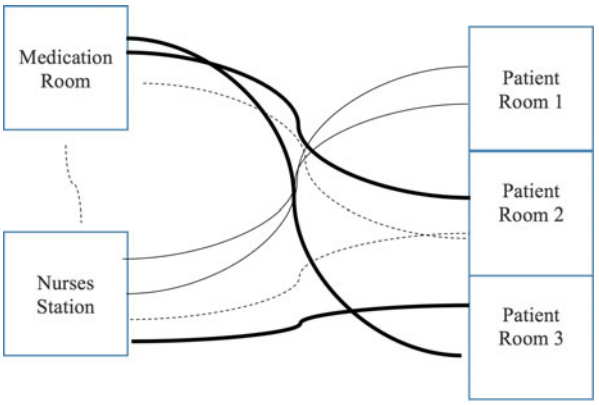

Fig. 7.5 An example of a spaghetti diagram that shows the movement of three nurses in a clinical setting. The type of line (*regular*, *thick* and *dashed*) shows the movements of a nurse in a pre defined time frame

"spaghetti diagram" is derived from the representations that often resemble a plate of spaghetti. The diagrams record the current state for specific paths through a process. The spaghetti diagram helps determine the efficiency of a space, by making it easier to identify wasted motion. Through spaghetti diagramming it is easier to quantify the impact of a layout on a process over time.

A spaghetti diagram can be created by

- Diagramming a layout of the physical 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, spaghetti diagrams use symbols. However, the notation is not as extensive as many other diagrams. Spaghetti diagrams rely on the use of lines. The lines are often squiggly rather than straight, color coded to visualize the various workflows (Fig. 7.5).

Swimlane Diagrams

Another visualization of workflow is the swimlane diagram. A swimlane diagram looks much like a swimming pool that has been divided into swim lanes. 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 to show what is done, by whom, and in what sequence as well as dependency and time [34]. 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 swimlane can be depicted either horizontally or vertically.

Swimlane diagrams can depict different types of work flow [34]:

- 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

Visualizing a swimlane diagram relies on the symbols shown in Fig. 7.6.

Today, various software applications can be used to create these four diagrams (process map/flow charts, data flow, spaghetti and swimlane diagrams. For example, Microsoft (i.e. Visio) offers applications with features and functionality for drawing and inserting shapes in the creation of these diagrams.

Examining Workflow Through Advanced Statistical Modeling

As data collection methods advance and more data are available to examine workflow, sophisticated quantitative data analysis techniques that are powered for large sample sizes, become possible. Quantitative data analysis techniques are useful because they can establish statistical relationship between process and outcome variables. In this chapter we describe three quantitative techniques; (1) Markov Chains, (2) Petri-nets, and (3) Discrete Event Simulation. We selected these techniques from among 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 [36, 37]. 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

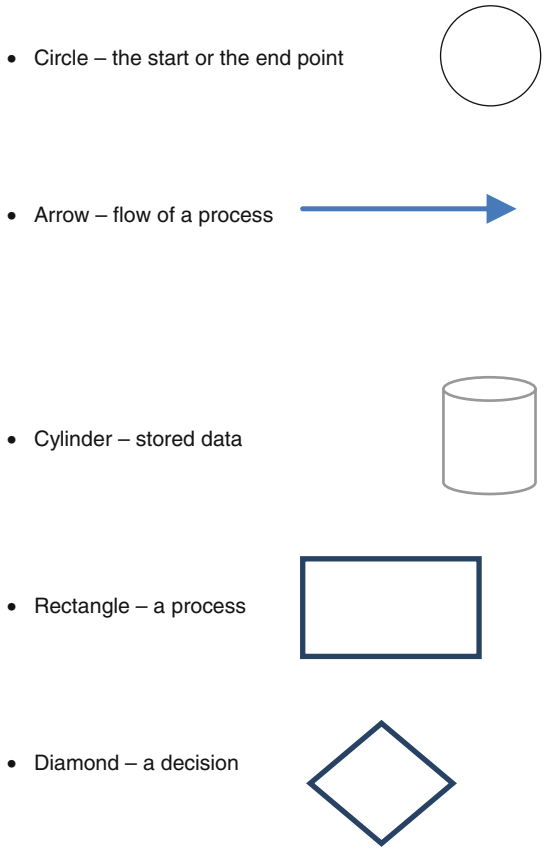

Fig. 7.6 The symbols that comprise a swimlane diagram

initial distribution accounting for the probability of being in one state at time t = 0 [38]. In modeling workflow, **Q** is a set of patient care events (e.g. triage started, physician assessment), **A** is a matrix of probabilities associated with transition 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 [39, 40]. MC has been shown to work with simulated data [41] and has the potential for analyzing data in-situ [42] such as modeling workflow patterns quantitatively. The goal of the analysis is to identify MCs that represent sequences of high-probability clinical actions, or in MC terminology, chains of states.

Petri-Nets: A Petri-Net (Fig. 7.7) is a directed bipartite graph, in which the nodes represent transitions (i.e. discrete events that may occur), places (i.e. conditions), and directed arcs (that describe which places are pre- and post-conditions for which transitions) [43, 44]. Petri-Nets model workflow by focusing on cases. Cases (or instances) are the objects, which need to be handled by the workflow. The object that is being processed highlighted instead of the subjects who process the object. Examples of cases are insurance claims and patients. The actual state of the system

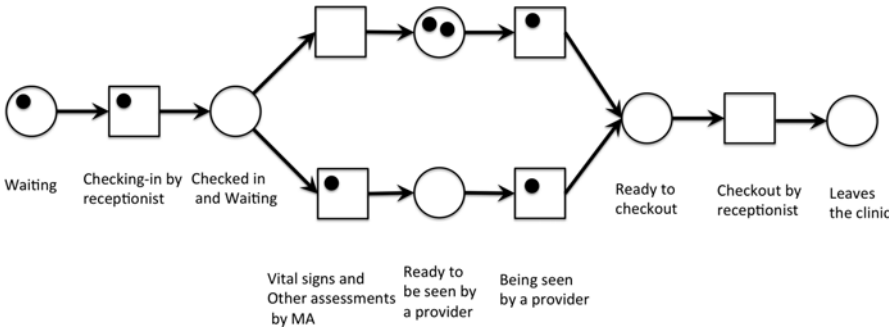

Fig. 7.7 An example of a Petri-net diagram showing the position of patients and caregivers in a clinic setting

is determined by the tokens (represented by filled circles), which are passed from place to place, undergoing transformations as they go. The Petri-Net in Fig. 7.7 shows seven tokens (i.e. seven patients). The diagram depicts the stage of the seven patients in a clinic setting. In this example, one patient is waiting in the first position, while the receptionist is checking in another patient. In this system there are two providers and each has a medical assistant (MA). The upper leg of the diagram shows the activities of one provider-MA dyad where the MA is idle, one patient is with the provider and other two patients are waiting for the provider. In the lower leg, the MA is with a patient and another patient is with another provider.

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 arrival rate of patients and service (encounter) time of clinicians. Simulation is useful to illustrate how the performance of multiple events affect 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 settings. The results will inform changes to the intervention before implementing any changes. For example Zhou et al. [45] 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 be used to process the data and simulate the care delivery setting. Hoot et al. [46] used DES to forecast overcrowding in EDs.

Selecting Appropriate Methods

Multiple considerations go into selection of methods for understanding workflow. Research questions and study aims should drive the selection of methods. Quantitative methods are generally most appropriate for answering questions related to 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, rationale for usage or non-usage of technology, and impact of technology on collaboration and teamwork.

The complexity of workflow demands the application of 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.

A critical consideration when designing a workflow study is consideration of 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 work group (e.g. nurses within a single clinic), a specific work group 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 boundaries of the study 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? Clearly 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, but also require a significant investment in time and personnel. Methods such as extraction of workflow data from health information technology (HIT) require appropriate technological resources and training on analysis. Workflow studies need to consider what methods contribute to the understanding of 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 as well as changes in technology, physical space, or personnel. Process performance can be examined in terms of clinical outcomes, patient satisfaction, or operational measures such as utilization and patient waiting time. Gaps in performance may be identified based on complaints, comparison with similar processes in other units or organizations, or identified as part of a culture of continuous improvement. As more data is collected

Table 7.1 Ten steps of process redesign as suggested by Karsh and Alper [49]

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

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 the development of new clinical guidelines to standardize care, resulting in significant quality improvements [47].

Changes to the building blocks of a process include; tasks, people, the physical environment, and information and 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 a common chronic disease or improve access by providing more examination rooms for additional providers. New information technologies (e.g. EHR, mobile applications) are currently a key driver 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 need to work with providers to ensure consistency with best practice. In addition, EHR systems support new capabilities, such as the ability to track and support all patients with specific chronic conditions or to give providers access to patient data anytime, anywhere [48]. 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 [49]; (2) Sociotechnical Principles for Redesign [50]; (3) Systems Engineering Initiative for Patient Safety (SEIPS) [51]. These frameworks overlap with each other but also have different focuses.

Karsh and Alper [49] suggest a ten step work system analysis (Table 7.1). This analysis is based on systems engineering principles. Clegg [50] proposed 19 principles of redesign based on sociotechnical principles (Table 7.2). SEIPS model highlights five components of work system and the interplay among them (Fig. 7.8).

Applying systematic approaches to process redesign increase the likelihood that desired goals will be achieved. These guidelines can mitigate the following common problems that

Table 7.2 Nineteen principles of redesign by Clegg [50]

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

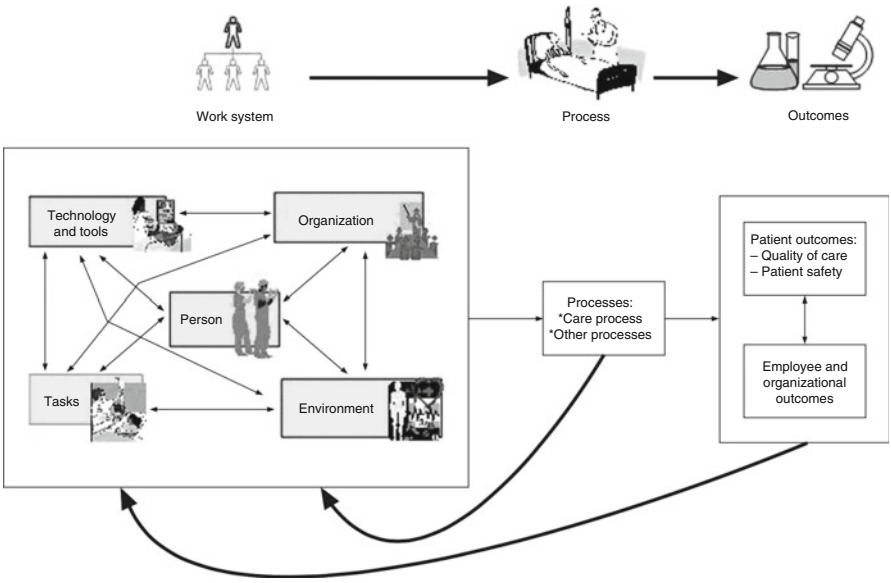

Fig. 7.8 The Software Engineering Initiative for Patient Safety (SEIPS) model

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 [52]. 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 [52]. 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. They must recognize participants and support the time and effort to develop a redesign, and be willing to implement 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) is a continuous approach for enhancing process delivery and performance, and is used extensively in healthcare. 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" [53]. In 2001, 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 [54].

Defined in this context, quality improvement encompasses not only clinical outcomes but also patient satisfaction and access to care. Donabedian [55] 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, which seek to create the structure and processes that improve performance, build an understanding of the relationship between process and outcomes, and thus support quality assessment and improvement. Informatics and process interventions can reinforce one another, creating new capabilities that can yield better outcomes.

Important Quality Improvement Frameworks

Several different models of quality improvement are used in healthcare settings. They share some common features including; iterative cycles of improvement, use of quality tools (such as flow charts or other visual process descriptions), active engagement of frontline staff, and the need for leadership commitment [56].

Plan-Do-Check-Act

One of the most popular methods used to guide cycles of quality improvement in clinical settings is a Plan-Do-Check Act (PDCA) or a Plan-Do-Study-Act (PDSA) approach. Also known as a Deming Cycle or the Deming Wheel, named after W. Edwards Deming, a leader in the field of quality improvement. As with all QI methods, the PDSA cycle encourages a methodical approach that emphasizes understanding issues before jumping to potential solutions [57]. In the "Plan" phase, a problem is identified 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 to understand how potential system elements (e.g., personnel, technology, environment, methods) might contribute to the problem. In the "Do" phase, a pilot testing of a solution may be carried out. During the "Study" or "Check" phase, the proposed change is undertaken to determine if it has been successful. 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 (following which it goes through another PDSA cycle).

While the PDSA cycle forms a foundation for continuous quality improvement, it is focused on testing changes and is more effective embedded in an infrastructure that ensures that important problems are addressed and quality improvement efforts are sustained. As an example, the PDSA cycle is one component of the model for improvement [58], but a second component 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 [59], rather than in a sequence of iterative cycles, and that sustaining and spreading changes is difficult. Quality improvement methods such as Lean and Six Sigma also build from and use PDSA cycle, but include additional philosophies and structures that support problem definition, measurement, and sustainability. Table 7.3 compares the Lean and Six Sigma approaches, which are described in more detail below.

Lean Methods

Lean is a QI strategy that emphasizes value and process from a customer perspective, respect for people, and continuous improvement [56, 60]. The **Lean** philosophy, as well as its supporting principles, originated with Toyota automotive industry [61]. 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 [61].

The use of **Lean** in healthcare settings has grown dramatically in the past 5 years, and 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, as well as an effective approach for supporting the implementation of specific practices and activities within a practice setting [62]. Several healthcare organizations have used **Lean** to achieve significant operational improvements, including Thedacare, Virginia Mason, Cleveland Clinic, and Intermountian Healthcare [63, 64]. At Thedacare, Touissant and Berry [65] augmented traditional **Lean** philosophies to include unity of purpose, or tying the goals of individual projects 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 as well as management approaches that provide infrastructure for ongoing improvement. One commonly used tool is an A3, or A3 problem-solving [57, 66]. A3 is a plan for solving an identified problem and a structure for moving through continuous improvement cycles (PDSA cycles) to achieve a desired goal (Table 7.3).

Table 7.3 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 Figures and numbers are valued
Tools and Methods	Process mapping, spaghetti diagrams, identifying seven types of wastes, 5S (workplace organization), root cause analysis/fishbone diagrams, results boards	Similar tools as 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 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

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 (RPIWs) [67].

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 [68]. Often both the current state of the process and a desired future state are mapped. As solutions are tested and measured, a *results board* is updated to display the outcomes in a prominent location. To support sustainability and a culture of continuous improvement, **Lean** also includes specific management activities, such as *Gemba walks*, which involve going to see the actual process and understand issues by talking with those who do the work. Daily *huddles*, which are short meetings that often occur in front of a results board, which bring staff together to keep them up to date on the activities of their work area and enable them to raise and address issues as they occur, preventing larger problems from developing [57]. Tools such as fishbone diagrams that were developed in the context of other QI approaches are also commonly used.

Six Sigma

As with Lean, Six Sigma has elements that are focused on problem-solving at the project level, as well as infrastructural elements that support sustaining a QI effort and ensuring an impact on 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 [57]. 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 [57] 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, but the Green Belts or Black Belt assigned to the project also has the knowledge to design more sophisticated experiments to test and analyze results. Many healthcare organizations combine elements of Lean and Six Sigma, creating Lean Six Sigma programs to promote and support QI efforts.

Important Components of Quality Improvement

The biggest opportunity to improve patient outcomes in the near future will probably come not from discovering new treatments, but from learning how to deliver existing therapies more effectively [69, 70]. Therefore improving quality is a critical aim for most health care delivery organizations and they initiate quality improvement studies using various approaches, which may yield different levels of success [71]. The unique features of organizations make it impossible to develop prescriptive rules for success [71]. However there are five principles common to successful projects: (1) Participation and teamwork, (2) Leadership, (3) Being data driven/data monitoring and dashboards, (4) Focus on value-added activities and (5) Embrace continuous improvement.

Emerging Trends

We identified three important emerging trends that will be central to workflow, process redesign and quality improvement. The first trend is the availability of big data for workflow studies [72, 73]. Electronic health records (EHR), electronic medication administration records and Radio-frequency identification technologies allow data to be stored for every patient. As a result, detailed data can be generated and obtained for very large sample sizes at a reasonable cost. The second emerging trend is examining workflow in non-traditional health settings such as the home and community [74]. As more health activities are conducted in the home and community settings, a better understanding is needed of how these settings and traditional care settings (hospital and clinics) are connected to each other. The third emerging trend is visual analytics and its contribution to workflow studies and process redesign [75]. Visual analytics can assist in identifying patterns and variations of workflow even in very complex situations [76].

Furthermore, an important trend in health care delivery that is related to workflow research is to identify potential patients at risk using data analytics. EMS and other paramedical personnel (community paramedics) are being deployed to find these patients and intervene. Therefore, hospital admissions can be prevented by actively managing these patients as outpatients [77].

Summary

Workflow can be defined as defined as the flow of work through space and time. It is a key component of the design and implementation of health informatics interventions; because 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 methodologies to capture and analyze workflow. These methodologies include qualitative, quantitative, visualization and statistical

approaches. We further provided a survey of process redesign, which included three process redesign frameworks. At the end of the chapter, we presented a survey of quality improvement in health care with three frameworks for performing quality improvement.

Application Exercise/Questions for Discussion

1. Please describe how a data diagram could have prevented the communication breakdowns in the case study?
2. Please describe the difference between a process map and a data flow diagram. How do they each impact the study of workflow?
3. What is the difference between the ostensive and performative aspects of routines? How do these differences impact workflow?
4. What kinds of workflow questions are suited to study qualitatively versus quantitatively?

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Chapter 8
Analytics

Christopher G. Chute

Learning Objectives

1. Understand the scope of analytics
2. Articulate diverse use-cases
3. Realize the dependency of analytics on comparable and consistent data
4. Cite relevant health information technology standards
5. Understand the role and limitations of data normalization

Key Terms

Quality improvement, practice analytics, learning health system, accountable care organization, risk adjustment, research analyses, data governance, statistical methods, machine learning, data standards, data normalization.

Case Vignette

Arthur is a quality manager at a large healthcare system and would like to understand the secular trends about the impact of case-mix on patient outcomes. He retrieves the past three decades of administrative data in the form of ICD codes at his institution, and runs them through a DRG case-mix grouper program. He has

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historical data on length-of-stay information for the same period, which he considers a proxy for outcomes—shorter stays being a better outcome. He creates a risk-group-adjusted outcome rate by year for his organization. He is pleased to see overwhelming evidence that his organization is enjoying shorter stays overall, but is puzzled by the erratic variations between successive years. He seeks interpretive advice from a colleague who has a deep grasp of health care analytics, and begins to appreciate his errors.

Introduction

Analytics, or the interpretation and analysis of data, is ubiquitous throughout human industries and modern society. The emergence of commodity computing and big data have refocused the importance of analytics in virtually all domains of human endeavor. Healthcare, as the largest segment of the United States economy, was somewhat late to the analytics party. Nevertheless, it has more than caught up with other segments of the economy, with analytics now being central to management, operations, clinical decision support, comparative effectiveness analysis, and best evidence discovery. It pervades biomedical research and clinical practice. No modern education in the health sciences is complete without some aspect of analytics. Given the intense dependencies of analytics on data, the marriage between informatics and analytics has deep roots and operational implications.

Data Dependencies

It is impractical to undertake any consideration of health analytics without first considering the underlying data. Put simply, analyses will only be as good as the data—garbage in, garbage out. While attention to data quality is best placed at the points of collection, data analysts typically find themselves downstream from this process, having to cope with what they have. However, there are due diligence steps one can take to "clean" problematic data. Whether one considers this a stage of analysis or simply good data hygiene is eminently debatable. Nevertheless, the point remains that even cleansed data cannot overcome serious problems of incomplete, misclassified, or chaotic original data.

Data Quality

Problems with data, particularly clinical data arising from healthcare records, are sadly common [1] and often refractory to improvement [2]. The primary reason is the asymmetry in cost vs. benefit by those who enter the data vs. those who analyze it. Virtually all the benefit of investing in data care, diligence, curation, and editing

accrues to the analyst. The expense, time, energy, and resources are borne by clinicians who have access to the most complete picture through their direct interactions with patients, but no incentives to invest in improving data quality. Overwhelmingly, clinicians have insufficient time to care optimally for patients. Reallocating from this time deficit for the sake of data quality has historically brought clinicians no palpable benefits—only costs.

That being said, there are categories of data quality frequently encountered, each with its remediation.

Missing Data

There are limited mysteries about missing information. It is simply not recorded. There is, however, no shortage of reasons why or how that information is missing [3]. With luck those reasons will be specified. The HL7 [4] health data standards development organization, described below, has long grappled with how to represent missing information; it currently specifies what it calls "flavors of null," which include 14 reason codes for missing information [5], such as "not asked" or "not applicable."

From an analyst's perspective, there are really only two immediate considerations. Does one include cases or records with missing information, or drop them from the analysis? Obviously, it depends on what is missing. If it is the dependent variable (the main question you are asking about, such as mortality), then one really has no choice but to eliminate those records from the analysis. However, if some predictor variables are missing, a common effort is to guess what they should be, based on other records in the dataset. This is called imputation [6], and techniques for achieving it are beyond the scope of this chapter; it alone is the topic of many textbooks [7]. Conventionally, however, statistical methods (another kind of analytics) are used to predict what those missing values are most likely to be, based on the values for other cases in the dataset that have identical or similar covariates.

Minimally Specified Data

This modality of data-quality compromise results from users picking the most general answer during manual entry, to avoid the chore of finding the more specific or appropriate answer – for example, just entering the code or answer appearing at the top of a drop-down list. Entries at the top of value-set choices are typically of the "not otherwise specified" flavor, precisely because of user shortcut behaviors. Such behavior is evident when examining the frequency distribution of values associated with a particular element, where the vast majority of responses can be attributable to the first value on the list. Rarely is this correct, as more specific responses are often known, but simply not specified.

Analysts should appreciate that the generators of data most often have little if any incentive to spend time and resources seeking the most specific value, attributable to the misaligned-incentive paradox. This can be mitigated by analysts creating reports and feedback of immediate value to data generators, typically clinicians, thereby

incenting their investments towards data quality to ensure valid reports. When value for the time investment can be seen, that investment will generally be made.

Data Entry Errors

Sometimes a data value is just wrong. This is not a subtle concept, and we can all think of circumstances where this could happen in clinical environments. Sources of error are most commonly human, where users put a right value in a wrong place, or accidently select a wrong value.

Sometimes these errors are systematic, where a decision is made by a group or an individual to "re-use" a data field for something else completely – for example, putting a call-back page number in a normal range field, because the normal range may vary from day to day and one is supposed to call the lab to find out what it is at that time. Systematic errors can most times become apparent by examining a frequency tabulation of responses, where invalid values or data types appear dramatically outside the range.

Finally, data can be incorrectly classified. This happens when a naïve user of a strict classification, such as the ICD, is unaware of all the inclusion and exclusion rules that surround correct use. For example, anemias due to blood loss are not classified under anemia, but rather as an acute blood loss. Coding this as anemia is a misclassification under the rules of the ICD. Sadly, statistical classifications like the ICD are rife with such specific coding rules, and most clinicians are hopelessly under-informed about those rules. The rules themselves are reasonable, because they reflect required properties of statistical classifications which by definition must be mutually exclusive and exhaustive – that is, they cannot count things twice. Whether physician ignorance of the rules is reasonable raises the question of whether clinicians should code data directly, without machine or coder assistance; regardless, it presents a serious challenge to data analytics.

Data Consistency

For data to be appropriate for analysis or inferencing, it must first be comparable and consistent; by definition, one cannot compare non-comparable datasets, never mind including them in meta-analyses across datasets. This notion of comparability and consistency is distinct from data quality, in that datasets may be complete, fully specified, and correctly classified, but simply invoke differing data standards as their foundation. For example, one dataset may have chosen ICD-10 as the basis for diagnostic classification, while another may have chosen SNOMED CT.

Readers may question why this is not simply a matter of mapping to address the data consistency question. The fundamental challenge is that all cross-terminology maps, particularly between vocabularies of differing resolution (where many terms in a source terminology map to a single term in the target) lose information. For example, while government-sanctioned maps to crosswalk SNOMED to

ICD-10CM are published [8], there is substantial evidence of incompleteness and ambiguity in these maps [9].

The challenge of data normalization has not gone unnoticed or without much effort. Virtually all health organization use data transformation or translation utilities, such as an interface engine. It is also an active field of research on effort to achieve scalable data transformation from heterogeneous sources for secondary use and analytics [10].

The salient point is that any analysis that seeks to combine semantically dissonant data must accept the likelihood of bias in that analysis. The largest source of bias is toward the null, meaning that the statistical power of analyses across datasets that involve different coding systems will be diminished, sometimes substantially, due to the loss of discriminating detail.

Provenance

Finally, the source of data can factor into how the data might be used. Provenance is the metadata about the many "w's" (who, what, when, where, why, whither, etc.) and thus can permit—if present—an analytic determination of source. For example, a dataset may contain a combination of drug use information arising from prescription, dispensing, self-reported, or NLP-derived (extracted from textual reports, such as history and physical dictations using natural language processing software) data. Ideally, provenance metadata will distinguish these data sources, so that a study protocol that may be highly sensitive to misclassification error may choose to exclude drug information with moderate to high uncertainty, such as NLP-derived data, from their analysis.

Provenance can be represented as primary data rather than metadata in a data schema, for example, which laboratory conducted a specific laboratory examination and on what date. The esoteric debate as to when provenance is treated as primary data and when it is treated as metadata would be academic were it not for the tendency of many analytic datasets to be stripped of what is considered metadata, and deemed by many as irrelevant to an analytic question. Data analysts do not always have the luxury of reference to the full information source, and thus may not enjoy access to important provenance data. This can then become a special case of missing information, where instead of missing a subset of values, the entire variable (or class of variables) is absent. Responsible data analysts must make a determination as to whether an analysis missing critical metadata such as provenance would have such a significant impact on validity, and therefore should not be attempted. This may be particularly germane for clinical data arising from multiple enterprises [11].

Patient Identifiers

Perhaps the most critical element of provenance in healthcare is the identity of a person for which records and information from multiple sources is being matched. Misclassifying two or more persons as the same, or failing to fold together complete

information for a single person may be a tolerable error at the level of population analyses, but can be disastrous in a decision support analyses applied to a specific patient. Given the self-evident importance of patient identifiers to disambiguate patients with similar names and incomplete demographics, establishing a National Patient Identifier was a centerpiece concept of the original HIPAA legislation in 1996. However, since 1999, congress has consistently defunded HHS, effectively prohibiting any US government action to establish a national patient identifier. The turning point came in a 1998 National Committee for Vital and Health Statistics subcommittee hearing, where privacy advocates asserted that any national identifier would be a major threat to patient privacy [12].

As a consequence of congress prohibiting the establishment of a national patient identifier in healthcare, the present practice for matching patient identity is to use surrogates, such as name, address, date of birth, and other identifying characteristics, to generate a local estimate for a patient identifier. This method is fraught with error [13] despite having a vast literature and significant spectrum of commercial master-patient identifier software offerings [14]. The significant likelihood that analysts may incorrectly merge clinical data, as a consequence of ersatz identifiers, must be carefully considered in all analytic use cases that involve patient data from more than a single source.

Analytic Modalities

At their core, health care analytics share attributes across all modalities of practice: they involve data, they apply some kind of inferencing methodology (statistical or machine learning), and they derive an interpretation. Despite this fundamental commonality, health care analytics has diversified into tribal communities of practice who barely recognize that they are all really doing the same thing. They typically define their own societies and meeting venues, read their own literature, and evolve divergent vocabularies to describe their common tasks. It is difficult for an analyst trained and working in one modality to transfer easily to some others, not because the underlying principles differ, but rather due to cultural distinctions among the communities.

Discovery

Discovery research at heart is a systematic analysis of patient conditions, interventions, and outcomes in order to discover what helps and what hurts. Discovery research has deep roots in healthcare, dating to statistical investigations of clinical outcomes by Ernest Codman [15] at Massachusetts General Hospital and the Mayo brothers [16] in the early twentieth century. Of course, these early pioneers relied exclusively on human abstraction from paper records and pre-computer methods for tabulation and analysis, but the basic foundations of patient data curation and

inferencing were established. What was novel and distinguishing 100 years ago is today standard practice across academic medical centers, greatly enhanced by the proliferation of electronic health records (EHRs) and ubiquitous computing resources. Today, discovery research in healthcare has evolved into many foci, mostly related, but distinguishable.

Clinical Epidemiology and Outcomes Research

The emergence of modern epidemiology and rigorous analysis of long-term outcomes is conventionally credited to the pioneering work of Richard Doll and Bradford Hill, who first reported the now well-accepted association between smoking and lung cancer in 1950 [17]. The healthcare community and epidemiology practice have matured in the subsequent 65 years, though the foci on specially-collected study data, minimizing biases, and maximizing generalizability remain their hallmark. Epidemiologists have long mined longitudinal patient records to discover disease natural history and treatment outcomes [18]. What is different today is the emergence of EHRs that enable the rise of large-scale efforts, such as the Clinical Data Research Network of the Patient-Centered Outcomes Research Institute (PCORI) [19]. Indeed, the entire notion of "high-throughput clinical phenotyping" from EHRs, portable algorithms for cohort identification within EHRs [20], has dramatically accelerated the pace and reduced the cost of epidemiological studies from EHRs.

Health Services Research

Health Services Research (HSR) is arguably a bi-modal social science focusing on healthcare, divided between policy evaluation and impact analyses. The latter bears examination in this chapter. What distinguishes HSR from other modalities is practitioners' long tradition of using administrative data, mostly health care claims data, as the source of health information for their underlying research. Historically, this was the only modality of data available in the volume needed to identify large-scale, generalizable patterns of care and consequences of interventions or illness on lengths of stay, hospital readmission rates, and costs of care. The HSR focus on national-level administrative claims data, while shallow on a per patient basis, is considered the harbinger of "big data" analyses in healthcare. This is manifest in the early, influential work of Wennberg on small-area variations in healthcare [21], which transformed our understanding of what is "appropriate" care.

The HSR community is adding depth to this trend by increasingly incorporating structured EHR data, such as medication use or laboratory observations, when available. This is engendering a palpable convergence between the traditions of clinical epidemiologists, who themselves are adding claims data from outside their institutions to capture outcome data, and those of the HSR community.

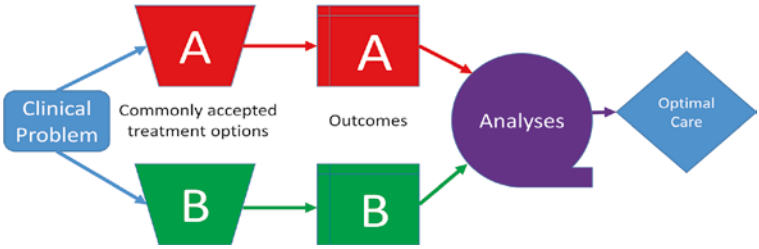


Fig. 8.1 The role of analytics in comparative effectiveness analyses

Comparative Effectiveness Analyses

Comparative effectiveness research is a synthesis of clinical epidemiology and health services research, applied to empirical comparisons of which among two or more alternative treatment paths demonstrate the highest value healthcare. Value in this context may be variously interpreted, but traditionally it is the widely cited "triple aim" of better care for individuals, better health for populations, and lower per capita costs [22]. At heart, comparative effectiveness is an analytic process, though the difficult part is gathering unbiased outcome data, ideally beyond the treating organization, or individuals and populations. The role of analyses if depicted in Fig. 8.1.

Comparative effectiveness research is highly dependent on the underlying quality and integrity of source data, such as administrative health data or EHRs. This is because such research is rarely done with prospectively collected, protocolized data, but rather through analyses of routinely collected data. This point is what primarily distinguishes comparative effectiveness research from prospective clinical trials.

Clinical Trials

Classical clinical trials are distinct from all modes of analytic research in that they deal with experimental, prospective data. Specifically, subjects are randomized to receive one or more experimental treatment protocols, whereas a control or conventional therapy group does not receive the experimental treatment. The analytic question invariably reduces to which group of patients fared better, conventionally as a metric of treatment response, or more strictly overall mortality. However, again, the nuances of how to undertake this analysis could be and often is the topic of an entire textbook.

The challenge of good clinical trials execution transcends the analytic phase. Appropriate randomization (for example, stratifying on confounding variables, such as age or disease stage) must be incorporated early in the design phase process. While analytic strategies can attempt to accommodate for residual confounding

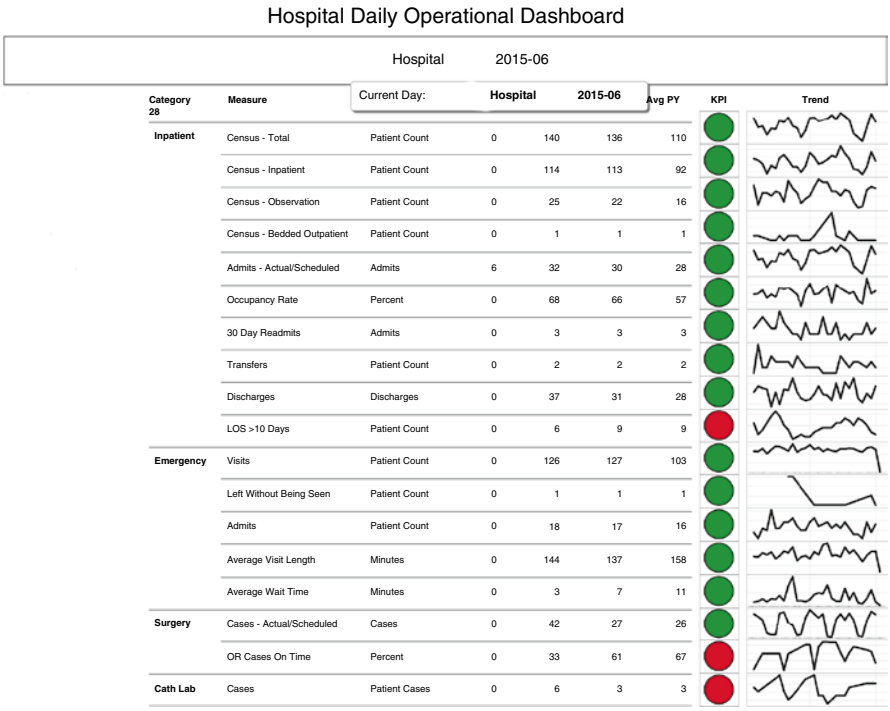
(that is, the influence of co-variants that were not coordinated in the randomization process), they cannot completely overcome a flawed clinical trials design. There are specialized design approaches that can optimize the validity of a clinical trial, such as a cross-over design. In cross-over trials, the treatment group switches to become the control group, and vice versa. Obviously, such trials mandate short-term outcomes. For example, long-term overall mortality would be rather uninterpretable in a cross-over design. Regardless, such design nuances have profound impact on the appropriate analytic approaches, factors that an analyst must understand and accommodate.

There are modalities of clinical trials that absolutely require the participation of the data analyst in their execution. Adaptive randomization, introduced 20 years ago [23], involves the periodic re-calculation of treatment allocation weights across randomization variables, based on the observed randomization in the trial at a given point. It has since become the standard for relatively small clinical trials with multiple arms, where treatment allocation balance may not enjoy the luxury of large numbers [24].

Monitoring

In the twenty-first century, the one thing we have in abundance is data. Indeed, managing and reacting to the vast volumes of data has become the focus of the entire "big data" movement [25]. Monitoring, primarily in the form of dashboards, has become a dominant modality of analytics, and specifically of its subfield, visualization. While visualization covers a broader scope than monitoring alone, the use of graphics, such as dials or bar charts, to view the status or progress of signals or events is widely used in healthcare. Within intensive care units, trace signals and point estimates of continuous waveform data, such as heart rate, blood pressure, respiration, ventilator settings, and more esoteric things such as pulmonary arterial pressure via Swan-Ganz catheterization, are commonplace; they are all invariably monitored, either via display for human reading, computer tracking for out-of-range events, or both. More mundane information, such as days revenue outstanding, hospital bed occupancy, or revenue by payer, can also be monitored through dashboards, as illustrated in Fig. 8.2.

The role of the analyst here is multilayered. At one level, the appropriate signals and data must be captured, validated, and normalized. At another layer, collaboration with human factors experts and clinicians should be undertaken to explore the best way to present that information, including not presenting most of it until a range threshold violation warranting attention takes place. Questions as to whether one should present a number alone or with some associated dynamic graphic must be considered. Where the data is shown, how it is clustered, what colors are used and whether colors change by value, how frequently the data is updated, and how one can understand trends over time all factor into these analytic considerations.



Category 28	Measure					Avg PY	KPI	Trend
Inpatient	Census - Total	Patient Count	0	140	136	110		
	Census - Inpatient	Patient Count	0	114	113	92		
	Census - Observation	Patient Count	0	25	22	16		
	Census - Bedded Outpatient	Patient Count	0	1	1	1		
	Admits - Actual/Scheduled	Admits	6	32	30	28		
	Occupancy Rate	Percent	0	68	66	57		
	30 Day Readmits	Admits	0	3	3	3		
	Transfers	Patient Count	0	2	2	2		
	Discharges	Discharges	0	37	31	28		
	LOS >10 Days	Patient Count	0	6	9	9		
Emergency	Visits	Patient Count	0	126	127	103		
	Left Without Being Seen	Patient Count	0	1	1	1		
	Admits	Patient Count	0	18	17	16		
	Average Visit Length	Minutes	0	144	137	158		
	Average Wait Time	Minutes	0	3	7	11		
Surgery	Cases - Actual/Scheduled	Cases	0	42	27	26		
	OR Cases On Time	Percent	0	33	61	67		
Cath Lab	Cases	Patient Cases	0	6	3	3		

Fig. 8.2 Example of an analytics dashboard displaying an array of metrics and indicators for healthcare operations and fiscal management (Used with permission of Indiana University Health, Inc.)

Decision Support

Healthcare is often described as comprising just three things: information about the patient, knowledge about treatments or disease natural history, and some kind of intervention. Interventions can range from surgical procedures to prescribed medication; sometimes no intervention at all can be the wisest course. What guides healthcare providers in choosing optimal interventions goes back to medical knowledge. Historically, all medical knowledge was mastered by humans and applied through thoughtful judgment. Increasingly, we are finding that information about the patient can be matched to known patterns of disease and health progress. Prior knowledge in the form of clinical trials, observational research, and an increasingly sophisticated understanding of human physiology down to the molecular level is an integral component of biomedical knowledge in the modern era and can provide the conceptual scaffolding for the clinical decision process. Translating that knowledge into a machine-executable decision framework and executing on available data is the core challenge of clinical decision support (See Chap. 6).

The intersection of informatics and clinical decision support is when all medical knowledge is rendered in a computable format. Specifically, among a range of

alternatives, discrete variables and their specific values determine which treatment path is optimal. Computational methods to recommend clinical decisions range from trivial "if then" rules to complex machine learning algorithms. The rules themselves can invoke forward- or backward-chaining logics. Again, a full consideration of decision support is a chapter (Chap. 6 in this volume) if not a volume unto itself. The relevance to our consideration of analytics is that at its core, clinical decision support is an analysis of available data about a patient that involves matching to computable knowledge and making an inference about the best treatment path among alternatives for a given pattern of patient data.

Conformance

While laws and regulations are arguably as old as human history, they have become particularly prominent in the practice of modern healthcare. Within healthcare today, determining whether regulations pertain, and what actions are indicated, is increasingly a data-driven process. Similarly, establishing whether regulatory requirements have been satisfied is typically determined by examining the corresponding performance and monitoring data. For example, hospital length of stay expectations are well characterized for many diagnostic groups. Costs attributable to deviation from those expectations are typically borne by the healthcare provider, and thus it is of significant interest to know how often and why such deviations occur.

In parallel with fiscal monitoring are requirements for adherence to quality metrics. Such metrics, expanded on below, typically require the calculation of a numerator condition, such as patients receiving a specific therapy, divided by the denominator condition, such as patients with a specific disease. An overwhelming example of required conformance with quality metrics is the recent Meaningful Use regulations published by the Office of the National Coordinator for Health Information Technology [26]. Consistent with modern informatics expectations, all these quality metrics are designed, or at least intended, to be calculated from underlying electronic health records. Virtually all healthcare providers have found generating such metrics to be a formidable analytics challenge [27].

Management and the Learning Health System

In the not so distant past, healthcare and hospital management reduced to assuring that an adequate volume of high reimbursement procedures were undertaken to ensure a positive cash-flow revenue base. The historical volume-driven mode of managing healthcare by maximizing quantity was challenged with the advent of the "value-based" healthcare revolution [28]. This premise suggests rewarding healthcare providers for providing value, consistent with the triple aim goals outlined above [22], rather than rewarding high volume. Operating on this premise, a movement has emerged emphasizing the "Learning Health System [29]" (LHS). The

simple precept of a learning health system is that data and information about patients are carefully collected and curated, and that knowledge deriving from comparative effectiveness analysis of that data is systematically reapplied to continuously improve healthcare outcomes and reduce costs. In fact, LHS is an adaptation of the decades old Deming cycle, or the Plan, Do, Study, Act (PDSA) model [30]. Obviously, analytics is core to the Study phase of this continuous improvement model.

The Learning Health System movement is having its effect in the emergence of Accountable Care Organizations [31] and is having a palpable effect on healthcare payment reform [32]. Indeed, the entire emergence of "Obamacare" is centered around the precept of changed fiscal incentives, rewarding value and prevention above volume in healthcare services. However, to achieve the goals of value-based healthcare and to operate as an accountable care organization, considerable resources must be expended on patient data collection and management, and most importantly the appropriate analyses to optimize care pathways and clinical management in order to maximize healthcare outcomes and value. The rise of accountable care organizations will probably impact the scope and demand of healthcare analytics more intensely than any previous healthcare innovation, including discovery research.

Fiscal

No consideration of healthcare analysis would be complete without at least mention of fiscal operations within a healthcare organization. As outlined above, what is being optimized is in transition from volume to value, but nevertheless careful tracking of resource versus revenue remains a fundamental activity in any healthcare enterprise. The modalities of analytics are myriad, and include among others key performance indicators, revenue cycle tracking, activity-based costing, total cost of care estimation, financial reporting, budgeting, fiscal forecasting, revenue recognition, reimbursement modeling, package pricing, and profitability. The boundary between accounting and analytics may be arbitrary, but it is clear that moving into the future more comprehensive analytics using the underlying clinical and physical data will be central to the financial survival of any healthcare organization.

Perhaps the most analytically intense aspect of fiscal management is the challenge of "case mix," which attempts to adjust for severity of illness. This topic is described more completely below.

Analytic Methodologies

As readers no doubt either knew or suspected from the spectrum of use case applications outlined above, the nature of analytics in healthcare is vast. Expertise in one area does not necessarily translate into capabilities in another. Here, the major modalities of analytic methodology are outlined.

Tabulation and Deviation

Arguably the simplest, though by no means trivial, analytic methodology is case or event counting. Virtually all metrics, such as quality metrics, key performance indicators, and volume statistics, reduce to tabulating totals within a specified category. However, the challenge is not having computers add, but rather knowing precisely what categories of events, patients, or dollars to include in the tabulation. Invariably, well-established and published metrics define clear specifications of exactly what should be counted. Translating those specifications into an accurate rendering of the real world raises questions about characterization of time intervals, demographic definition, disease classification, severity metrics, and innumerable covariates. Each of these in turn is a full topic, but most of them reduce to semantic consistency, and are typically mediated through controlled terminologies and classifications (see above).

While simply counting such elements poses challenges enough, it is in understanding deviation from prediction that tabulation proves its worth. This in turn implies an underlying model of expected behavior or outcomes, which invariably arises from statistical or machine learning analysis. Establishing what kind of thresholds, ranges, or gaps should be used to define a reportable event is again a function of prior analytic effort.

Visualization

Tabulated information, while valuable, is enhanced by visual presentation. Most humans are better able to grasp the meaning of numbers and deviation from expected values if data is conveyed graphically. The discussion of dashboards above conveys some aspects of this, though visualization covers a broader spectrum of topics. The most basic form of visualization, uniformly used by all data analysts, is a graphical distribution of the values for a particular variable. This can be a scatter plot in combination with another variable, such as time, or a bar graph of discrete values for nonquantitative data types. Visual review of "outliers," which are variables outside the typical range for a specific variable, can provide insight about data quality or extreme situations bearing greater attention.

Visualization can and should be incorporated throughout the data analytics process. For example, following a statistical analysis such as a regression, it is often helpful to graph the "residuals," which are the differences between observed values and their corresponding statistical prediction. Figure 8.3 depicts a poorly fit statistical model, based on residual visualization. Again, significant outliers in the residual plot, or patterns of outliers, can suggest an improved analytic model, such as a logarithmic transform, or helping to choose among various multivariate models used in the statistical prediction.

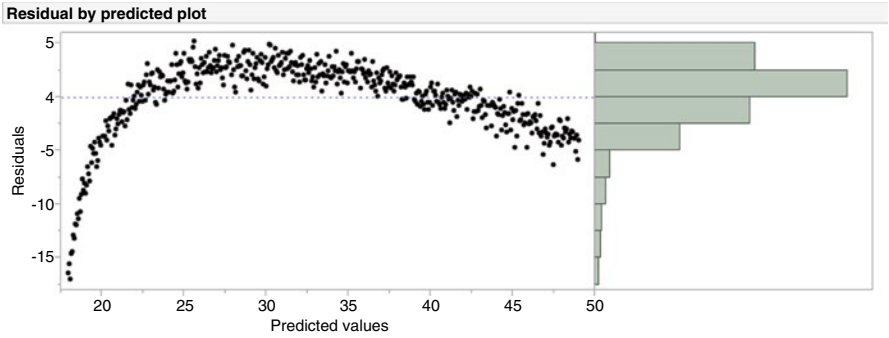


Fig. 8.3 A plot of residuals from a simple linear regression against predicted values. Well-fitting models are evenly distributed around the "0" line; this graph shows a visually obvious curvilinear deviation from a uniform fit. Notice that, by definition of a linear regression, half the values are above and below the line. Nevertheless, the "non-linear" fit is obvious to the eye

Statistical Models

The question of what constitutes a "statistical model" vs. a machine learning model has been hotly debated. As it happens, the two overlap significantly. For the purposes of this brief discussion, we will consider analytic models based on probability distributions, such as the normal or Gaussian, binomial, or Poisson distributions, as traditionally statistical or parametric (meaning they have parameters associated with the probability distribution). Many nonparametric statistics, including rank-order comparisons, have a long tradition prior to the advent of computing and are conventionally regarded as statistical methods. While hardly an exhaustive list, some more common statistical methods are enumerated here.

Linear Regression: This is what you learned in high school, where a continuous numerical variable, called the dependent variable, is estimated from one or more dependent variables. These models most typically invoke the normal or Gaussian distribution as their underlying parametric model. Equation 8.1 shows the simplest linear model, with the computed parameters being m and the intercept constant b, which estimate how x can predict y.

$$y = mx + b \tag{8.1}$$

Logistic Regression: In this kind of analysis, the dependent variable is always 1 or 0, true or false, alive or dead. As such, it must invoke a different parametric distribution, and by definition it uses the binomial distribution or logistic model.

$$F(t) = \frac{1}{1 + e^{-t}} \tag{8.2}$$

It can be demonstrated that the range of F(t) goes from 0 to 1, which is exactly what is needed for such true or false predictions. Conventionally, the variable t is expressed as a linear combination of explanatory variables, closely resembling our linear regression model:

$$t = \beta_0 + \beta_1 x \tag{8.3}$$

Replacing the expression of t in Eq. 8.3 for its dependent appearance in Eq. 8.2 creates the conventional equation for logistic regression.

Poisson Regression: While less common than logistic, Poisson regression is helpful when the expected outcomes go beyond 1 or 0, specifically to a rare event, on the order of a handful, in a large population. This is typically used when a "cluster" of unexpected events is observed and can provide a statistical probability of how significantly a purported cluster differs from an expected underlying rate of events. A classic example is statistically testing whether an unusually large number of leukemia cases in proximity to an environmental exposure significantly exceeds the rate of leukemia observed in a similar population.

Survival Analysis: The family of survival analysis is quite large. In general, these are a subset of time-dependent models which compare time to event, such as death, between two populations. Typically, one population is an experimentally treated group, while the other is a control group. A commonly used survival model is the proportional hazards or Cox regression model, which divides time into a sequential set of discrete ranges, computing what is effectively a logistic regression within each range, and pooling the estimates across all ranges. There are restrictions to the kinds of data that can be correctly estimated using proportional hazards. For example, Cox regression requires that within each time range the event risk or hazard must be consistently greater for the same group across all time ranges; this is called the proportional hazard assumption.

Nonparametric Methods: As we have seen, most statistical methods invoke a parametric distribution or statistical model to estimate probabilities or association. For example, simple correlations statistics invoke a Gaussian or normal distribution. There are many methods to do simple correlation without invoking a parametric model, typically involving rank-order characterization. For example, Spearman's rank correlation allows data that may be significantly skewed or otherwise nonlinear to be compared based on a statistical association of the ranks of data. Correspondingly, the Wilcoxon signed-rank test allows a statistical equivalence between two simple measures to be estimated without invoking any parametric distribution. This is again appropriate for highly skewed or nonlinear data.

The family of nonparametric statistics, most of which significantly predate the advent of computing, is relatively large. Thus, a bland assertion that all nonparametric methods are machine learning methods conflates the definition of historical statistical methods and those that arose only with the advent of machine computation.

Machine Learning

The family of machine learning models is quite large, and arose by definition after the advent of affordable computing. The simple characterization of machine learning is that the computer "discovers" the association between the dependent variable and its predictors, although invariably some underlying model must be in place. For many years, adherents of machine learning vaunted the superiority of their techniques above that of the pre-computing statistical methodologies. However, it can

Table 8.1 Analytic mythologies by property

	Property			
Analytic approach	Enumeration	Graphics	Parametric models	Inferencing
Tabulation	☑			
Visualization		☑		
Statistical models	✓	✓	✓	☑
Machine learning			✓	☑

☑ Fully and always demonstrates property

✓ May or partially demonstrates property

be readily demonstrated that machine learning methods such as Neural Networks are in fact simply a generalization of logistic regression [33]. All neural networks effectively invoke the logit assumption (Eq. 8.2). Obviously, when each node of a neural network can be expressed in terms such as Eq. 8.3, single-layer neural networks are mathematically identical to logistical regression. Multilayer neural networks, or multilayer perceptron, are correspondingly identical to nested logistic regressions. The similarities between methods were not recognized by the statistical or machine learning community for at least a decade, because they used different vocabularies and conceptual frameworks to describe and publish their methodologies.

Other common methods of machine learning include support vector machines, k-nearest neighbor analyses, decision trees, and Bayesian networks. Their detailed description is beyond the scope of this chapter, but the reader may gather that there is a large and complex field of study to master the application of machine learning methods in data analytics.

A summary of these analytic methodologies by their properties appears in Table 8.1.

Analytic Exemplar

An overview of data dependencies and statistical methodologies may describe analytics, though it is perhaps most helpful to consider high-profile examples of analytics applied to healthcare in modern healthcare delivery enterprises. We will consider two kinds of case mix adjustment methods, and more examples of quality metrics.

Diagnostic Related Groups

Diagnostic Related Groups, or DRGs, were initially developed in the United States in the 1960s to group similar patients for health services and health economics research. They became adopted by the federal government and subsequently all healthcare payers as a mechanism for grouping payments to providers based on their classification within a DRG matrix. DRGs are essentially a clustering of

diagnostic and procedural codes, today divided into approximately 1000 medical or surgical groups, where each DRG has a precise algorithmic definition. These definitions are executed by computer program called a "grouper" which also accounts for age, gender, discharge status, and the presence of complications or comorbidities. There are many grouper algorithms and software solutions available, though the Centers for Medicare and Medicaid Services (CMS) annually designates a vendor-provided product that is widely considered to be the official U.S. DRG product. While the algorithms are technically public, they effectively function as a black box in most healthcare organizations. This does not inhibit a large secondary market vending products to optimize "up coding," where the data, particularly the sequence of clinical codes, are reordered to maximize reimbursement recovery.

From an analytics perspective, entire departments in healthcare provider organizations manage and curate the data stream that goes into the DRG grouper. There are in fact considerable analytics that precede the generation of the final stream of diagnoses, procedures, and demographics that will ultimately be entered into a grouper. As value-based healthcare and Accountable Care Organizations form an increasing segment of the healthcare industry, such esoteric optimizations for volume-based reimbursement will become increasingly moot.

ACGs

The original goals of DRGs were to group patients clinically to facilitate the analysis of outcomes and costs. DRGs today are used exclusively for hospital inpatient care, and with the increasing transfer to outpatient procedures and practice, they are becoming insufficient to manage complex healthcare enterprise strategy. ACGs, originally ambulatory care groups, have come to parallel DRGs among healthcare providers. Like DRGs, they have a 30-year history [34], although ACGs have enjoyed greater transparency and generalizability in healthcare. ACGs today also enjoy a broader spectrum of data inputs, including medications, and increasingly laboratory data in addition to the traditional demographic and administrative codes.

The implication for data analytics is that unlike DRGs, ACGs can address a much broader spectrum of use, leverage a richer range of inputs, exhibit more transparent calculation, and enjoy more versatile application. The age-old question of whether "my patients are sicker than yours," as measured by underlying disease severity approximated by case mix, can be more meaningfully addressed with tools such as the suite of resources within ACGs.

Quality Metrics

Quality metrics have come under unified management by the creation and operation of the National Quality Forum [35] (NQF), a nonprofit, nonpartisan, membership-based organization created to convene quality metric developers and endorse designated healthcare-related metrics. The NQF publishes a wide spectrum of quality

metrics generated by a collaborating partnership of authoring organizations. These metrics are collated into more than 100 portfolios, though they designate a subset of these standards as NQF-endorsed.

Standards are published as textual descriptions, which include several components: a measure description, numerator statement, denominator statement, exclusions, and risk adjustment status. It is typically left as an exercise to an analyst to translate these metrics into executable algorithms and institution-specific computer code. NQF has invested considerable energy to ensure the comparability and consistency of these metrics across healthcare organizations, specifically convening a value set committee to identify coherent semantics within and between NQF metrics.

A related and coordinated effort with the NQF is the publication of Clinical Quality Measures [36] by CMS. These are the metrics that must be used to qualify for meaningful use reimbursement under the Health Information Technology for Economic and Clinical Health (HITECH) Act [37], and cross reference NQF ID numbers where applicable. Where NQF measures are not cross-referenced, CMS does define the metric logic, including the specification of applicable value sets, in a similar manner.

The difficulty with both of these measures has been the effort to include value sets that cover multiple coding systems. Specifically, many NQF and CMS metrics specify ICD-9-CM, ICD10 CM, and SNOMED diagnostic codes as valid values for identifying cases for the numerator and denominator. As outlined above, this is a recipe for metric inconsistency, a problem recognized and being addressed by the NQF value set committee.

Caveats and Cautions

Let us return to our case vignette and examine some of the concerns that careful readers of this chapter might now appreciate. Let us focus initially on data, since that ultimately is the most important input into any analytic process. Arthur proposes to use 30 years of ICD data, though he failed to recognize that the ICD has been a changing code system for most of that time frame. Each year, the CDC and CMS publish the version of ICD-9-CM to be used for the next fiscal year. Historically, there have been frequent changes of codes and their assigned meanings. Thus to use a catalog of 2015 codes and values for ICD will not generalize over a three-decade span; the meaning of many codes has changed. To be unaware of this source of data error would no doubt grossly misclassify large numbers of patients, increasing in proportion the further back one goes.

Another concern is the grouper software being used. Like the ICD, the grouper software is republished each year, and is dependent on the meaning of ICD codes for that year. Using a 2015 DRG grouper across 30 years of data is unlikely to return interpretable results.

Arthur's basic assumption that length of stay is correlated with better outcomes may have some basis in theory, but the overwhelming secular trend has been to reduce length of stay due to fiscal pressure and capitated care payments. Thus any interpretation of length of stay must be made in the context of the secular period and those fiscal pressures.

The general admonition is that any data analyst must be thoughtful about the underlying data that he or she might use, its appropriateness to the question at hand, its currency in terms of secular specifications, and its semantic consistency with related data with which it would be compared. The questions of analytic methodology must also match the problem at hand; for example, analysis of a randomized, crossover clinical trial cannot be done with the same tools and techniques used to tabulate quality metrics. While that might seem obvious, the literature is rife with examples of grossly inappropriate and misleading analytic methodology.

Emerging Trends

Big Data

In 2012, in a report to the NIH director by the Data and Informatics Working Group [38], it was observed that:

Colossal changes in biomedical research technologies and methods have shifted the bottleneck in scientific productivity from data production to data management, communication, and interpretation.

Our scientific challenge is not so much creating the data, but analyzing and interpreting it. This is a rallying cry to data analysts and informatics experts around the world. We are confronted by an ever-increasing amount of data, growing exponentially. The roles, opportunities, and indeed responsibilities for data analytics will only correspondingly grow. The degree to which analytics can or should be semi-automated, so the data becomes self-describing and in a sense self-inferencing, raises intriguing questions. It is clear that traditional models of downloading data sets, laboriously cleaning them, and subjecting them to weeks if not months of systematic analysis and interpretation will not scale into the future. Modalities and methods for data analytics into the future will inevitably change, as indeed the nature of data generation and previously unimaginable capacity for data preservation accelerate.

Omics

A sub-type of big-data, is the rich detail and analytic challenge presented by the "omics" zoo, including genomics, proteomics, metabolomics, and a potentially unbounded number of related biological disciplines. While genomics is

somewhat past an "emerging" trend, it continues to evolve with the advent of large-scale, next-gen, whole genomic sequence data on patients and parts of patients. Already, oncology response to kinase inhibitors is well-predicted by the genome of the tumor, which—by the nature of cancer—changes over time and location within a tumor. Thus, analyses of cancer information can include multiple versions of full somatic genomes, in addition to germ-line genetics. Analyses of "omics" data is traditionally considered within the purview of bioinformatics, and embodies analytic techniques and expertise that is unique to that problem space.

Personal and Home Health Devices

It is often written that within 5–10 years the vast amount of healthcare data will be generated outside of healthcare delivery enterprises, centered in home and personal monitoring devices connected wirelessly to our personal health clouds. The opportunity to examine continuous, 24/7, waveforms of blood pressure, glucose measurements, respiration, ECG, and no doubt other complex analytes over months if not years for specific patients raises unbounded potential to modify our notions of disease and health modeling and monitoring. Correspondingly, our ability to capture on a similarly continuous basis physical activity, sleep, apnea, and even diet, will force us to rethink our notions of preventive health. The analytic implications again are staggering, as we will have to completely reconsider the scale and scope of what we can, could, and should subject to analytic inferencing. While our goal will remain the improvement of healthcare, these changes may introduce new notions of data access and sharing, coupled with issues of intellectual property and privacy.

Ubiquitous Computing

Moore's law, which states that the cost of computing will exponentially decline while the power of computing exponentially increases, has held sway for over 40 years. We now find perfectly capable computers that would be the envy of World War II codebreakers embedded in every USB thumb drive. The power of the average cell phone dwarfs that of the entire NASA enterprise in the era of the Apollo missions. An increasing number of personal devices are incorporating more and more computing capability, together with communication and identification properties, that make the Web of Things [39] an increasingly realistic aspiration. Again, the analytic implications for data generation, preprocessing, downstream aggregation, and continuous analysis and interpretation will fundamentally transform our present, relatively limited, notions of data analytics.

Summary

Data, knowledge, and interventions remain core to the healthcare process. However, at least two of these, data and knowledge, are intertwined with analytics. One cannot generate data-driven knowledge without analytics, which is the basis for evidence-based decisions in the twenty-first century. Interventions will increasingly be determined by knowledge resources that arise from analytic activities. Thus, analytics is central to any meaningful progress in operation in the vast healthcare enterprise that makes up the largest sector of human industry in the world today. The explosive growth of data collection, the decreasing cost of storage, the exponential expansion of health-related data collection devices, and the acceleration of computing capacity all speak to fundamental changes in the way data analytics can and will contribute to the healthcare process. The methods are many; however, the principles remain few. The overarching goal will always be to learn from observation what ultimately helps or hurts in our practice of healthcare, and to predict in order to prevent circumstances injurious to persons and overall wellbeing.

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Part III
Health Information Systems

Chapter 9
Information Technology Systems

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Learning Objectives

1. Understand the difference between structured and unstructured data
2. Understand how data typically needs to be changed to fit into a database
3. Understand the ACID concept of a database
4. Cite the difference between a relational and non-relational system
5. Cite various types of network topology
6. Understand how a system architecture is represented
7. Describe a 3-tier software architecture
8. Compare compiled vs. interpreted software languages
9. List 3 software design considerations.
10. List 4 safeguards that HIPAA describes
11. List 3 types of security attacks

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Key Terms

Structured/Unstructured data, ETL, relational database, schema, entity relationship diagram, health information exchange, network topology, application programming interface, waterfall method, agile method, Structured Query Language, HIPAA.

Case Vignette

Jane is the Chief Medical Informatics Officer (CMIO) of a large healthcare system and would like her enterprise to invest in a new electronic medical record (EMR) system. She will need to make a convincing argument, and hopes to keep the technically oriented Chief Information Officer (CIO) happy by showing it will indeed scale to the requirements of an upcoming merger. She would like to justify some of the claims made in the sales-oriented, splashy presentations of the EMR companies with her own 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 companies use agile programming methodologies. One of the EMR companies is pushing a 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, she would like to go with an EMR that uses agile programming practices, a standards-based Application Programming Interface, and a relational database system.

Introduction

This chapter contains information on the fundamentals of IT in health care. Whereas Chap. 10 reviews information systems used in health care, this chapter focuses on managing the IT building blocks of informatics: data, software, and networks. The chapter presents information useful for managing data and IT systems from the clinical perspective. While the chapter attempts to be comprehensive in covering topics as broad as data, system evaluation and security, it is not exhaustive on its topics. Readers are strongly encouraged to use the references and illustrations to further their understanding.

Data and Databases

Data is the lifeblood of Health Information Technology (HIT) systems. Key objectives of HIT systems include gathering, storing, managing, sharing, and utilizing

data. In this section, we will discuss the concept of data, 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 and Their Sources

Data are raw facts about a patient, procedure, result or process; they include numbers, short phrases (e.g., POSITIVE, COUGH), codes (e.g., 4548-4), sentences (e.g., "The patient complained of diarrhea and a fever."), and long paragraphs of text. When placed into context, data provide information to support diagnosis, treatment, and health maintenance. Data generally fall into one of three broad categories:

- **Structured data**: These data make up the majority of information that are entered by clinicians and technicians into electronic health record (EHR) systems, for record-keeping and billing purposes. Structured data are stored in a variety of standard formats and terminologies (as will be discussed in Chap. 11) that can be interpreted and manipulated by computers. 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**: Data that are not stored in an easily computable format. Primarily this includes all of 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 the structured data, but they usually cannot be used directly in a computable environment such as a decision support system. Natural language processing [1] (NLP) is a way to extract computable meaning from this text. However, due to the many variations of both how things can be said in human languages and how text is structured, NLP is currently fraught with difficulty and is prone to errors.

  Examples of unstructured data: clinical notes, financial and legal documents.
- "**Big**" **data**: An emerging category that includes a combination of structured and unstructured data, but distinguished because it is difficult to process [2]. The reason these data may be so difficult is they may either require an extremely

large storage footprint (like images or genomics from next-generation machines), or they may be so extraordinary complex that it take 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 that is working its way into medical records.

Examples of "big" data: radiological images, genomic, and exomic data.

Data are created using EHR systems as clinicians document their work; and data can be imported from an EHR or a component system (e.g., laboratory module). Data can also originate outside an EHR system, which include both patient-reported data and community information as elaborated in Chaps. 19 and 20. Patient-reported data are being used both to reconcile the medical record with patient experiences and to collect subjective information on patient perception of disease burden. Community information is becoming more important as medical data are used for population and public health. Understanding local health policy, regional socioeconomic statuses, and environmental conditions at home as well as work are becoming important for addressing the social determinants of health beyond acute illness.

Interoperability: Mapping and ETL

Data are stored in many different systems throughout a hospital or health system. In order 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 the Health Level Seven (HL7) standards body. 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 11 discusses interoperability in more detail, so 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 the available programming interfaces. The biggest stumbling block in this step is to understand what data reside where and what they mean. 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. Or, diagnosis codes which represent billing diagnosis might not represent the actual diseases with which the patient is suffering. 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 a variety of proprietary formats, it is necessary to bring all of these formats into alignment so that the data can be analyzed together. This task, known as data mapping, is often quite complex and discussed at length in Chap. 11.

Table 9.1 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

- **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 are in transit or being processed, structured data are 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 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 many find it 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 separate line. A simple example of information all three formats is below.

A sample data structure representing a patient's weight at an encounter is presented as XML, JSON, and CSV in Table 9.1.

Storing Data (Databases)

In enterprise systems, data are stored in databases. A database is a collection of tables. A table is a collection of data organized in rows and columns. Most people are familiar with tables from using a spreadsheet program, such as Microsoft Excel®. In a table, rows represent individual records (e.g., a patient) whereas columns represent attributes of each record (e.g., name, weight, gender). A table is usually a

collection of related records, such as all patients seen in the clinic or all tests performed in the lab. Databases are generally collections of tables that have relationships. For example, a database may contain a Patient table and a Problem List table. Whereas each row of the table represents one patient, the Problem List table may contain multiple problems for a patient but entered over time on different dates. Databases organize as well as manage (e.g., control access, facilitate updates) the tables, attributes, and the relationships among the data, attributes, and tables.

Relational Databases

The gold standard for database storage is the relational database [5]. These are also known as SQL databases because database programming is done in the Structured Query Language (SQL). SQL 92, the version of the language that was released in 1992, is a standard across most database systems. Many changes have been made to the standard language since then, but there is incompatibility across database platforms concerning features introduced since SQL 92. Therefore, database programmers tend to become an expert 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 but, beyond SQL 92, they implement these features in very different ways. A popular open source database used in smaller health IT projects (such as for research systems) is Postgres, which offers many of the same features as the commercial equivalents but without the same level of support or guarantee of functionality.

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 in such a way that information is not duplicated across tables. This is known as normalizing the data [6]. 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. In order to determine how many encounters occurred in 2014 with patients who were 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 usually referred to as the **primary key** (the column of the primary table to be joined) and the **foreign key** (the column of the secondary table to be joined). In the above example of the patient and encounter table, both

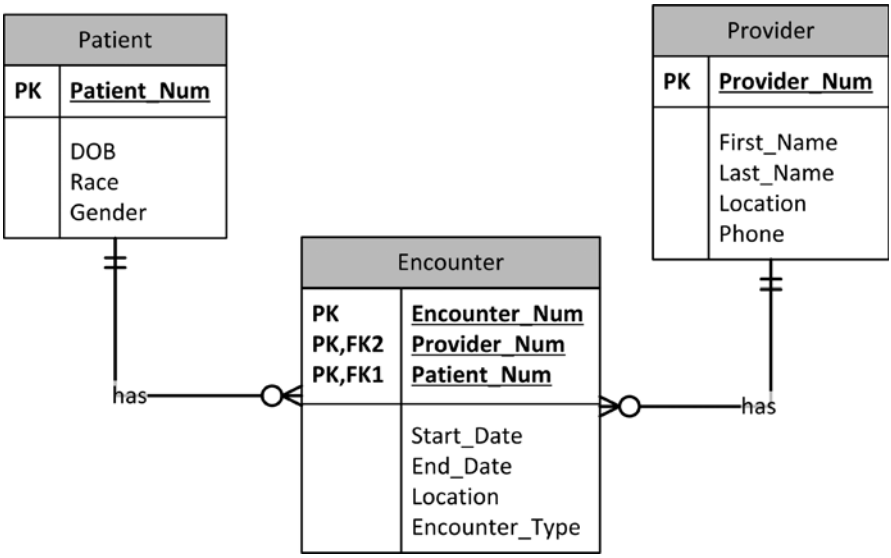

Fig. 9.1 Entity relationship diagram for a simple database schema. Datatypes omitted for readability

tables would include some type of patient identifier. More technical details of SQL joins can be found in the section "Programming".

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 datatypes. Usually the keys of the table are demarcated by boldfacing or otherwise highlighting them. Lines are drawn between boxes in which 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 (under the assumption that a patient can have only one provider per encounter). A variety of schemes for annotating the relationship exist. An ERD diagram based on this discussion that uses the popular "crow's foot" annotation method is shown in Fig. 9.1.

Structuring a database schema and normalizing the tables 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, though third normal form is the level of normalization proposed by relational database pioneer EF Codd and is the general standard for minimizing data repetition. 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 for e.g., gender, race, and ethnicity), but if the available data could change dramatically over time, it is often better to use an entity attribute value (EAV) format, which is a special way of normalizing the data that provides great flexibility for schema changes [7]. 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), and 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. 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. Most common are the star schema and the snowflake schema prototypes, 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 NIH-funded i2b2 database framework for clinical data warehousing, which is free and in use at over 100 sites nationwide, uses a star schema format [8].

Database Integrity and Performance

Because databases are often accessed by many systems simultaneously, it is critical that no two systems modify the database at the same time. Furthermore, databases must be resilient to failures (such as of 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 actually running transactions consecutively, but 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 it means that database changes cannot be stored only in memory (which has a much faster access time), even temporarily.

Columns on tables can be indexed, which speeds up searches significantly. Defining indices is highly dependent on the intended application, and it relies on the database's query optimizer, which maximizes the performance of index use.

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. Popular NoSQL approaches include:

- **Massachusetts General Hospital Utility Multi-Programming System** (**MUMPS**): MUMPS is of particular importance to the clinical informatics community [9]. This is a database format developed in the 1970s at the Massachusetts General Hospital, prior to the existence of relational databases. It is still widely used in clinical 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)" 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 in the same way as SQL and use a more traditional language for user interaction (see the section "Programming"). MUMPS is also known as M or Caché®, the name of the most popular MUMPS implementation.
- **MapReduce databases**: MapReduce is an algorithm developed by Google that allows optimized querying in "massively parallel" environments [10], where hundreds of computers execute portions of queries simultaneously. Each query is split into many small subtasks. When the hardware is available, the ability to parallelize complex computing tasks into inexpensive computing nodes is very appealing. Hadoop is a popular open source MapReduce database.
- **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 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. In this example this is only a performance issue, but in practice the linearity of relationships can be quite confining. On the other hand, the performance is very good if the schema fits these constraints.

Examples of NoSQL Databases: FlockDB (a graph database used by Twitter), MongoDB and CouchDB, and Hadoop (MapReduce Document databases), Caché® (a widely-used MUMPS database). Most NoSQL databases are open source but many provide recovery and support contracts for commercial use.

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 data on individual patients for review by their caregivers [11]. 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). Newer systems can search within a patient chart to find particular keywords in unstructured data, or they can draft a patient note for a visit based on the structured data entered for that visit. Many other innovations continue to emerge. Although fully homegrown Health Information Systems are becoming less common, recent government initiatives are encouraging open standards for integrating smaller, single-purpose "apps" with Health Information Systems [12, 13].

Data Warehouses

Data warehouses are increasingly used within hospital systems for uses such as 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 are refreshed anywhere from a weekly to an annual basis, depending on the applications for the warehouse and the amount of data.

Health Information Exchange

Various initiatives to share information across health systems are collectively dubbed "health information exchange" or HIE. Some types of HIE include:

- **Transferring a single patient's records** to a new hospital system. An example is the Direct project from the Office of the National Coordinator for Health Information Technology [14].
- **Aggregating patient data across hospital systems**. These central repositories gather thousands of patients' data from many hospital systems so that a single query can find the patient's history at all of the member hospitals. These are sometimes called RHIOs (Regional Health Information Organizations). One of the oldest and largest RHIOs is 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 [15].
- **Sending questions to the data**. A newer modality of health information exchange involves "bringing the questions to the data," or distributing queries to health systems and only aggregating the results. This provides a variety of privacy and security improvements over aggregating, at the expense of performance. Many new government initiatives take this approach, such as Query Health [16], PCORnet [17], and the NIH ACT network.

Knowledge Discovery and Data Mining (KDDM)

KDDM refers to the use of statistical methods on data to discover information that is not intuitively obvious upon inspection [18]. In practice, much preliminary knowledge discovery occurs through simple searches through aggregated patient data (such as chart searches or "cohort finding queries" on data warehouses), but KDDM can also be much more complex [19]. 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 [20]. Classification algorithms are known as supervised learning, because the correct outcome is known and can be used to train the parameters of the algorithms. Such algorithms are usually trained on a training set of data, meaning that the exact statistical model used is developed from a set of data where the true positives are known. The accuracy of these algorithms is then evaluated by the behavior of the algorithm on a test set, where the true positives are unknown.

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. For algorithms where sensitivity can be varied, the output of the algorithm is often presented as a Receiver

Operator Curve (ROC), with sensitivity plotted against 1-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 are recommendation algorithms, which are used in consumer e-commerce platforms such as Netflix and Amazon to suggest purchases to customers based on the previous purchase history [21]. This type of algorithm has been used e.g., to generate drafts of decision support and suggest ontological relationships among data elements in standardized vocabularies [22, 23].

The data format required for KDDM is somewhat different than data transport or storage. Where 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.

Networks and Network Architecture

In this section we will discuss the ways that 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 a variety of physical media, including copper wire, fiber optic cable and wireless radio transmission. Networks convey a variety of 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 each other in support of 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 to each other. In network topology, computer systems are visualized as nodes on a graph 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, in which 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, in which a backbone circles around to connect its ends together 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 together. An enterprise network is likely a hybrid.

In a hybrid topology, the constituent network segments connect to each other via specialized network devices. Network devices may boost the physical signal to allow networks to extend over longer distances.

7-Layer Network Model

Another way to think about networks is by looking at the way 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 9.2 shows the network layers of the 7-layer Open Systems Interconnection (OSI) network model [24] of the International Standards Organization (ISO).

Firewalls are a special case in that they are security devices that operate at multiple network layers. The firewall passes approved network packets and blocks

Table 9.2 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.

unapproved or suspicious network packets, in accordance with a list of approved network addresses, application port numbers and network protocols. They may also scan network traffic for known viruses or for 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).

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. In order for the network to correctly route and reassemble the packets at the destination, a packet header of routing information is added to each data packet. Therefore, the actual number of bits transferred increases by some amount, typically in the 5 % to 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 to the target audience. The most common of these are network topology, application structure, 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 types of architectural diagrams is key to communicating with IT professionals.

Figure 9.2 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 to each other with a (Layer 2) switch at the Clinic

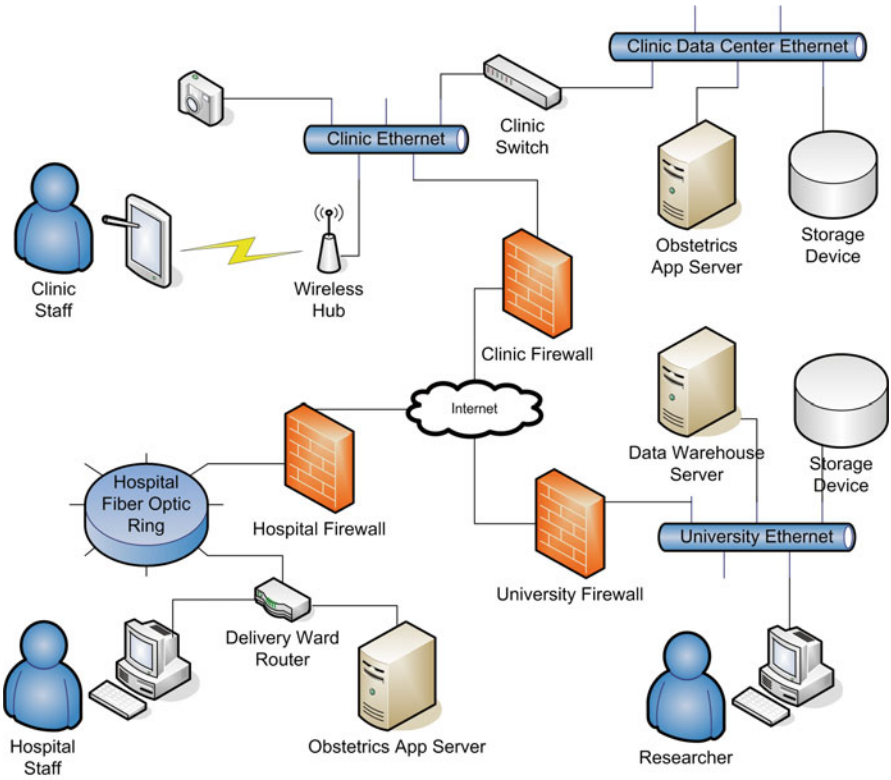

Fig. 9.2 Network architecture diagram of sample obstetrics system

- 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).

In Fig. 9.3, a UML Activity Diagram shows how the application logic works at Layer 7. The major features of the UML Activity Diagram are:

- swimlanes, the vertical boxes that group together the activities according to who and where the actor is (Clinic Provider, Obstetrics Application, Hospital Provider, Data Warehouse or University Researcher).
- Processes are represented as boxes with rounded corners, data stores as boxes with less rounded corners
- Flow of control is represented as solid arrows
- Flow of data is represented as dashed arrows
- Split and join operations on the flow of control are shown as dark bars. In our system this occurs where clinic provider performs the sonogram and note & observation entry.

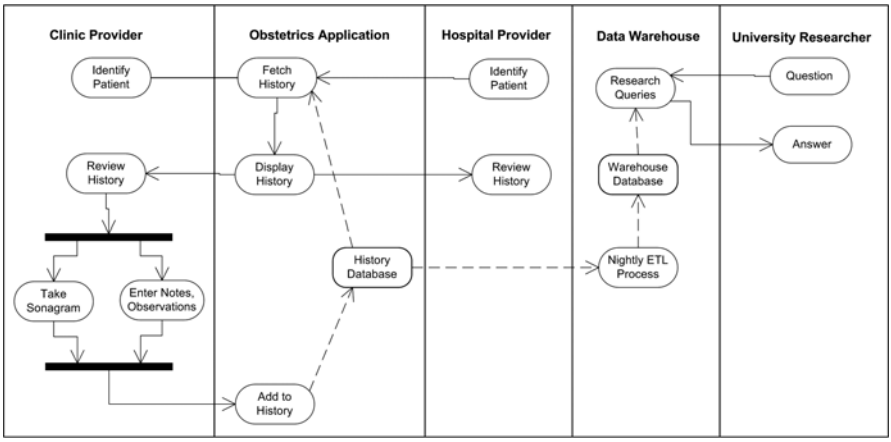

Fig. 9.3 UML activity diagram of sample obstetrics system

UML stands for Unified Modeling Language, which Grady Booch, Ivar Jacobson and James Rumbaugh developed in the mid 1990s [25]. In 2000, the ISO adopted UML as a software design standard. An activity diagram is only one type of diagram in the UML family, which includes many other types of 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 the flow of data from one process to another. The Data Flow Diagram in Fig. 9.4 shows:

- A starting point at a double circle
- Every line is labeled with the data elements in motion
- 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. 9.5, 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 users of the system, 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.

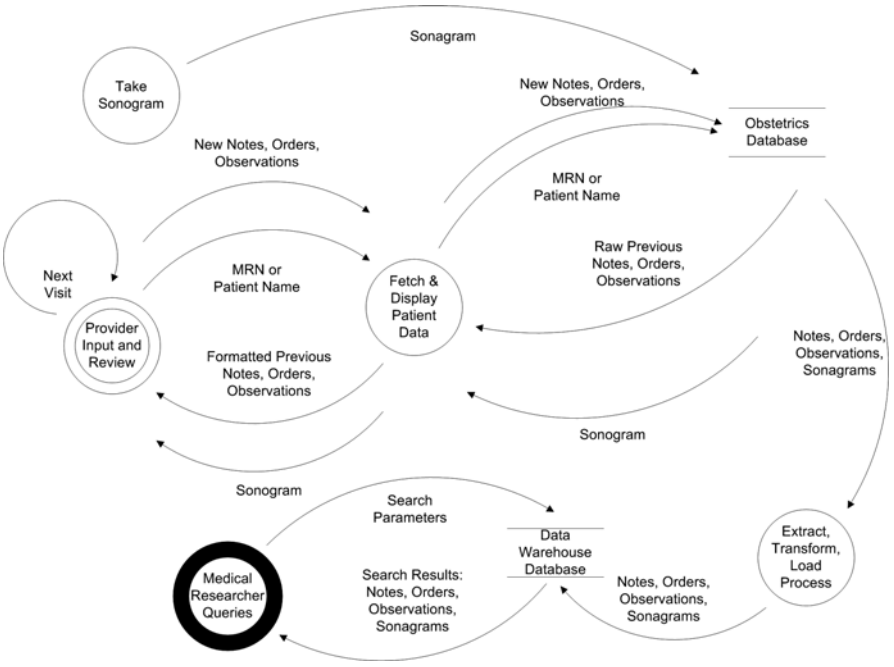

Fig. 9.4 Dataflow diagram of sample obstetrics system

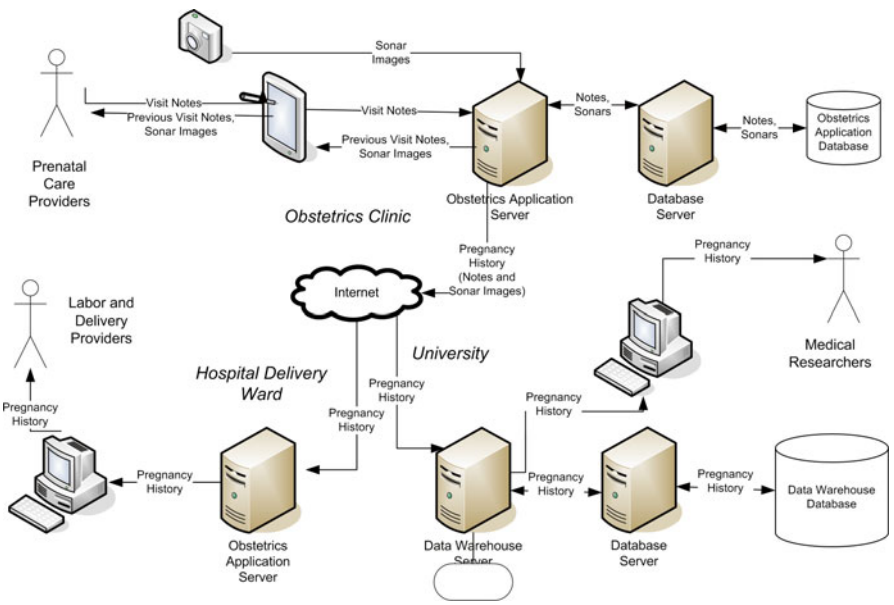

Fig. 9.5 Enterprise architecture diagram of sample obstetrics system

- 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 3-tier architecture is common: (1) user interface 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, for example a web browser, then we call it a thin-client application. If some or all of the application logic is loaded onto the front-end PC, then we call it a thick-client application. If the application resides on multiple servers, then it is called a distributed application, and similarly, 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 maintenance 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 the cost of a system.

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 is often no longer the case. Virtual servers, or to be more precise 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 the twenty-first century, even with inexpensive PCs. Grid computing extends the parallel computing notion to groups of physical servers, such as all of the PCs in a building or all of the servers in a data center. Some types of applications can leverage parallel or grid computing to speed themselves up many times, 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 the 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) [26]. Some common frameworks for general-purpose SOAs include SOAP (Simple Object Access Protocol) [26], REST (REpresentational State Transfer) [27, 28], CORBA (Common Object Request Broker Architecture) [29] and ICE (Internet Communications Engine) [30] .

In addition to the general-purpose frameworks, a number of interface standards are specific to the exchange of medical information. These include HL7, CDA and CCD, and FHIR message protocols and ICD10, LOINC and RXNORM terminologies. (For more information on these, see Chap. 11, Clinical Data Exchange, System Integration, and Standards.)

Software, Computer Languages and Programming

The software is the command center that controls the components in the system architecture. Like spoken language, software can be written in a variety of programming languages. These vastly differ from one another. Most programming languages are extensively documented online. Here we will cover the most important approaches from the perspective of clinical informatics, with a focus on data.

Data Types

In programming languages, data are stored in variables. Variables are holding cells for data that varies as a program executes. In relational databases, data are also stored in cells in database tables. In MUMPS, this distinction 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 type of data that can be stored. Languages can be strongly typed or weakly typed, depending on the degree of computer verification that variables match their defined data type. Weakly typed languages, which do not enforce such checks, are harder to debug and run less efficiently, but 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, these columns 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 3-tier architecture. In, for example, an Electronic Health Record system, the software development component provides the user interface and control structure that guides the functionality of the system. 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 is an implementation of set theory to ask questions of 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. To answer questions involving multiple tables, we would use a join with a common column between the tables known as a "key". 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.

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 might 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 a variety of 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 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 language which also improves upon Java and is used for web applications using the "Ruby on Rails" framework.

Procedural programming is more straightforward in that 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 of the popular languages that support procedural programming also support some type of object-oriented programming. Procedural languages are particularly popular as scripting languages. Scripts are short programs that control the functionality of other computer programs, most frequently web pages. Popular procedural languages that also support object-oriented programming and are widely used for scripting include Python and PHP.

A notable exception is the language C, which is a procedural language that does not support object-oriented programming and is also not well suited to scripting. Rather, 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 high complexity), it is still widely used today.

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 because the primary motif is set theory, control structures are not a central component of the language. 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 of 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 perform an operation 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 the way specific features in the language are implemented. For example, Jython, a version of the language Python that runs in the Java virtual machine, is generally slower than the interpreted language Python.

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. Software code that is self-contained can be distributed in "libraries" that can be used by other software developers. Thousands of these libraries exist for any given language; they provide 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 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. A good 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 becomes very important. Performance of computer algorithms can be determined mathematically through complexity analysis. Practical performance of a 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 often the final product is either: not what was envisioned by those providing the requirements, or the requirements change 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, 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 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 [31]. Agile methodologies use the same approach as the spiral method (shifting between iterations and planning phases), but 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 **sprints**, short cycles (typically 30 days or less) which begin with planning and requirements gathering and end with a new release of the product. The sprints are not defined prior to the sprint's beginning, which makes this approach very resilient to changing needs. All of 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. To build software with quality from the outset, popular methods include: pair programming, code reviews, and software documentation prior to writing the code [31]. 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 create **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, in order 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 compare the software to what it was designed to do, and may be performed by the software developers or by dedicated testers. Software validation testing is performed by the end users and requirements gatherers, and makes sure that the software performs the function that it was originally intended to. 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 [32]. However, the code might still be copyrighted and might have restrictions on how it can be changed or used. There are dozens of open source licenses that define exactly how program code 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 and some languages, such as Java, can be run on multiple computer platforms. Generally, however, 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 system 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, but the principles embedded in these regulations are good security practices for any type of data.

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 breaches of e-PHI security and with additional rights for patients to view and limit access to their own data. Many states have additional patient privacy regulations.

Here is the core of the Security Rule:

The HIPAA Security Rule [33] 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 smart phones 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 that are 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. These various roles are managed by network level software that maintains which roles receive which set of authorizations.

(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 it is transmitted over a network. Encryption of the data is a must, either by using a VPN (Virtual Private Network) or a point-to-point protocol such as SSL (Secure Sockets Layer), in which 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.

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 determine 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 that are exchanging data. The system in the middle acts as 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 up 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 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 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. A 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.

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. This allows organizations to share deidentifed data sets for research purposes, and a number of consortia are doing just that, for example the Shared Health Research Information Network (SHRINE) [34].

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 for 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" [35].

Emerging Trends

As this chapter is being written, three emerging technologies worth noting include:

- NoSQL databases are considered to be cheap, scalable solutions that will become highly competitive with relational databases that are currently the mainstays of data analytics. Although that destination is premature, it clearly will open up 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 up the user interface of the EHR system to novel ways of presenting data and providing decision support. The concept of a marketplace would allow Apps to be bought and sold to accommodate niche needs throughout the system by a large workforce of developers.
- Sensors or wearable devices on the body (e.g., Fitbit, Apple Watch) are collecting massive amounts of data. The ability to sift through the data to extract insights will define much of the way that we view physiology in the future.

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.

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Chapter 10
Health Information Systems and Applications

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Learning Objectives

- Describe the four key functions of a health information system
- Understand the difference between patient-specific and knowledge-based data
- Give examples of clinical versus administrative data
- Identify advantages and disadvantages of structured versus unstructured data
- Identify common applications of health information systems
- Describe some challenges of implementing widespread Telehealth technologies

Core Content

Health Information Systems and Applications

- Types of functions offered by systems
- Types of settings where systems are used
- Electronic health/medical records systems as the foundational tool
- Telemedicine

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Key Terms

- Electronic Health Record
- Electronic Medical Record
- Health Information Systems
- Hospital Information Systems
- Knowledge Based Systems
- Personal Health Record
- Structured Data
- Telehealth Systems
- Telemedicine
- Unstructured Data

Clinical Vignette

A patient is hospitalized for new onset diabetic ketoacidosis. Upon discharge, the hospitalist sends a summary of the patient's hospital encounter to the patient's primary care physician (PCP). The patient calls the PCP's office to make an appointment. The office staff collects the patient's demographic and billing information and enters it into the electronic medical record (EMR). The patient goes to their appointment with the PCP who documents the visit in an EMR and orders a new medication. While using the EMR the PCP sees an alert that reminds them to check renal function and as a result orders the appropriate laboratory tests. After a week, the PCP has a virtual visit with the patient. The PCP asks the patient how they are tolerating the medication changes and reviews the results of the lab tests.

Introduction

This chapter explores the concept of a health information system and the components that comprise it. The term 'health information system' means many things to many stakeholders; where a critical care nurse may consider the system to be an order entry and documentation application, a financial analyst may consider the system to be a series of codes and interactions with other financial systems. First, there will be a consideration of the perspectives of these systems – who are the users of health information systems? What must the system accomplish in order to fulfill their needs? How does that impact the type and use of data? With these perspectives considered this chapter will review the applications that together comprise a health information system, including personal health records (PHRs), hospital information systems, telemedicine and telehealth systems.

Perspectives of Health Information Systems

In 2008, the World Health Organization set out the following definition of a health information system. "The health information system provides the underpinnings for decision-making and has four key functions: data generation, compilation, analysis and synthesis, and communication and use. The health information system collects data from the health sector and other relevant sectors, analyses the data and ensures their overall quality, relevance and timeliness, and converts data into information for health-related decision-making [1]".

The clinical vignette illustrates some of the stakeholders in health interactions: the patient, the hospitalist, the primary care physician, and office staff. Applying the key functions of the definition above, consider the viewpoint of each of these stakeholders. What role does the patient have in data generation? From a clinician's perspective, the patient is the source of the majority of information. He or she relates the history that the clinician captures, and it is their examination that the clinician performs. The patient may have a role in compiling data as well, such as retrieving the results of previous laboratory or imaging studies for analysis; and may also have a role in analyzing their data. Radermacher et al. have stipulated that a patient's preferences are weighed in conjunction with scientific evidence, a clinician's experience and judgment, and clinical circumstances to comprise the process of clinical decision making [2]. Finally, the patient has an integral role in the use of the clinical information, for ultimately it is their behavior that may need to change for the entire interaction to be successful.

Consideration of other perspectives are left as an exercise for the student but offer one additional consideration – the stakeholders listed above are a fraction of the total stakeholders of the health information system. Consider a hospital system and many others are identified: imaging technicians, physical therapists, speech and language pathologists, consulting physicians, health information management personnel, revenue cycle personnel, and administrators are examples. The complexity is compounded when one considers the various settings where each of these stakeholders may use a health information system. The needs of a nurse in an ambulatory clinic vary from those working in a surgical center, an emergency room, or a psychiatric unit. For a health information system to be successful, it must support at least these four key functions for all of its stakeholders.

Information Perspective

In the consideration of a health information system it is useful to divide data into two categories – that which relates to a particular individual patient and that which does not. The first set of data is defined as patient-specific information. The latter set can be construed as data derived from other sources of knowledge, be it a categorization of all known medical diagnoses or a list of postal codes in a given region.

Summarily, the second set of data is termed knowledge-based information. Knowledge-based information may apply to one or many patients. Take the example of a medication in a health information system. Information available on the medication itself in the system may include its name, any aliases, common prescription information such as dosages and frequencies, and perhaps even availability or cost. Many patients may be taking the same medication, but each patient has their own prescription for the medication with the dosage and frequency specific to them. This concept of patient-specific information versus knowledge-based information is reflected in the design of most medical record systems. In general, there will be a database of all known or relevant medications stored in a single location, with applicable pointers placed in the charts of all patients who are prescribed one of these medications.

Functional Perspective

The consideration of the information stored in a health information system is aided by another distinction – the intended use of the data. Clinical data can be defined as data collected with the intent of driving medical care. A clinician's examination findings, laboratory results, diagnostic imaging reports, and recordings of vital signs are all examples of clinical data. The volume of clinical data changes based on the context of the encounter: while a single set of vital signs may suffice for an entire outpatient encounter, such data may be recorded once a minute or more frequently in critical care settings. In contrast, we can consider administrative data to be that which is collected to support managerial functions. Examples of these functions may be seen in Table. 10.1.

The distinction between these two types of data is not always clear. For example, clinicians may capture a patient's weight at each visit to drive decision making regarding diet and exercise counseling; but a municipality might reuse aggregate measures of weights to drive decision making around where to create additional public recreation spaces. As reuse of clinical data increases, there has been increasing pressure on clinicians to capture data that may not be needed for the individual patient sitting in front of the clinician. For example, under the Meaningful Use program from the U.S. Centers for Medicare and Medicaid Services (CMS) that incentivizes the adoption and use of health information systems, surgeons are required to capture a patient's height during a postoperative surgical follow up visit,

Table. 10.1 Common managerial functions

Utilization review
Coding analysis
Clinical research
Public health registries
Quality initiatives
Vital statistics
Data warehouses

despite it having no clinical significance [3]. Another example is the recent recommendations from the Institute of Medicine that health care providers use information systems to capture data on the social determinants of health, including occupational, educational, and socioeconomic information on patients [4].

Composition of Data

A third distinction useful in the consideration of data stored in any information system is how that data is stored. Structured information is that which is stored as discrete data points such as gender, age, name, items in a review of systems, physical exam, and so forth. Unstructured data is information that is stored in aggregate. A common clinical example is free-text narratives, such as a clinician's record of a patient's presenting history, the 'history of present illness'; or their intentions in the management of a patient's health, the 'assessment and plan'. Structured data is generally much more easily used and reused but comes at the cost of increased cognitive burden in its capture.

Returning to our previous example of a medication prescription. To complete this in a structured system, a clinician might have to:

(a) Search for and select the correct medication;
(b) Enter the dosage desired;
(c) Enter the frequency desired; and
(d) Enter any specific patient instructions or parameters.

This can be contrasted with free text writing 'metoprolol 25 mg PO qday for HTN'. While this unstructured example takes advantage of several shorthands common in clinical practice, it is done for illustrative purposes. Consider now a desire to search for a cohort of patients who have an active prescription for hypertension. In a system of structured data elements, one could simply query the clinical parameters field for diagnoses relevant to hypertension. In a system of unstructured data elements, this analysis would require either manual chart abstraction or complex analytical approaches.

It should be noted that both structured and unstructured data are the foci of active research in informatics. Natural language processing aims to use machine learning algorithms to discretize unstructured data (see Chap. 9). Advents in human-computer interactions aim to make clinically relevant forms available in convenient form factors at a clinician's fingertips during a clinical encounter, thus overcoming much of the cognitive burden in the capture of structured information (see Chap. 13).

Applications of Health Information Systems

When considered in sum, a Health Information System should meet the needs of all participants interacting with the system. To complete this task, systems are comprised of multiple applications working in concert. These are described below.

Electronic Health Records

There has been some debate as to the distinction between electronic health records (EHRs) and EMRs. For the purposes of this chapter the definitions of the United States Office of National Coordinator for Health Information Technology are used. They state: *An EMR contains the standard medical and clinical data gathered in one provider's office. Electronic health records (EHRs) go beyond the data collected in the provider's office and include a more comprehensive patient history* [5]. In other words, an EMR contains all functionality necessary for a provider to store and retrieve their own information about a patient. An EHR expands this by incorporating and contributing to external data sources.

As the healthcare landscape has evolved in the United States over the past several decades, so too has its EHRs. Originally, medical records in the United States were developed as tools for a single department or use – repositories of patient demographics, laboratory information systems, and so on. With the advent of initiatives such as Patient Centered Medical Homes, EHRs are expanding to take on multiple roles. The most recent certification criteria for EHRs in the United States, the ONC 2014 Edition EHR Certification Criteria [6], postulates that an EHR may be comprised of one or more systems that in concert offer a set of functionality.

Core Functions of the Electronic Health Record

The Institute of Medicine defines the eight core functionalities of an EHR [7] as:

- Health information and data
- Result management
- Order management
- Decision support
- Electronic communication and connectivity
- Patient support
- Administrative processes and reporting
- Reporting and population health.

Health Information and Data Storage – Health information and data storage is an EHR's fundamental capability to store the clinical data regarding a patient's health care. Medical and nursing diagnoses, a medication list, allergies, demographics, clinical narratives, and laboratory test results are examples of data points that can be considered in the set relevant to an EHR.

Results Management – Results Management is an EHR's capability to store data gleaned from clinical procedures. Laboratory studies, radiographic investigations, and consultation reports are examples of such.

Order Management – Order Management and Order Entry are terms used to describe an EHR's capability to capture and facilitate clinical directives in the context of the provision of health care. A common variant is an order entry method that

directly captures medical orders from providers; this is known as 'computerized provider order entry' or CPOE.

Decision Support – An EHR's capability to aid clinical judgment is Decision Support. Decision support may be context-specific, such as procedure specific documentation templates or drug-drug interaction alerts; or not, such as antibiograms.

Electronic Communication and Connectivity – EHRs may support direct exchange of data with end users (Electronic Communication) or other systems (Electronic Connectivity). For more details on Electronic Connectivity (see Chap. 11). Common examples of electronic communication include electronic mail or web interfaces.

Patient Support – Any process by which an EHR directly interacts with a patient to support the provision of care can be considered Patient Support. Examples include appointment and medication reminders.

Administrative Processes and Reporting – EHRs may support administrative processes such as appointment scheduling or billing. They may also generate reports that facilitate the administration of health care, such as service utilization rates.

Reporting and Population Health – EHRs may have capabilities to support the management of the health of a population. Examples include a report of a provider's patients that meet a standard of care, or contribution to a health department's disease registry.

EHRs may offer additional tools to augment one or more of the core functions described above. Some examples:

- The ability to verify a medication is being administered to the right patient at the right time can be augmented by real-time scanning of a barcode.
- Specialized communication functions may exist for creating and dispersing on-call schedules and patient handoff reports.
- Dashboards may collect and present quality metrics using a method with a lower cognitive burden for clinicians.
- Billing modules may collate and communicate subsets of clinical information to external stakeholders and systems.

The Healthcare Information and Management Systems Society (HIMSS) has developed a model for tracking progress of implementing various functions of a health information systems at a given health care institution (See Table. 10.2) [8]. The model consists of eight stages numbered zero to seven, beginning with implementation of laboratory, radiology, and pharmacy information systems and culminating with advanced communications between health information systems.

Two functions of the health information system have been the subject of more intense research – Health Information and Data Storage, and Order Management. This focus may be due to the greater proportion of time health care providers tend to spend on these functions. As a result, we too shall examine these in greater detail.

Recall from the earlier discussion that data stored in an information system may be captured in either structured or unstructured format. These same principles apply to the capture of health information. A physician may use a specific template to capture the results of an endoscopic examination and then dictate an operative

Table. 10.2 HIMSS EMR adoption model

Stage	Cumulative capabilities
Stage 0	Some automation. Laboratory, Radiology, Pharmacy Ancillaries not all installed.
Stage 1	Laboratory, Radiology, Pharmacy Ancillaries all installed.
Stage 2	Central Data Repository; Controlled Medical Vocabulary; Clinical Decision Support (CDS); may have document imaging; may have health information exchange capabilities.
Stage 3	Nursing/clinical documentation; CDS with error checking; Picture archiving and communication system (PACS) available outside of radiology.
Stage 4	Computerized provider entry; CDS with clinical protocols.
Stage 5	Closed looped medication administration.
Stage 6	Physician documentation; CDS with variance and compliance capability; full radiology PACS systems.
Stage 7	Full electronic medical record; clinical care document transactions to share data; data warehousing; data continuity with emergency departments, ambulatory and outpatient areas.

Adapted from [8] with permission from HIMSS Analytics

report of the same procedure. Regardless of method, Rosenbloom et al. [9] noted that four factors influence satisfaction with electronic documentation tools: efficiency, availability/accessibility, expressivity, and quality.

There are ongoing issues with electronic clinical documentation such as increased time spent by providers entering clinical data for documentation. Where before providers may have spent around 4 min documenting on paper, they spend upwards of 15 documenting electronically. The notes on paper were concise and now, they may contain many pages of laboratory data, diagnostic imaging reports and detailed dispensing instructions for medication lists. This extraneous data makes electronic clinical documentation difficult to understand. Electronic clinical documentation also introduces the issue of copying and pasting where sections of notes are copied and pasted from one day to the next. The risk of copying and pasting clinical data is that it may be incorrect or internally inconsistent within the note thereby making the clinical note difficult to understand. Because electronic clinical documentation can be bogged down with extra data, clinical notes are difficult to read and in many cases, not read at all. Information that is captured in clinical documentation not only serves to convey clinical meaning between providers, it also is being reused for other purposes including billing/insurance purposes, compliance, quality initiatives and public health. Front line providers are burdened with entering data into clinical encounters that they would not have done previously because of this secondary reuse of data [10].

New errors arise in electronic clinical documentation including documenting on the wrong patient or on the wrong encounter (documenting on an office visit when the patient is hospitalized), failing to save a note and the note is lost, notes that are labeled as the wrong note type (History and Physical labeled as a Progress Note).

Correcting these types of documentation errors is more challenging in the digital age than it was on paper [11].

The fidelity of data stored in health information systems has been of particular concern, especially as providers may incorrectly use tools such as 'Copy and Paste' to meet documentation requirements. In 2003, Hammond et al. [12] presented findings from the US Department of Veterans Affairs analysis of the prevalence of copying and pasting in progress notes. They created a severity scale ranging from 1–6, where one was of no risk and six of major risk. In their analysis, they noted that 9 % of notes studied contained copied or duplicated text, while one in ten electronic charts contained an instance of high risk copying.

Perhaps no function of the health information system has been as heavily researched as computerized provider order entry. Studies such as Bates et al. [13] have found that CPOE reduces errors, but others such as Han et al. [14] found an increase in mortality after implementing such systems. Both studies have undergone subsequent re-analysis and reinterpretation. In 2003, Payne et al. [15] presented the rationale for order sets – compilations of orders commonly generated as part of a single workflow. The rationale presented suggests that order sets reduce time to enter orders, reduces errors and increase accuracy, increase completeness, and provide a platform to enforce decision support and application of best practices. However he found that at 6 months after creation of order sets, only 13 % had been used. Ash et al. [16] conducted a telephone survey in 2007 to assess the extent of unintended consequences of CPOE workflows. The survey suggests that implementation of CPOE may alter the underlying workflow of order management with new issues specific to these new workflows.

Derivative Systems of an EHR

As previously discussed, the health information system may be comprised of one or more systems acting in concert to provide a spectrum of functions. While the EHR is a common source of data in the health information system, the analysis of that data and presentation of subsequently generated information is not limited to the EHR. One or more derivative systems may exist, which can be defined as those systems that extract information from an EHR for the purpose of subsequent analysis and information synthesis. Such systems need not draw from the EHR alone, they may draw from data warehouses, which are central repositories of integrated data from one or more disparate sources. Such warehouses may include quality survey data or billing data and allow for analysis not possible with a single information source. One example of this was the Observational Medical Outcomes Partnership, as described by Stang et al. [17] Other systems exist that draw information from multiple health information systems. Registries, or collections of information about individuals usually focused around a specific disease or condition, are an example of this type of system [18].

Practice Management Systems

In the 1980s and 1990s, healthcare providers would generally install a practice management system alongside an EMR. While the EMR contained all the information relevant to the provision of healthcare, practice management systems provided the functions necessary to support the business of healthcare – scheduling appointments, registering patients, submitting claims for payment, and so on. Similar to other areas of the health information system, one or more systems may act in concert to provide a practice management solution. As with the evolution of EMRs previously mentioned, practice management systems have been increasingly integrated into the health information system. Such integrations feature advantages such as a single database of patients and integrated billing workflows.

Personal Health Records

In other areas of informatics, the consumer has become increasingly involved with the information system. Demos et al. [19] cite a trend of eroding manual transactions in the United States in the context of the banking industry. While interpersonal interactions are at the heart of most healthcare workflows, many routine transactions, such as requesting medication refills, could be managed through more automated processes.

While such transactions may be supported through the provision of a patient portal, these are to be held distinct from PHRs. Patient portals provide a window for patients to directly access the EHR. Through such windows patients may accomplish functions as allowed by the healthcare institution, and may include refill and appointment requests. In contrast, PHRs are used by patients to maintain and manage their own health information. These are currently held separate from the legal record of health care providers in the United States. Just as with other aspects of the health information system, PHRs may also incorporate data from multiple sources [20].

Hospital Information Systems

The needs of a hospital are specific enough that many apply the term ‘hospital information system’ to a health information system tailored to these needs. As with other health information systems, the hospital information system is often comprised of several systems working in concert to provide the necessary functions to all its stakeholders. Some of these functions are seen in Table. 10.3.

Table. 10.3 Hospital information systems

Admission, discharge, and transfer (ADT) systems	Laboratory Information System (LIS) {e.g. Sunqest, ApolloLIMS}	Nutrition and Dietary Management Systems
Patient registration systems	Radiology Information System (RIS) {e.g. GE Centricity PACS, McKesson Horizon Medical Imaging}	Specialized systems for common procedures (such as pulmonary function testing, echocardiography, endoscopy)
Master patient index	Picture Archiving and Communications System (PACS)	Specialized systems for medical specialties such as obstetrics, ophthalmology, dermatology, anesthesia, or oncology
Inventory/Materials and Supply Chain management {e.g. Omnicell, Pyxis}	Pharmacy Systems	Infection Control management systems
Systems to collect and report quality or administrative metrics	Anatomic Pathology Systems	Professional and Hospital billing systems

Knowledge Based Systems

Knowledge based systems are those which apply previously compiled information to solve complex problems. While there are many such systems, they commonly attempt to represent knowledge explicitly, via constructs such as ontologies and rules, rather than implicitly, such as in computer code. Some examples common to health information systems include:

- Information Retrieval Systems – systems that index information available from other sources for facilitated querying and retrieval.
- Decision Support Systems – systems that analyze patterns in health data and present information intended to influence the behavior of healthcare providers (see Chap. 6).
- Question-Answering Systems – systems that allow querying, generally in natural language, and present facts pertinent to the inquiry.

Telemedicine and Telehealth Systems

Any system that facilitates the provision of healthcare where the patient and the provider are in disparate geographic locations can be considered a telemedicine or telehealth system. While the simplest modern example is telephonic systems, technology is available to include other information streams such as photographic and videographic systems, remote health monitoring systems, and more.

There are important challenges to overcome before telemedicine is widely adopted, including third-party reimbursement issues and cross-state medical licensure of providers. Given these, modern applications are generally limited to situations where it is impractical to have a direct patient-provider interaction. For example, teledermatology and remote critical care systems are being used when providers are in limited supply; remote home monitoring is being used when there are geographic or transportation-related barriers. Because of lower financial barriers and lack of need for a direct patient-provider interaction, teleradiology is currently one of the most common telemedical applications.

One example of using telehealth to replace in person care is with the work that Kaiser Permanente is doing [21]. A third party vendor provides videoconferencing capability that is integrated into Kaiser's EHR. Patients make appointments online for 20 min visits with a provider. For the appointment the patient logs into the patient portal to have a video conference visit with the provider. If the provider encounters a need that cannot be provided through the videoconference, such as listening to the lungs or checking blood pressure, the patient is referred to a care center for an in person visit.

The Veteran's Administration is an active user of telemedicine to provide primary care services to rural areas and to expand their ability to provide mental health care [22]. Patients come into the clinic to visit with their mental health provider, but also have virtual meetings in between scheduled appointments to provide ongoing support.

Summary

The nature of health IT takes on multiple definitions given the complexity and variety of stakeholders and their requirements of the system.

Questions for Discussion

- What are some of the ways that Electronic Medical Records perform Decision Support?
- What are the common functionalities of an EHR?
- What is the ideal way to capture data from providers? In a structured or an unstructured format?
- What are the ways that clinical data is used?
- Who are the various stakeholders who need the information within an EHR?

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Chapter 11
Healthcare Data Standards and Exchange

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Application Exercise

Based on the clinical vignette:

- Describe how you would identify patients from disparate health care systems to uniquely identify them. What standards would you use?
- Select three standards that you would utilize for sharing data and explain what issues might arise by utilizing these. Describe how the standards are structured.
- Determine how a message would be sent for sharing and why you would prefer a specific mechanism for delivery.
- Based on standards you selected, explain how you might advocate for a change in the standard based on your clinical needs.
- Describe the four different ways that changes are made to healthcare standards.

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Biomedical Informatics Core Competencies

1. Acquire professional perspective
2. Implement, evaluate, and refine
3. Produce solutions

Case Vignette

As a clinical informatics champion for your hospital system you are asked to develop a method for sharing the data with other healthcare institutions within your city. These data are important because many patients rotate between the various hospital systems and vital information is often lost or interventions repeated due to the limited access to the data. Are there mechanisms for sharing data? How would you identify the patients across disparate electronic health record systems? Which standards would you select for sharing, and why?

You are asked to setup a new electronic clinical information system for your practice. You will have a mix of inpatient and outpatient encounters for your practice. How do you plan to document these encounters and more importantly bill (get paid) for what you are doing? What standards are in required? How to you make sure that your special clinical needs are covered?

Introduction

Without any conscious awareness, we depend on many kinds of standards every day. Weighing yourself in the morning, plugging your plethora of gadgets into electrical outlets, getting cash from an ATM, connecting your laptop to wireless networks at work, home, and the coffee shop – these ordinary activities are almost effortless, in large part because of accepted standards. Standards are powerful enablers of technological progress anywhere that variation creates inefficiencies. Standards are shared formats or definitions that constrain the possible variations down to a normalized form or common meaning. They make it possible to communicate efficiently, swap out components, and build complicated systems out of many interacting parts [1].

Standards are important to healthcare in many areas, from the most basic scientific measurement standards to standards of clinical practice (e.g. guidelines (See Chap. 5)). Our focus in this chapter is on the role of healthcare standards (both technical and clinical) in facilitating clinical data exchange. We emphasize the standards used uniquely in healthcare, and while important, we consider more general scientific and technical standards (e.g. cryptography, network protocols (See Chap. 10)) out of scope. Specifically, we will focus on standards for specifying persons (e.g., patients, doctors), transactions (e.g., encounters, medication orders), and data (e.g., systolic blood pressure) in health care.

Health information technology has the potential to improve the quality and efficiency of care, but the success of these systems depends in part on the clinical data within their purview. Too often, clinical information systems function like "islands" or "silos" and cannot get the data when and where it is needed. A major reason for this problem is that many systems cannot communicate effectively (i.e. they are not "interoperable") with each other because they lack shared conventions for the syntax (structure) and semantics (meaning) of clinical data. Each one stores patient data elements in a different format and with different codes and names for the same concepts. The only way to efficiently move and aggregate clinical data is by adopting data exchange standards.

How Are Healthcare Data Standards Created and Maintained?

There are four common methods to create standards [2, 3]. *Ad hoc* standards are developed as people and organizations come together and agree to use a common but informally developed specification. For example, in the early days before there was a standard for describing the contents of a digital radiologic image, the American College of Radiology/National Electrical Manufacturers Association created an ad hoc method for picture archiving and communication system (PACS) images to be sent to electronic health records systems. This method eventually became known as DICOM. *De facto* standards emerge as one earns a large enough for a critical mass of adopters to make its system the standard. An example of a de facto standard is harder to find in health care, but a familiar example is the ubiquitous Microsoft Word Binary File Format (*.DOC) for word processing documents. Given the widespread utilization through the years, even outside of Microsoft software, this file format for electronic documents has become de facto standard. Government agencies or other authoritative bodies can also create standards and require (*mandate*) their use in certain contexts by fiat, a formal authorization for usage. An example of mandated standards include the U.S. Standard Certificate of Death that was required by the National Center for Health Statistics, a part of the Centers for Disease Control and Prevention (CDC). Many of the key health data standards are developed by a *consensus* process. The consensus process can be closed or open though an "open standards development policy" is preferred. The American National Standards Institute (ANSI), a private nonprofit organization, has developed a formal consensus process with open balloting and public review and an accreditation program for organizations that develop standards. Not all standards are amenable to ANSI's process. It would not be feasible nor desirable to have every new concept in a medical vocabulary voted on (with an appeal process), incorporated into a draft, etc. Most terminology standards are created by a controlled process (that varies by terminology) with expert review rather than the open ballot process required by ANSI.

The development and ongoing maintenance of a standard is typically stewarded by a Standards Development Organization (SDO) that has overall responsibility and ownership. The SDO employs a multistep process in producing standards to ensure

Table 11.1 Examples of United States Standards Development Organizations (SDOs)

SDO	Standard
ASC X12 (Accredited Standards Committee X12 (ASC X12)	Claim Benefits and Payments
ASTM (American Society for Testing and Materials)	CCR (Continuity of Care Record
National Electrical Manufacturers Association (NEMA)	DICOM
HIBCC (Health Industry Business Communication Council)	Health Industry Bar Code standard (HIBC)
IEEE (Institute of Electrical and Electronics Engineers	Medical Information Bus (IEEE 1073)
NCPDP (National Council for Prescription Drug Programs)	SCRIPT (i.e, e-prescribing standard)

quality, integrity, and input. ANSI itself is not an SDO but is an SDO accreditation organization. An example of an ANSI accredited SDO is HL7, and example of an HL7 developed standard is FHIR (Fast health Care Interoperability Resources. Another SDO that is responsible for many healthcare standards is ASTM that developed the Continuity of Care Record (CCR), a core data set relevant administrative, demographic, and clinical information facts about a patient's healthcare. IEEE (Institute of Electrical and Electronics Engineers) is an SDO and is responsible for biomedical technology in healthcare. Please see Table 11.1 for a list of example national SDOs and their affiliated standards in the United States.

What Are Information Standards Organizations and How Do They Differ from SDO's?

Information standards organizations are organizations that solely exist to foster, promulgate and the authors would argue to coordinate standards. What creates confusion is these organizations may set rules and framework for development with a different approach than SDOs. The organization employs experts to develop the standard. A further source of confusion is that these organizations may house SDOs. For example ASTM is a standards organization but housed the HL7 SDO till it be became an independent entity. Examples of standards organizations are in Table 11.2.

The Standards and Interoperability Framework organization (S& I Framework) is a collaborative community of participants from the public and private sectors who focus on ways to facilitate the functional exchange of health information, to harmonize standards related to interoperability, and to ensure these standards meet the objectives and priorities of healthcare priorities, health outcomes, and meaningful use (www.siframework.org). The S& I Framework works with SDOs as key partners to extend existing standards, or develop new ones as necessary.

Table 11.2 United States Standards Organizations

American National Standards Institute (ANSI)
Integrating the Healthcare Enterprise (IHE)
National Institute of Standards and Technology
S&I Framework
Workgroup for Electronic Data Interchange (WEDI)

International Standards Organizations

CEN (Comité Européen de Normalisation) TC 251 – Technical Committee on Health Informatics – www.cencenelec.eu/standards/Sectors/healthcare/

The European Committee for Standardization (CEN; Comité Européen de Normalisation) is a non-profit standards organization that was founded in 1961 to develop standards and specifications for both healthcare and non-healthcare related services. The work is done through multiple subcommittees. For healthcare related settings, CEN and the European Committee for Electrotechnical Standardization (CENELEC) develop standards for safety, quality and performance requirements for medical devices on the European market as well as providing interoperability of health information systems in Europe (CEN / TC 251). The organization works closely with other global organizations for optimization of the standards.

ISO – Technical Committee 215 on Health Informatics – www.iso.org/iso/iso_technical_committee?commid=54960

The International Organization for Standardization (ISO) is an international standard-setting group that has members from throughout the world and was founded in 1947. Within healthcare the ISO has a technical committee 215 that deals with health informatics. The ISO/TC 215 seeks to facilitate coherent and consistent interchange and use of health-related data. The ISO/TC 215 was started in 1998 and includes 33 countries that actively participate with 26 "observing" countries (as of 2015). They have released more than 100 reports including on personal health device communication and point-of-care medical device communication. From within the United States, the American National Standards Institute (ANSI) is the representative for the ISO.

What Is Certification?

Certification is a process in which a "neutral body" certifies that a vendor conforms and complies with the standard [3]. Neither Standard Development Organizations nor Information Standards Organizations certify that vendors are compliant with a standard. For example, HL7 does not certify vendors as compliant and this is one reason why HL7 version 2.x had such variability in vendor implementation. The Office of the National Coordinator (ONC) through the ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) coordinates testing and certification of

systems to assure the required technological capability, functionality, and security to maintain consistency across certified products. In addition, the certification process is designed to give confidence to providers and patients that certified products are secure and can work well with other systems. – *http://www.healthit.gov/policy-researchers-implementers/certification-bodies-testing-laboratories*

How Are Standards Selected and Adopted for a Particular Purpose?

Use of standards for a particular purpose may be driven by either, or both, "bottom up" and "top down" approaches. Standards may achieve significant market penetration by organic (bottom up) adoption across an industry. Many standards demonstrate the "network effect", which means they become more valuable as more people use them. If you are the only person in the world with a phone, it will not be very useful to you. But, if everyone on the planet has one, then a phone becomes a much more helpful technology. In the same way, the more data producers that can output their results in a particular standard format, the more valuable that standard becomes to data receivers. It is a virtuous cycle.

At the same time, regulations from government agencies that require use of certain standards can significantly accelerate their use. A prominent recent example of this approach is the Meaningful Use regulations in the United States, which provides incentives to hospitals and providers who use certified EHR technology. The EHR certification process requires use of designated standards for enabling technical and semantic interoperability so that health information can be efficiently and securely exchanged across care settings [4]. There is evidence that this approach is beginning to bear fruit. A recent ONC report to Congress [5] noted that more than six in ten hospitals electronically exchanged patients' health data with providers outside their organization, an increase of more than 50% since 2008. However, even with this improvement in transportability of patient data, there is substantial work to be done as a study showed only 14 % of providers sharing data with providers outside their organization from 2009 to 13 [6].

Many factors can contribute to the selection of a standard for a particular use case. Cost, fitness for the intended purpose, ease of implementation, and many other factors could all be important determinants. In the U.S., the HIT Standards Committee is a federal advisory committee charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. As one example of a formal selection process, the HIT Standards Committee developed a set of six criteria [7] based on maturity and ease of implementation and adoption:

1. Maturity of the specification
2. Maturity of the underlying technology components
3. Market adoption

4. Ease of implementation and deployment
5. Ease of operations
6. Intellectual property

Patient Identifier Standards

Anyone who has worked in a clinical setting recognizes the importance of the medical record number (MRN). It is required to uniquely identify a patient and align the clinical documentation to the correct person. Patient identifiers such as the MRN ("for whom" the service was done) and National Provider ID (NPI) ("by whom" the service was rendered) are essential components to allow for uniquely tracking information within an electronic health record system.

Within the U.S. there are many challenges with MRNs, but the biggest is the inability to match these unique identifiers across the different health record systems that assign them. Health Information Exchanges (HIE) and hospital networks have sought to connect disparate systems with unrelated MRNs by algorithms that incorporate surname, social security number (something that may or may not be present), telephone number, and other demographic features. Within an HIE, the ability to match patient records in a single center showed a sensitivity, specificity and positive predictive value of 95.4, 98.8 and 99.9 % respectively [8]. However, a single incorrectly linked piece of clinical data could have devastating outcomes.

In 1997 Health and Human Services released a statement saying "The need for unique patient identifiers has become urgent and critical. The widespread implementation of information technology and the emergence of computer-based patient records have paved the way for its potential success". Unfortunately the desire for a *Unique Patient Identifier* (UPI) has yet to come to fruition within the United States despite many years and a rapid proliferation of electronic health care data. This means the "for whom" portion of identification standards is yet to be resolved and is unlikely to in the near future in the United States. We are therefore left to use more cumbersome methods that require intermittent manual review and ongoing optimization.

The "by whom" portion of identification was resolved in the United States by the Centers for Medicare and Medicaid Services with the *National Provider Identifier* (NPI). This 10-digit numeric identifier replaced the previous unique provider identification number (UPIN) in 2007 and is required for medical billing to both government and private insurance. The NPI's ten digits allow for the first nine to be uniquely identifying with the 10th digit a check digit based on the Luhn algorithm for validation. The NPI can be utilized as the identification within electronic health record systems, for prescriptions, and for many other utilizations. This provider identification does not replace either the Drug Enforcement Administration (DEA) or the local state license number.

Recently there has been an increased push towards having specific medical devices uniquely identified through a *Unique Device Identification (UDI)* (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification).

The UDI would allow a "by whom" mechanism for non-human services that are provided (e.g. pacemaker). This trend has been pushed to allow more accurate reporting of adverse events, allow for specific identification of a device by providers, and to prevent counterfeit devices from being on the market. The Food and Drug Administration (FDA), who mandates utilization of the UDI, will phase in the requirement starting in September 2014 and ending in September 2020.

The key to identification standards is for wide-spread utilization. Government mandates for both NPI and for UDI have allowed for widespread (NPI) and future (UDI) utilization across health systems. The hope is that in the near future a UPI can be adopted to complete the "for whom" and "by whom" loop. However, there is still a need to add additional identification standards such as "where" or "in what setting" the care was delivered [9].

Terminology Standards

Controlled terminologies or controlled vocabularies (a way to organize knowledge for subsequent retrieval) are essential for capturing, storing, and processing electronic patient data. The prose with which clinicians describe health is inherently nuanced and ambiguous. While humans revel in the rich expressiveness of language, computers falter. Computers need controlled terminologies because they enable reusability of the data within and among system. As we discuss many different healthcare coding systems, there are many labels for these things that are often used interchangeably. You might be wondering what the difference is between a terminology, classification, and nomenclature. For our purposes we will use definitions based on ISO Standard 1087 (Terminology work – Vocabulary) and Giannangelo [10]:

- *term: designation of a defined concept in a special language by a linguistic expression*
- *nomenclature: system of terms elaborated according to established naming rules*
- *vocabulary: a collection of words or phrases with their meaning (i.e. a dictionary)*
- *terminology: a set of terms representing the system of concepts of a particular subject field*
- *classification: a system that organizes like or related entities*
- *semantics: the insertion of meaning via relationships (see SNOMED CT below)*

Another somewhat subtle distinction is the term *ontology*. In the context of information science (ontology also refers to the philosophical study of the nature of being), an ontology is a formal representation of some pre-existing domain of reality in a way that allows it to support automatic information processing [11–13]. In the context of healthcare terminologies, an ontology could be thought of as a terminology that contains some formal representation of definitional information. Ontologies serve to represent a truth (e.g. body temperature) and do not reflect the presence or absence of this knowledge.

In this chapter, we cannot provide an all-inclusive list of healthcare terminologies. There are, in fact, whole textbooks devoted to the subject [10]. Our intent is to highlight those that are in most widespread use and of greatest importance the field of clinical informatics.

Healthcare "Billing" Terminologies and Classifications

International Classification of Diseases (ICD) – www.who.int/classifications/icd/en/

The International Statistical Classification of Diseases and Related Health Problems, more commonly known as ICD is an international standard that is published by the World Health Organization (WHO) and was put in place for morbidity reporting. Originally known as the International List of Causes of Death to International Statistical Classification of Diseases the first usable version was ICD-6 that was published in 1949. This has undergone revisions through the years with the most notable ones with ICD-9 in 1978 and ICD-10 in 1990.

The ninth revision has been used extensively as a billing mechanism in the United States under the International Classification of Diseases, Clinical Modification (ICD-9-CM) and is the requirement for Medicare and Medicaid claims along with the majority of private industry. ICD-9-CM contains both diagnostic and procedure codes within both inpatient and outpatient settings. Volumes 1 (tabular listing) and 2 (index) contain diagnosis codes while Volume 3 contains only procedure codes.

The National Center for Health Statistics (NCHS) and the Centers for Medicare and Medicaid Services (CMS) are responsible for all changes and modifications to ICD-9-CM and the standard is updated every October 1st. Table 11.3 shows the structure of ICD-9-CM.

While the ninth revision has been dominant, the 10th revision for the ICD was endorsed by the World Health Assembly in 1990 and began being used by WHO Member States in 1994. The revision increased the number of codes to more than 155,000 up from the 17,000 in ICD-9-CM.

ICD-10 has been adopted throughout the world, however ICD-10-CM has been a challenge in the United States. In August of 2008 the United States Department of Health and Human Services (HHS) proposed that ICD-10-CM would replace ICD-9-CM on October 1, 2013, however HHS delayed this to October 1, 2014, and then again until October 1, 2015.

The majority of the dissent to the implementation of the ICD-10-CM system in the United States has focused on its use within electronic health record systems. In particular, detractors question the benefits and see limitations in increasing the number of codes from 17,000 to 155,000. While many would argue that having more granularity will allow for better representation of the diseases and services rendered, this level of granularity can have humorous (V97.33 "Sucked into jet engine") and likely unnecessary (Y92.146 "Swimming-pool of prison as the place of occurrence of the external cause") consequences.

Table 11.3 ICD-9-CM index of diseases

Diseases covered	ICD-9-CM codes
Infectious and parasitic diseases	001–139
Neoplasms	140–239
Endocrine, nutritional and metabolic diseases, and immunity disorders	240–279
Diseases of the blood and blood-forming organs	280–289
Mental Disorders	290–319
Diseases of the nervous system and sense organs	320–389
Diseases of the circulatory system	390–459
Diseases of the respiratory system	460–519
Diseases of the digestive system	520–579
Diseases of the genitourinary system	580–629
Complications of pregnancy, childbirth, and the puerperium	630–679
Diseases of the skin and subcutaneous tissue	680–709
Diseases of the musculoskeletal system and connective tissue	710–739
Congenital anomalies	740–759
Certain conditions originating in the perinatal period	760–779
Symptoms, signs, and ill-defined conditions	780–799
Injury and poisoning	800–999
Supplementary classification of factors influencing health status and contact with health services	V01–V89
Supplementary classification of external causes of injury and poisoning	E800–E999

The resolution of these additional codes has also been a challenge for electronic health records that will have to correctly "map" the codes to what is being performed clinically.

Current Procedural Terminology (CPT®) – www.ama-assn.org/go/cpt

The Current Procedural Terminology (CPT) is a standardized terminology that is owned and maintained by the American Medical Association (AMA) and first published in 1966. Its original focus was on codes for surgical procedures. While CPT now covers a broader domain, it surgical procedures codes have been used widely.

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) enacted and the Department of Health and Human Services (HHS) published the "Final Rule" that selected CPT for reporting physician services for payments for CMS. CPT is broken into three categories:

Category I: Numeric codes for procedures that are within the scope of medical practice in the United States (e.g. 45385 "Colonoscopy with polypectomy"). Within this category there is an assignment of relative value units (RVUs) by the Relative Value Scale (RVS) Update Committee (RUC).

Category II: Alphanumeric codes for tracking performance measurement (e.g. 3725 F "Screening for depression"). These codes all contain the "F" designation. It is anticipated that these codes will be important for Pay-for-Performance (P4P) measures.

Category III: Temporary codes for new or emerging procedures and are removed after 5 years from the time of publication (e.g. 0346 T "Ultrasound, elastography"). These codes all contain the "T" designation.

The AMA retains a panel of 11 physicians that are nominated by multiple medical societies, health insurance plans, and by CMS. This CPT Editorial Panel meets three times a year to discuss new and emerging technologies and any difficulties with the CPT® codes.

Healthcare Common Procedure Coding System (HCPCS) – www.cms.gov/medhcpcsgeninfo/

The Healthcare Common Procedure Coding System (HCPCS), pronounced "hick picks", is a billing coding system based on the AMA CPT that was started in 1978 to provide a descriptive standard for billing services in health care.

Similar to CPT codes, the HCPCS was required for reporting services to CMS in 1996 due to HIPAA. This coding is necessary for billing Medicare, Medicaid, and other commercial health insurance programs. HCPCS is broken into two categories with a now retired category III:

Category I: Numeric codes from AMA CPT (See section on CPT).

Category II: Alphanumeric codes for primarily non-physician services and not represented in Category I (e.g. B4034 "Enteral feeding supply kit; syringe fed, per day").

Category II codes are broken down into: (1) Permanent National Codes, maintained by the CMS HCPCS Workgroup, (2) Dental Codes, maintained by the Current Dental Terminology (CDT) from the American Dental Association (ADA), (3) Miscellaneous Codes that represent services that are not currently available in a coded manner (e.g. a service that is provide while a new code is under the HCPCS review process), and (4) Temporary National Codes that allows for providing a code prior to the next January 1 annual update to HCPCS.

Category III: Local codes (now discontinued since the end of 2003).

Diagnosis-Related Group (DRG) – www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/

The Diagnosis-related Group (DRG), also known as the MS-DRG, is a system that describes a bundle of services that a hospital might provide. The system was maintained by the U.S. Congress in 1982 for creation of a prospective payment system (PPS) to control costs. In this setting Medicare paid a flat rate per case for inpatient hospital care to reward hospitals for efficiency. The groupings allowed for a likely expenditure based on the underlying disease and co-morbidities that a hospital was likely to accrue.

Initially the system for "bundled" services was trialed in 1980 in New Jersey and became much more wide-spread in the early 1980s for Medicare services. These services can range from "Chest pain" (313) to "Liver transplant" (006) and consist of 470 unique codes with number 999 (previously 470) as "ungroupable". The DRG codes are maintained by the Department of Health and Human Services (HHS).

Clinical Standard Terminologies

SNOMED Clinical Terms (SNOMED CT®) – www.nlm.nih.gov/snomed/

SNOMED Clinical Terms (SNOMED CT) is a multi-lingual clinical terminology that is used in many countries. The terminology was originally created by the College of American Pathologists (CAP) and was the combination merger from SNOMED Reference Terminology (SNOMED RT) and the United Kingdom National Health Services Clinical Terms (Read Codes).

SNOMED CT is owned, maintained, and distributed by the International Health Terminology Standards Development Organization (IHTSDO) in Denmark. The IHTSDO itself is owned and governed by more than twenty-seven member organizations. In the United States, the National Library of Medicine (NLM) is the member organization of the IHTSDO and distributes SNOMED CT under the IHTSDO's uniform international license at no cost for use within the U.S. SNOMED CT is one of the suite of standard terminologies designated by the United States government for electronic health information exchange.

The NLM makes SNOMED CT available both through the UMLS and also in the native SNOMED CT file formats produced by the IHTSDO. The NLM also maintains a SNOMED CT browsing service at https://uts.nlm.nih.gov/snomedctBrowser.html that requires a free account for access.

SNOMED CT is a concept-oriented terminology that allows for machine readability numeric (e.g. 104817019 "left cusp of aortic valve"). The structure of the terminology is from larger concept (e.g. "body structure") towards more specific concepts (e.g. "anatomical or acquired body structure" ->"anatomical structure" ->"body organ structure" ->"organ part" ->"cardiovascular organ part" ->"heart part" ->"cardiac internal structure" ->"cardiac valve structure" ->"aortic valve structure" ->"structure of cusp of aortic valve" ->"structure of left cusp of aortic valve"). The system allows for relationships both to and from the specific concept (e.g. "is a" and "part of") as well as synonyms (e.g. "left coronary cusp").

SNOMED CT provides both pre-coordination and post-coordinated expressions. A pre-coordination expression refers to a single concept defining one clinical idea (e.g. "burn of skin"). Post-coordination expressions describes two or more terms that can be combined by an expression to represent a new meaning (e.g. "burn of skin" by "hot water" on "index finger") [14].

SNOMED CT contrasts from ICD-9/10-CM in that it is designed as a relationship of concepts that goes above and beyond the simple listing that is present in

ICD. This has both advantages and disadvantages. While the relationship status of SNOMED CT allows for complex associations including synonyms, these do not easily aggregate towards a specific concept that a clinician would make use of for either billing or for reporting a disease state.

As described by Cimino in his *Desiderata for controlled medical vocabularies in the twenty-first century* the optimal vocabulary must have "vocabulary content, concept orientation, concept permanence, non-semantic concept identifiers, polyhierarchy, formal definitions, rejection of "not elsewhere classified" terms, multiple granularities, multiple consistent views, context representation, graceful evolution, and recognized redundancy"[11, 15]. This listing of attributes is considered to be the "holy grail" of medical terminologies and contains many ideas that themselves could constitute a chapter in a book. For illustration purposes, we highlight that according to the Desiderata, an optimal vocabulary possesses broad and comprehensive concepts that have only one meaning with terms neither changed nor deleted, and uses unique identifiers that have no semantic (logical) meaning. Astute readers will note that ICD violates many of the Desiderata criteria.

Logical Observation Identifiers Names and Codes (LOINC®) – loinc.Org

Logical Observation Identifiers Names and Codes (LOINC) is a universal code system for identifying laboratory tests and clinical observations in electronic messaging. LOINC was developed by the Regenstrief Institute and the LOINC Committee in 1994 to support exchange and aggregation for care delivery, outcomes management, and research.

The current release of LOINC, version 2.50 (December 2014), contains more than 73,000 concepts covering the full scope of laboratory testing (chemistry, microbiology, etc.) and a broad range of clinical measurements (e.g. vital signs, EKG, patient reported outcomes, etc.). LOINC has a sophisticated data model for representing answer lists, panels of individual observations, and other details like help text, units of measure, and more. Based on formal naming conventions, LOINC also carries names for document titles (discharge summary, radiation oncology consult note, etc.), radiology reports and section headings (social history, objective, etc.).

LOINC has become widely adopted as the standard for laboratory and clinical observations in the USA and internationally. Today, there are more than 37,000 registered users from 166 countries and it has been translated into 18 variants of 12 languages. Many countries have adopted LOINC as a national standard. Within the USA, the Meaningful Use program requires LOINC in messages reporting laboratory test results, exchanging medical summaries, and sending data to cancer registries and public health agencies.

Each LOINC term is assigned a unique identifier (the LOINC code) and a fully specified name containing six main axes:

1. component (e.g. what is measured, evaluated or observed),
2. kind of property (e.g. mass, substance, catalytic activity),
3. time aspect (e.g. 24 h collection),

4. system type (e.g. context or specimen type within which the observation was made),
5. type of scale (e.g. ordinal, nominal, narrative)
6. type of method (e.g. procedure used to make the measurement or observation).

The combination of axis values produce names that are detailed enough to distinguish among similar observations. Of the six axes, only the method is optional and used only when necessary to distinguish among clinical important differences.

The Regenstrief Institute continues to develop and maintain LOINC. New concepts are added to LOINC based on submissions from end users, with new releases being published twice yearly. In addition to distributing the terminology, Regenstrief makes available at no cost a variety of supporting tools and resources, including the Regenstrief LOINC® Mapping Assistant (RELMA®) and online search application at http://search.loinc.org.

Drug Standard Terminologies

RxNorm – http://www.nlm.nih.gov/research/umls/rxnorm/

RxNorm is a standardized terminology set that provides normalized names for clinical drugs and links to synonyms within First Databank, Micromedex, MediSpan, Gold Standard Drug Database, NDF-RT from the Veterans Health Administration, and Multum. RxNorm is maintained by the National Library of Medicine (NLM) and gives both generic and branded names of prescription and over-the-counter drugs in the United States.

Since RxNorm is an aggregation of multiple sources of drug information each concept is sourced for a common meaning (e.g. 198013 "Naproxen Tab 250 MG=Naproxen 250 mg In 1 TABLET ORAL TABLET). This process allows for (1) ingredient (e.g. naproxen, (2) strength (e.g. 250 mg), and (3) dose form (e.g. "tab").

RxNorm is available through the NLM for free in the United States with a UMLS® Terminology Services (UTS) account. RxNorm is released as an update the first Monday of each month.

National Drug File Reference Terminology (NDF-RT) - http://www.nlm.nih.gov/research/umls/sourcereleasedocs/current/NDFRT/

The National Drug File Reference Terminology (NDF-RT) is a standardized terminology system for modeling drug characteristics including ingredients, chemical structure, dose form, physiologic effect, mechanism of action, pharmakinetics, and related diseases. The NDF-RT was created and is maintained by the United States Department of Veterans Affairs, Veterans Health Administration (VHA) and is part of RxNorm.

National Drug Code (NDC) – http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm

The Drug Listing Act of 1972 established through the Food and Drug Administration (FDA) that all drugs that were manufactured must be registered. This created a National Drug Code (NDC) that utilizes a three-segment number that serves as a universal identifier of the product.

The NDC number (e.g. 21695-255-90 "Lipitor 40 mg Tablet Film Coated") uniquely identifies the product NDC (e.g. 21695), the proprietary name (e.g. Lipitor), the non-proprietary name (e.g. atorvastatin calcium), the route (e.g. oral), the substance name (e.g. atorvastatin calcium), the package description (e.g. 90 tablet film coated in one bottle), and the labeler name (e.g. Rebel Distributors Corp). This highly detailed system allows for direct ability to identify a specific marketed product with the substance as well as the method for distribution.

The NDC is maintained by the FDA and is listed in the NDC Directory. This directly is updated daily to maintain an up-to-date listing of manufactured drugs. The NDC is a challenging system to utilize in comparison to RxNorm as it does not allow easy grouping of similar products. However, the detailed codings allow for excellent pharmacy integration and they can be mapped through the UMLS® to matching codes.

Other Healthcare Related Terminologies

There are many standardized nursing terminologies in use today, such as the Clinical Care Classification (CCC), Omaha System, Nursing Intervention Classification (NIC), Nursing Outcomes Classification, International Classification for Nursing Practice (ICNP) and the Perioperative Nursing Data Set (PNDS). Programs such as Meaningful Use have promoted a parsimonious set of core standards for EHRs, including standard terminologies such as SNOMED CT, LOINC, and RxNorm. There are active programs of work to enhance the nursing-related content in the dominant global healthcare terminologies (e.g. SNOMED CT and LOINC), including harmonization and mapping of elements from several nursing-specific terminologies. Given the trajectory towards using fewer distinct standard terminologies we will not describe each of the nursing specific terminologies in detail here. Table 11.4 shows the standard nursing terminology and a summary of what is contained.

Current Dental Terminology (CDT) and SNODENT – http://www.ada.org/en/publications/cdt and http://www.ada.org/en/member-center/member-benefits/practice-resources/dental-informatics/snodent

The Current Dental Terminology (CDT) is the HIPAA standard (since 2000) for dental procedures and for electronic dental claims. The CDT is maintained by the American Dental Association (ADA) and has previously been included in HCPCS Category II, however it is now maintained exclusively by the ADA and updated annually. An example code is D3347, "retreatment of previous root canal therapy – bicuspid". CDT is distributed within the UMLS®. SNODENT is an internationally recognized subset of SNOMED CT that is curated by the ADA. SNODENT supplements the CDT. SNODENT focuses on diagnostic and patient features, while the CDT focuses on procedures and treatments.

Unified Medical Language System (UMLS) – https://uts.nlm.nih.gov/

Due to the plethora of terminologies that have developed from multiple mechanisms there was a pressing need for a standard to link the different standards.

Table 11.4 Listing of standardized nursing terminologies and the content they cover

Nursing standardized terminology	Content/scope	Reference
Clinical Care Classification (CCC)	Provides a standardized coded framework for assessing, documenting, and evaluating nursing care holistically, over time, across settings, population groups, and geographic locations.	www.sabacare.com/
Omaha System	Consists of three relational components: (1) Problem Classification Scheme (client assessment), (2) Intervention Scheme (care plans and services), (3) Problem Rating Scale for Outcomes (client change/evaluation)	www.omahasystem.org/
Nursing Intervention Classification (NIC)	Comprehensive, research-based, standardized classification of interventions that nurses perform including clinical documentation, communication of care across settings, integration of data across systems and settings, effectiveness research, productivity measurement, competency evaluation, reimbursement, and curricular design.	www.nursing.uiowa.edu/cncce/nursing-interventions-classification-overview
Nursing Outcomes Classification (NOC)	Comprehensive, standardized classification of patient/client outcomes developed to evaluate the effects of interventions provided by nurses or other health care professionals	www.nursing.uiowa.edu/cncce/nursing-outcomes-classification-overview
International Classification for Nursing Practice (ICNP®)	A classification of nursing phenomena, nursing actions, and nursing outcomes that describes nursing practice.	www.icn.ch/what-we-do/international-classification-for-nursing-practice-icnpr/
Perioperative Nursing Data Set (PNDS)	Perioperative-specific, standardized nursing vocabulary recognized by the American Nursing Association (ANA) and is mapped to SNOMED CT®.	www.aorn.org/PNDS/

The Unified Medical Language System (UMLS) was established in 1986 to provide this service. This "Rosetta Stone" of the healthcare terminologies has integrated 58 separate sources (2014AB Release) that include the main terminologies for clinical data exchange and system integration.

The UMLS is maintained by the United States' National Institute of Health (NIH) National Library of Medicine (NLM). The UMLS provides a "Metathesaurus" that allows for terms and codes from multiple standards (e.g. ICD-10-CM, LOINC, CPT) with a unique identifier. There is also a "Semantic Network" that shows the broad categories (semantic types) and their relationships (semantic relations). Lastly it provides a lexical tools to provide natural language processing.

Data Exchange Standards

Health Level Seven International (HL7) – www.hl7.org

Health Level Seven International (HL7) was founded in 1987 and is an American National Standards Institute (ANSI) accredited standards developing organization for providing a framework for the exchange, integration, sharing, and retrieval of electronic health data. Of all the standards to know as a clinical informatician, the HL7 standards are probably the most critical because they provide the means for transmitting data across healthcare information systems (both local and external).

The "seven" of HL7 comes from the seventh level (application level) of the International Organization for Standardization (ISO) seven-layers of communications model for Open System Interconnection (OSI). HL7 develops its standards as a collaborative effort of many volunteers. HL7 members include individuals and organizations of many types, such as commercial entities, governmental, and non-government agencies.

HL7 has published several primary versions of its standards, but currently there are two widely used and both have some controversy. HL7 version 2 was released in 1987 with the most recent update to 2.7 in 2011. This version is used in 35 countries and 95 % of US healthcare organizations. HL7 version 2.x is organized into several different message types (e.g. Admission Discharge Transfer or Observation Result). Each message type has a set of segments that contain fields delimited by the "|" character. For example an observation result (ORU) message would contain segments such as the MSH (Message Header), the PID (Patient Identification), the OBR (Observation Request), and the Observation (OBX). And inside the Observation segment, there are separate fields to identify the data type, observation identifier, observation result value, units of measure, etc. Figure 11.1 shows an example HL7 version 2.x message. While it is important for informaticians to be aware of this general structure a detailed understanding of the specifics is not required (e.g. you can always Google it).

HL7 version 3 was begun in 1995 and initially published in 2005. The version 3 of HL7 was a large departure from the previous version, and thus has been met with significant resistance. HL7 version 3 utilizes a human readable Reference Information Model (RIM) in the Extensible Markup Language (XML). Figure 11.2 shows a HL7

```
PID|||12322^^^ Assigning authority ^MR ^Savage^Robert^^^^^L^|
```

Fig. 11.1 Healthcare Level Seven (HL7) Version 2 example.(Reprinted with permission from Health Level Seven® International)

Fig. 11.2 Healthcare Level Seven (HL7) Version 3 example.(Reprinted with permission from Health Level Seven® International)

```
- <ORU_R01.ORDER_OBSERVATION>
  - <OBR>
      <OBR.1>1</OBR.1>
    - <OBR.2>
        <EI.1>845439</EI.1>
        <EI.2>GHH OE</EI.2>
      </OBR.2>
    - <OBR.3>
        <EI.1>1045813</EI.1>
        <EI.2>GHH LAB</EI.2>
      </OBR.3>
    - <OBR.4>
        <CE.1>1554-5</CE.1>
        <CE.2>GLUCOSE</CE.2>
        <CE.3>LN</CE.3>
      </OBR.4>
    - <OBR.7>
        <TS.1>200202150730</TS.1>
      </OBR.7>
    - <OBR.16>
        <XCN.1>555-55-5555</XCN.1>
      - <XCN.2>
          <FN.1>PRIMARY</FN.1>
        </XCN.2>
        <XCN.3>PATRICIA P</XCN.3>
        <XCN.7>MD</XCN.7>
      - <XCN.9>
          <HD.1>LEVEL SEVEN HEALTHCARE, INC.</HD.1>
        </XCN.9>
      </OBR.16>
      <OBR.25>F</OBR.25>
    - <OBR.32>
      - <NDL.1>
          <CNN.1>444-44-4444</CNN.1>
        - <CNN.2>
            <FN.1>HIPPOCRATES</FN.1>
          </CNN.2>
          <CNN.3>HOWARD H</CNN.3>
          <CNN.7>MD</CNN.7>
        </NDL.1>
      </OBR.32>
    </OBR>
  - <ORU_R01.OBSERVATION>
    - <OBX>
        <OBX.1>1</OBX.1>
        <OBX.2>SN</OBX.2>
      - <OBX.3>
          <CE.1>1554-5</CE.1>
          <CE.2>GLUCOSE POST 12H CFST</CE.2>
          <CE.3>LN</CE.3>
        </OBX.3>
      - <OBX.5>
          <SN.2>182</SN.2>
        </OBX.5>
      - <OBX.6>
          <CE.1>mg/dl</CE.1>
        </OBX.6>
        <OBX.7>70-105</OBX.7>
        <OBX.8>H</OBX.8>
        <OBX.11>F</OBX.11>
      </OBX>
    </ORU_R01.OBSERVATION>
</ORU_R01.ORDER_OBSERVATION>
```

version 3 message. Although available for several years, version 3 of HL7 has not been widely adopted. This may be partially due to the reasoning for each version's creation. Version 2 was created by a small group of interface specialists and software vendors as an ad hoc standard, while version 3 was created by informaticians with a focus on modelling health care information and data for a wide range of use cases. Regardless of the controversy (or the reluctance to accept one or the other standard),

```
<gender>
  <coding>
    <system value="http://hl7.org/fhir/v3/AdministrativeGender"/>
    <code value="M"/>
    <display value="Male"/>
  </coding>
</gender>
<birthDate value="1974-12-25"/>
<deceasedBoolean value="false"/>

<address>
  <use value="home"/>
  <line value="534 Erewhon St"/>
  <city value="PleasantVille"/>
  <state value="Vic"/>
  <zip value="3999"/>
</address>

<contact>
  <relationship>
    <coding>
      <system value="http://hl7.org/fhir/patient-contact-relationship"/>
      <code value="partner"/>
    </coding>
  </relationship>

  <name>
    <family value="du">
      <!--  the "du" part is a family name prefix (VV in iso 21090)  -->
      <extension url="http://hl7.org/fhir/Profile/iso-21090#qualifier">
        <valueCode value="VV"/>
      </extension>
    </family>
    <family value="Marché"/>
    <given value="Bénédicte"/>
  </name>

  <telecom>
    <system value="phone"/>
    <value value="+33 (237) 998327"/>
  </telecom>
</contact>
```

Fig. 11.3 FHIR® version example.(Reprinted with permission from Health Level Seven® International)

they are both in active use and as an informatician you must be aware of both. Probably the most widely recognized component of the HL7 version 3 suite of standards is the HL7 Clinical Document Architecture (CDA). The CDA is a standard for specifying the structure and semantics of clinical documents. As part of the HL7 version 3 suite, the CDA derives its semantic content from the shared HL7 Reference Information Model and is implemented in Extensible Markup Language.

Fast Healthcare Interoperability Resources FHIR® (pronounced "fire") – (www.hl7.org/fhir/) is an emerging and likely impactful HL7 standard that looks to take to good portions of versions 2 and 3 and merge them with a focus on implementation. At the time of this writing FHIR has been published as a Draft Standard for Trial Use (DSTU), but there is also significant momentum for both FHIR development and implementation. Many major EHR system vendors have already started opening up new pathways to integration with their products using FHIR and are actively participating in FHIR's continued development. Figure 11.3 shows an example of FHIR.

Digital Imaging and Communications in Medicine (DICOM) – dicom.nema.org

The Digital Imaging and Communications in Medicine (DICOM) is an international medical imaging standard for handling, storing, printing, and transmitting across a specified network communications protocol with a specific file format definition.

DICOM was first published in 1993 and is implemented on nearly every radiology, cardiology, and radiotherapy device (e.g. CT, MRI, ultrasound). DICOM is maintained by the National Electrical Manufacturers Association (NEMA) and holds copyright to the standard. The DICOM image format (DICOM data object) includes name and medical record number so that these can never be separated from the image. DICOM

standards also leverage standard terminologies such as LOINC and SNOMED CT. Radiology is the primary domain of DICOM development and usage, but the standard has applicability in other domains such as Obstetrics and Gynecology and Cardiology.

Emerging Trends in Healthcare Data Standards

As this chapter goes to press, we note several trends that we anticipate will continue to drive evolution in healthcare data standards. The vision of creating a "learning health system" as articulated by the Institute of Medicine (IOM) [16] continues to drive many national initiatives. A key characteristic of such a learning health system is the ability to "capture the care experience on digital platforms for real-time generation and application of knowledge for care improvement". Further, the White House's recently announced focus "precision medicine" initiative [17] continues a movement towards disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. The only way to accomplish these goals is with a broad scope of interoperable health IT products and services that use common standards for the content and structure of health data.

Against this backdrop, we anticipate that the development and adoption of data standards will spread in both breadth and depth. Data from providers and care settings outside of the current emphasis on hospitals and primary care need to communicate on the same platform. This extends to clinical research settings, healthcare devices, and data directly from patients through patient-reported outcomes measures, wearable devices, and more.

The current digital infrastructure operates largely on a messaging and document exchange paradigm. But with the rapidly growing number of different data sources and applications that operate on them coming online in the "internet of health things", we anticipate a rapid growth towards the use of open APIs such as HL7's FHIR standard. Likewise, as the scope of available electronic health data extends deeper into the richness of genetic, behavioral, social, and other environmental factors that influence health, terminology standards such as LOINC and SNOMED CT will need to expand their content coverage.

The deep complexity of health knowledge and systems means that these transitions will not be easy. For example, a recent paper describing LOINC's approach to representing genetic testing results [18] noted that although specifications for reporting fully structured genetic variation and cytogenetic results have existed for several years, most genetic test results are sent today as narrative text.

Conclusion

Standards are critical for developers of systems, interoperability, and the exchange of information across health information networks. Planned and future development and enhancements to standards can both assure us of comprehensive information on our patients as well as providing quality and efficient care.

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Chapter 12
Information System Lifecycles in Health Care

Patricia P. Sengstack

Key Terms

System Development Lifecycle (SDLC) Clearly defined and distinct work phases which are used by system developers and informatics specialists to plan for, analyze, design, implement, maintain and evaluate information systems.

Needs Assessment A systematic process for determining and addressing needs or gaps between current and desired conditions.

System Selection The process of determining the best system to purchase or develop for an organization using requirements gathered from key stakeholders.

Governance The structure, people and processes that provide oversight to the management of clinical information systems.

Testing Processes that ensure proper functioning of information systems using testing scripts and system requirements.

Training Education provided to clinicians and other system users to ensure competency and safety in the entry and retrieval of patient data from the clinical information system.

Implementation The process of deploying a new clinical information system.

Business Continuity Ensuring that safe patient care will continue when a clinical information system is unavailable.

Downtime When a clinical information system is unavailable.

Evaluation The process of determining if a clinical information system is effective in meeting the desired need.

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Learning Objectives

1. Describe the process of selecting a clinical information system (CIS)
2. Identify elements of a clinical system implementation plan including models of user training and support processes to meet clinician needs
3. Differentiate between the different types of CIS testing and explain the importance of each
4. Assess an organizational downtime and disaster recovery strategy
5. Identify the key characteristics of effective clinical system governance at the organizational level
6. Develop effective methods to evaluate the outcomes of clinical system use

Core Content

Information System Lifecycle

- Institutional governance of clinical information systems
- Clinical information needs analysis and system selection
  - Methods for identifying clinician information system needs
  - Assessment of clinical process changes that will be required
  - Elements of a system requirements specification document (e.g., technical specifications, intellectual property, patents, copyright, licensing, contracting, confidentiality, specific organizational needs such as user training and support)
  - Risk analysis and mitigation
  - The costs of health information and communications technologies
- Clinical information system implementation
  - Elements of a system implementation plan
  - Models of user training and support processes that can meet clinician needs
  - Processes and mechanisms that obtain and respond to clinician feedback
- Clinical information system testing, before, during and after implementation
- Clinical information system maintenance
  - Disaster recovery and downtime
  - Clinical information system transitions and decommissioning of systems
- Clinical information system evaluation
  - Outcomes relevant to the clinical goals and quality measures
  - Qualitative and quantitative methods for evaluating clinical information systems
  - Evaluation plan design

Case Vignette

In a large geographically dispersed healthcare system, an organization-wide pharmacy council began the process of acquiring a new clinical system to better manage the use of antibiotics. Antibiotic stewardship systems that integrate pharmacy, laboratory and clinical information can have a significant impact on patient care as it relates to infection control, decision based treatments and costs. At the same time, a group of infection control practitioners identified the need to better manage the care of their patients, particularly the ones receiving antibiotics or diagnosed as septic. They began the process of investigating antibiotic stewardship systems to see if they could improve care with a new electronic tool. Meanwhile, the organization's electronic health record (EHR) vendor recently developed an integrated antibiotic/infection control system. The vendor's demonstration to the informatics team convinced them to proceed with presenting the system to an organization-wide decision making body to determine if the acquisition process should be initiated. With three disciplines vying for control, it became apparent that an organized approach was needed. This approach required a centralized method to obtain requirements from each of the stakeholders to better assess the potential systems available. Without this method, one can imagine that these three disparate work streams would result in duplication of effort, lack of organization-wide coordination and several frustrating political issues. After reviewing the potential systems with clear requirements in hand, the teams opted to select the EHR vendor's product, not because it met 100 % of the requested functions, but because it met all critical needs and provided full integration with the patient's medical record.

Introduction

CISs, whether they are large complex electronic health records (EHRs) or smaller specialty systems, have become mainstays in healthcare. They all follow the phases of the system development lifecycle (SDLC) as seen in Fig. 12.1. Initially, an organizational decision is made to acquire a system based on an identified need, followed by system selection. Implementation follows with associated testing and training. The go-live event is supported, and then the process of maintaining and evaluating the system ensues. Each of these phases requires understanding and focus to ensure these costly and complex systems are delivering the value proposition that's expected. Over the last decade knowledge has been gained and evidence has grown surrounding the best practices in each of these phases of the SDLC. This chapter describes each phase along with evidence based information and processes to successfully navigate a system through each one.

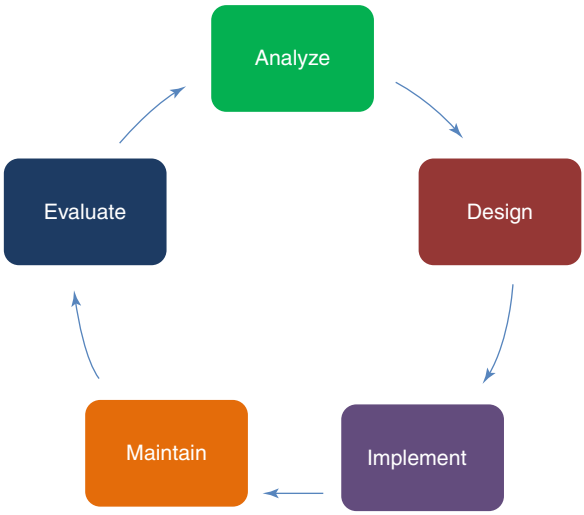

Fig. 12.1 System development lifecycle

Making the Decision to Purchase a CIS

The decision to purchase a CIS is one that requires organizational collaboration and commitment. Too often we see the vignette above played out leading to wasted time, energy and money. A focused approach with key stakeholder involvement is key to success. It's that simple, yet the underlying complexities make it a challenge in any organization.

To begin with, the decision to purchase a system is typically based on an identified need. This need can arise from multiple sources. It may come from frustrated infection control practitioners who cannot effectively assess antibiotic usage in their patients. It may come from physicians in the Emergency Department who struggle with triaging their sickest patients. It may come from a busy labor and delivery unit that needs a better way to capture fetal monitoring data. It may come from an organization whose strategic plan is to meet the federal government's meaningful use criteria, or it may come from an organization's need to better capture, report and analyze a population as part of an accountable care initiative Whatever the original source, the need must make its way up to the organization's decision makers in a coordinated way. How this happens in most organizations varies, yet without support at the highest level most requests are never granted.

The ultimate decision should be based on the organization's strategic plan. While requests for clinical systems can come from different departments, disciplines and individuals, it's the strategic plan that should drive the decision [1]. Sometimes it's politics, sometimes it's who you know, and sometimes it's who yells the loudest – but at the highest level of the organization, a clinical system should not be considered unless its implementation will support the mission, goals, and future plans of the organization.

Assessing the Need

When beginning to seriously consider the purchase and implementation of a CIS, a thorough needs assessment should be conducted. In this beginning stage, the "need" vs "want" question should be answered. Because other hospitals have purchased a particular system does not necessarily mean every organization must have the same system. Just because a great demonstration of a system was given at a trade show, does not mean it must be purchased. Work through the following questions with the requesters during any needs assessment:

- Why do we need this system?
- What is the problem we are trying to solve?
- How will it improve the care we deliver to our patients?
- Is there data to support the need?
- Can the system we already have be configured to meet the need or solve the problem?
- What is the impact on patient safety?
- Will it require changes to the clinician's current workflow?
- Does it have the potential to save money?
- What is the estimated cost? Initially and ongoing?
- Does it have the potential to save time or streamline a workflow process?
- What is the risk to the organization if we do not implement this CIS?
- How can those risks be mitigated?
- Does this system support the strategic plan?

Justification for moving forward must be convincing given that the implementation and subsequent maintenance of any new clinical system will be expensive not only in terms of dollars, but human capital as well. A strong case that supports the organization's strategic plan has a better chance of approval than one whose needs assessment has not been thoroughly conducted.

System Selection

Once a decision has been made to purchase a clinical system, the process of selection begins. Depending on the type of system desired, there may be several to choose from. The system could be one developed by an organization's current EHR vendor and have the advantage of being fully integrated. It could be a specialty vendor with a best of breed product that can be installed onto the organization's servers and subsequently integrated, or an application service provider (ASP) could be chosen to host a system on the vendor's server [1]. One strategy to gather information on systems available to meet the organizational need is to develop and distribute a Request for Information (RFI) or a Request for Proposal

(RFP). An RFI is used to obtain preliminary information about potential vendor products when there is not enough information readily available for decision making. It is simply a document or letter that informally solicits the requested information regarding a vendor's product [2]. Responses to an RFI can help an organization fine tune their requirements and system specifications in order to develop a strong comparison tool. This process may not be necessary if vendors in that particular space are known entities. The RFP is a more formal process and results in a response from the vendor describing how they would go about executing the project including pricing information. There are multiple templates for RFIs and RFPs available on-line, including one from the Office of the National Coordinator for Health Information Technology (ONC) specific to health IT projects [3].

RFI/RFP templates [4–6] usually contain the following elements:

- A confidentiality statement between all parties involved
- An introduction and purpose statement
- A brief description of the scope
- Abbreviations and terminology used
- The RFI/RFP procedure – how the potential vendor should deliver their response, who in the organization they should communicate with, and the time frame
- Background description of what is requested
  - Description of the organization
  - Description of the kind of product or service being requested
  - Statement of the need
  - System requirements both technical and functional
  - Qualifications of the potential vendor
- Proposed vendor solutions
- Criteria for how vendors will be evaluated by the organization (RFP)
- Pricing or estimated costs (RFP) – initially and ongoing
- Support provided by vendor (RFP) – initially and ongoing
- Vendor demographic information
  - Company's name address and website
  - Company's main products, services and customers
  - Number of years in business
  - Financial information
  - Description of business continuity management
  - Description of products or services that are already delivered to customers today, and could be comparable to what is being requested

When a list of final vendor candidates has been selected, the comparison process begins. A comparison tool to evaluate each potential candidate helps ensure that each vendor's system is evaluated using the same criteria. To create a

selection comparison tool, the key stakeholders, including those with clinical and technical expertise, participate. Items in this comparison tool should include the following:

1. Technical requirements – Requirements that specify the technical criteria that a system must fulfill, such as performance related issues, reliability issues and availability issues.
2. Functional requirements – Requirements that specify the functional criteria that a system must fulfill, such as a function or feature that must be included in an information system to satisfy the business need and be acceptable to the users.
3. Potential risks with mitigation – Any identified areas of concern with suggestions on how those concerns could potentially be addressed.
4. Ongoing resources needed – Once past implementation, it is important to determine what types and how many resources will be needed to support the system in the future.
5. Support provided – Vendor support before, during and after implementation. Determine what they provide, when they provide it (24/7/365) and how much it costs.
6. Total cost of ownership – An estimate of how much the system will cost, not just in terms of the software but hardware, licensing, human resources and other associated costs.

Table 12.1 illustrates the comparison of functional requirements among three vendors.

Vendor demonstrations are also helpful when making a system selection. They provide a forum for the end-users to get their hands on the system to assess its usability and evaluate if it meets their needs. With a real time demonstration, organizations can better ascertain whether or not the vendor's product will work for them. Vendors are often provided a script or a scenario prior to the demonstration so they can show potential customers how their system can support the identified processes. The outcome of vendor demonstrations is typically the elimination of some vendors from the potential pool of candidates [2].

Table 12.1 Functional requirements: vendor comparison

Areas of comparison – functional requirements for an infection control clinical system	Vendor A	Vendor B	Vendor C
Notifies user of positive blood culture result	Yes	Yes	No
Provides user with list of antibiotics sensitive to positive result	Partially	No	Yes
Alerts provider when patient has been on antibiotic for longer than 3 days	No	Yes	Yes
Can integrate lab data such as CBC with Diff	Partially	Yes	Partially
Can integrate patient temperature	Yes	Yes	Yes

System Implementation

Once a system is selected, preparations for implementation begin. Implementation represents the culmination of a significant amount of work, all leading up to the time that a system goes live. There are multiple components with moving parts that will need the skills of a project manager to orchestrate a multi-disciplinary and multi-skilled team effectively. One model designed to assist organizations as they address implementation of clinical systems is a socio-technical model developed by Sittig & Singh [7]. This eight dimensional model provides a conceptual framework that can be used to ensure the majority of these moving parts are identified and addressed throughout system implementation and beyond. Table 12.2 summarizes each of these eight areas.

The following areas of implementation planning will need to be addressed:

- Determining a go-live date and time
- Activation or go-live planning
- Training for end-users
- Go-live support and on-going support for end-users
- Follow up/Lessons Learned

Table 12.2 Eight dimensions of the socio-technical model [6]

Dimension	Description
Hardware and software computing infrastructure	Hardware and software required to run the applications including the computer, monitor, printer, keyboard, mouse; centralized data storage devices and all of the networking equipment
Clinical content	Data, information and knowledge stored in the system including structured and unstructured textual or numeric data and images.
Human computer interface	The screens and images that end-users interact with. The system's intuitiveness and usability that allow the user to navigate the system.
People	The technical team, clinical stakeholders, system users and administrators who interact with and make decisions regarding the system
Workflow and communication	How the system supports clinical care and workflow and how this is communicated across the organization.
Internal organizational policies, procedures, and culture	Clinical workflow involved with operating these systems needs to be consistent with policies and procedures.
External rules, regulations, and pressures	External forces that facilitate or place constraints on the design, development and Implementation of systems such as the HITECH Act of 2009 and its Meaningful Use initiative.
System measurement and monitoring	Effective system measuring and monitoring that includes: System availability; System use by clinicians; Patient outcomes and unintended consequences.

Determination of Go-Live Date

Selecting a realistic go-live date is important for a number of reasons. Most importantly, when a date is selected, many departments will increase their staffing levels to support the go-live. Clinical schedules are created weeks to months in advance. Last minute changes are incredibly frustrating and can be almost impossible to accommodate. Also, if an unrealistic date is chosen and the date gets pushed out multiple times the credibility of the project team and the software itself can come into question. Lastly, a delayed go-live means a delay until the organization is able to take advantage of the benefits of the new system.

When selecting the actual go-live date and time here are a few things to consider:

- Go-live at a time with less than usual clinical activity (i.e., 2 am or on the weekend)
- Consider technical timing in relation to system backups and various batch jobs that run automatically
- Request input from end-users for exact timing
- Avoid holidays, including local school holidays (staffing can be an issue – key resources may be parents without daycare for children)

Activation or Go-Live Planning

Preparations for go-live day need to occur well before the actual day or even the week prior to go-live. When to begin to focus on go-live planning depends on the size and complexity of the system and how many end-users are involved. For larger, more complex implementations like an organization's EHR, go-live planning should begin 4–6 months prior to go-live. For less complex clinical systems or system modules such as an Infection Control information system, planning for go-live should begin approximately 2–3 months prior to go-live [8]. This one moment in time is so short but so essential to plan carefully. A successful go-live will lay the foundation for a strong system and build credibility for the informatics and information technology (IT) teams.

Activation planning begins with gathering everyone together, preferably in the same room, to begin to draft a plan that will be followed throughout the entire activation process. Members of the team that should be present at this initial planning meeting include:

- Local technical team members (Database Administrators, Interface, Server, Network)
- Informatics specialists
- Project manager
- Vendor technical team members
- Training team

Together, this team can determine each granular task that needs to take place during system activation. This includes tasks that occur weeks prior to go-live, days prior to go-live and go-live day. In addition to the task itself, they should identify: who will complete the task, how long it will take to complete and if there are any required predecessors. This process can take more than one session as input is incorporated into a formal checklist including go-live timing to the very min. The end result is an activation plan that a project manager can orchestrate throughout the entire activation process. Table 12.3 is a partial example of an EHR activation planning checklist that begins the week prior to go-live.

Training

There is an inverse relationship between the need for system training and a system's intuitiveness. The less intuitive the system, the more training will be needed. Electronic health records are complex and multifaceted. They have linkages that require end-users to negotiate between different areas of the chart that can be confusing. While training end-users effectively oftentimes takes a backseat to more visible activities like system configuration, it can make or break an implementation. Poor training can produce decreased efficiency, staff turnover, patient care errors, and poor quality documentation followed by decreased billing revenue. Training is one of the last opportunities to positively influence performance and end-user acceptance toward what will be a big change in any organization [9].

Multiple instructional design models exist, but at their core, each contains the elements of analysis, design, development, implementation and evaluation. A widely known model that addresses these concepts is referred to as ADDIE. Each of these elements are described in the sections below [10].

Analysis

Initially, a needs assessment will help to shape the training design at three levels: Organizational, learner and task. By addressing the questions contained in Table 12.4 in each of these categories, the design team can begin to develop the content, objectives and format of education for system users.

Learner competency tools in the area of health IT have been developed and continue to be refined by the Technology Informatics Guiding Education Reform organization referred to as TIGER. This group has focused on informatics competencies of nurses in particular since 2004. They have defined the minimum set of informatics competencies that all nurses need to succeed in practice or education in today's digital era [11]. An extensive list of competencies is available on-line and organizations can use these to assess baseline competency of most clinical learners [12]. TIGER organizes these competencies into three broad categories and provides a granular listing of behavioral

Table 12.3 Example – activation plan checklist (Partial)

Wednesday March 7	**Est duration**	**Resource**
Send out 2nd Downtime Communication	10 min	Susy
Clinical Support Staff meeting (overview of events)	15 min	Sue & Patty
Validate new servers are up to date with hotfixes	5 min	Tom
Review SQL Server jobs and SQL Settings (Max Memory, MDOP)	5 min	Jennifer
Schedule downtime reports (Nsg & Pharm) for Friday night/Saturday Morning	60 min	Mike
Final Activation Planning meeting	60 min	All
Thursday March 8		
Verify pre-upgrade process for Observations and Documents	60 min	Tim, Jennifer
Friday March 9		
Copy/Backup	90 min	David
Update Training Workstations	90 min	Desktop Supp.
Saturday March 10		
Rescheduled MRD Reports Print	60 min	Scheduled
Announce downtime	5 min	Operators
Disable access to scmprod	5 min	Mark
Point workgroup to model	5 min	Tim
Sunday March 11		
GO LIVE – SYSTEM DOWN TO USERS		
Turn off SCM Batch Jobs	5 min	Tom
Copy ES Db backup from CCXAPENT to CCSXAPMASQL & Restore	30 min	Tim
Run Report Query (all reports completed)	10 min	Tim
Turn off All Services (order generation, reports, etc.)	10 min	Tom
Start – Move backup file to CCXAREPORT	5 min	Tom
Ensure interface queues are empty	5 min	Tony

Table 12.4 Questions to consider during training analysis

Assess the organization	Why is training needed? Is there an organizational strategic goal associated with the training? Is training a priority with resources allocated? Is training supported by key stakeholders?
Assess the learner	Who will need to learn to use the system? What is their current competency level?
Assess the task	What is the task that needs to be performed? What are the steps needed to correctly complete the task?

competencies or skills in each: Basic Computer Competencies, Information Literacy and Information Management. There are similar efforts aimed at competencies for physicians [13] and public health professionals [14] as well as efforts to synthesize competencies across informatics and information management disciplines [15].

Design

The design phase provides the outline or blueprint for training. One method to begin this work is to start at the end and determine what system users should accomplish during the training. With the outcome and any required testing in mind, the sequenced outline can be developed along with the instructional strategies for delivery using the principles of adult learning [16].

Development

With the outline in hand, the instructional development team can create the detailed content and learning activities to meet the objectives. This may include eLearning modules, classroom lectures, paper-based guides, story boards or even tip sheets. Additionally, a method to track completion and performance is developed during this phase along with the development of a plan to evaluate the training program overall.

Implementation

This next phase includes the development of the implementation plan as well as the execution of the plan itself. There are several tasks during this phase, including:

- Development of training methods for both the trainers and the learners. This is based on the assessed competency of the end-users as well as the complexity and length of training required:
  - Will end-users need to come into a physical classroom for training?
  - Will on-line learning modules be effective without classroom training?
  - Will both classroom and on-line training be available?
  - Will a hybrid approach work best with a combination of self-paced on-line materials and classroom time?
- Testing of materials to ensure accuracy and proper functioning
- Scheduling of training sessions. The goal is to train as close to the go-live date as possible. The principle of recency states that things most recently learned are best remembered. This can be a challenge if go-live dates slip.
- Conducting the training sessions
- Review of student feedback and evaluation immediately post training

Evaluation

Evaluating the effectiveness of training helps to ensure that all stated goals and objectives of the learning process are met. Feedback from learners and trainers are compiled, reviewed and addressed as needed to continue to improve training as an

ongoing process. Lessons learned should be incorporated as appropriate to refine methodologies and delivery strategies [9].

Because training of CISs occurs as new hires continually enter the organization, training is not a one-time event. Training programs must be established and supported on an ongoing basis. Additionally, organizations often find that users need a good review and more training on how to customize the system to better support their workflow. Courses offering advanced tips and tricks to improve users experience with the system can be offered.

Go Live

The activation plan with estimated timelines for each task will provide an estimate for the duration of the go-live. Using this estimate helps to make decisions on when to start the go-live process and when certain resources are needed to perform their specific tasks. For example, the system security team will be needed just prior to go-live to complete the final configuration for access to the new system. Those supporting the end-users once the system becomes available will have an idea what time they will be needed to begin rounding on the patient care units.

On the day (or night) of go live, the implementation team will assemble in a command center. Remote resources may also be needed for their particular tasks. A project manager orchestrates the tasks documented on the activation plan and acts as the conductor as interfaces are connected, the system is tested and validated, access is granted, the switches are flipped and the system is turned over to the end-users.

Go Live Support and Ongoing Support

The change inherent in the implementation of a new clinical system is incredibly disruptive. Comfort in care delivery methods are replaced with the unfamiliar. Providing support to end-users during an implementation is essential and requires planning and focus. Ensuring care providers can locate the patient's critical information including diagnosis, plan of care, medications, and current clinical information is necessary to ensure patient safety during the transition. The key components of end-user support include:

Immediately Following Go Live

- Make rounds hourly to clinical care areas affected by go-live
- Provide tip sheets attached to workstations
- Staff a support center to respond to calls 24/7 for at least the first week (for an EHR implementation)

- Post support center phone numbers in visible locations
- Document issues and develop Frequently Asked Questions (FAQs) and distribute
- Articulate to end-users that any immediate changes to the system will be for break/fixes or patient safety issues only. Other ideas for changes will be collected and reviewed by an organization-wide review committee.

Two Weeks After Go-Live and Beyond

- Assess calls made to the support center to determine need to staff 24/7
- Update system super-users on issues or unintended consequences and communicate how they are to be handled
- Ensure end-users are aware of the process to submit any identified issues with the system
- Provide a process for end-users to submit potential system enhancements or innovative ideas

Follow Up/Lessons Learned

Following any go-live, lessons learned should be discussed, documented and built into subsequent implementations. Some call the lessons learned meeting a "post mortem", although it's actually a misnomer since the system's life has just begun. This meeting is typically facilitated by the project manager and is conducted in a non-judgmental manner in order to illicit all thoughts and ideas on how to improve next time. A review of lessons learned from implementations in the past should be part of the standard operating procedure when developing implementation plans in the future.

CIS Testing

Establishing a robust testing process is key to the development of quality clinical systems both in the initial project implementation and maintenance phases. It requires planning and attention to detail. Unfortunately, testing often becomes a last minute exercise due to delays in preceding phases of a project. This makes it even more important to develop a good testing plan that results in a level of comfort that the system is going to work as designed and expected in order to provide safe patient care. The goals of testing are to evaluate if a given system is built according to its specifications and design, and to reduce the risk of critical problems when turned over to the end-user [17].

Testing of clinical systems is performed at multiple levels. Not all levels are required, but usually some combination of unit testing, function testing, integration testing, and user acceptance testing is performed. Each type or level of testing is

designed to cover core system functionality and scenarios, as it is literally impossible to test every single item and pathway in a clinical system. Testing is therefore a process to identify and mitigate risk. Different levels of testing expose different aspects of that risk [17]. The following is a brief overview of each testing level.

Unit Testing

Unit testing is the testing that's performed while an item or system component is being developed and before it is turned over to a testing team. It is performed by the builder or developer who creates the component. This testing is low level, and includes testing of foundational configuration such as spelling, font, color, and location of content. It also includes the testing of logical pathways that the code follows. For example, if a new order set was created, the developer would check to see if all items displayed properly when placing the order; that they were all spelled correctly, in the right order; and any individual items that had fields pre-selected were filled in correctly. Once this testing is completed, the component can be turned over to the test team for Function Testing.

Function Testing

This level requires that the functional requirements of the system have been defined and documented. Function testing typically requires the assessment of data flow to other systems. For example, if an order for a lab is entered into the CIS then it should appear in the lab system for that patient at the designated time. Most CISs must integrate with other systems, hence the need to test the functioning of an interface engine using standards such as Health Level 7 (HL7). HL7 provides a standard, industry supported methodology to send messages from one system to another [17]. That same lab order, once resulted should then flow back into the CIS in the right patient's chart indicating the time of the result and any other associated information. Other types of function testing may include:

- Printing and testing of various reports – automated and on demand
- End-user security privileges and access
- Integrated medical devices such as hemodynamic monitors or ventilators in the ICU

Integration Testing

While function testing ensures that a single action occurs as planned from start to finish, integration testing includes the entire process from multiple care providers' perspectives. Another way to think about integration testing is to consider a core

clinical activity or scenario, such as a blood transfusion. A physician begins by entering the order for a type and cross match that then flows to the lab system, the lab system provides the result and it posts back in the patient's chart. Orders are then placed for the blood and for the actual transfusion of the blood. These orders flow to the blood bank for order fulfillment. The patient's nurse is notified that new orders have been entered for the patient and awaits notification from the blood bank that the blood is ready for transfusion. If the organization uses bar coding for transfusion verification, the next testing step would be to ensure that the process to accurately scan the blood product works as planned and the patient is identified properly prior to administration. It's clear that integration testing can become complex as the testing team must utilize multiple access codes in the clinical system as they test using various roles in the process: physician, lab technician, nurse, and Blood Bank technician.

Performance Testing

Performance testing tends to be more technical than the types of testing described above. It entails creating scenarios that test a system when a high volume of users are accessing and using the system at the same time. Typically during performance testing, the tester creates scripts which get executed by a performance testing program. Technical expertise is required to generate and run scripts that can simulate various volumes of end-users accessing and using the system. Monitoring software should also be in place at this time to help validate that system memory, processor allocation, and response time still fall within the acceptable levels defined in the technical requirements of the system [17]. As an alternative to this highly technical approach there may be situations on a smaller scale where performance testing can be conducted by a group of people each performing tasks within the system simultaneously while response times are monitored.

User Acceptance Testing

Once unit, function, and integration testing have been successfully completed, it is important to get the system users involved. Bring the end-users into a testing center and in a development or practice environment have them test the new functionality. Care providers will be able to indicate if the screen layout makes sense, if the field names are accurate, if the data flows from screen to screen appropriately and if overall it supports their workflow. This later phase of testing is one of the most important and probably one of the least conducted. Omit this phase of testing and the project leader should plan on performing rework and hearing frustrations from end-users after go live.

Production Validation Testing

Once the new functionality is promoted into the live, production environment, it should be given one final test. A common mantra heard amongst developers is, "there's no test like prod". While a development or a test environment that mimics production works very well when creating new functionality, it will never be exactly the same as the live database. For this reason the builder should validate one last time to ensure that what they built is working as designed.

Regression Testing

After a system goes live there are numerous times throughout its life cycle when significant upgrades to the system and the database must be applied. New features and functions will continuously be added to enhance the system to support clinical care, and vendors will require routine updates, hot fixes, security patches, etc. In other words these complex CISs are in a constant and dynamic state of change. Regression testing is an attempt to assess the system's basic and core functions whenever significant changes are made. Because an entire system can never have 100 % of its functions tested, organizations develop regression testing scripts. These scripts are used by a testing team to validate that basic system capabilities are still functioning properly. Some organizations will use automated testing tools to conduct regression testing. Regression testing typically includes the testing of [17]:

- Order entry
- Clinical documentation
- Orders to other systems via HL7 messaging
- Previewing of key reports
- Alerts such as drug-allergy, drug-drug interaction
- Patient admission, discharge and transferring functions

Institutional Governance of CIS

Once implemented, CISs cannot be left on autopilot. Their ongoing management requires structure, processes and people to keep the system running and well maintained. While each organization will manage things differently, there are common elements of an informatics governance structure that are needed regardless of how "unique" an organization believes it is. To begin with, management of clinical systems requires leadership at the director level. Titles for this role vary, but Director of Clinical Informatics is one of the more common terms. In this position the work of managing and maintaining the system is orchestrated. Various

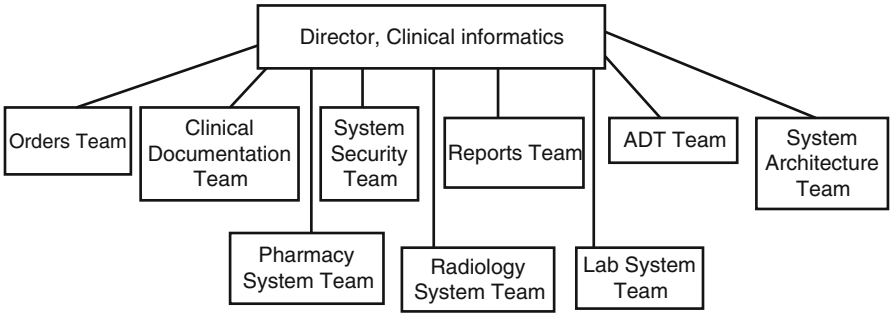

Fig. 12.2 Director of clinical informatics – reporting structure

teams of informatics specialists report to a director and work is performed in a matrix type environment with multiple informatics teams working together on most projects. The graphic found in Fig. 12.2 illustrates this concept using the EHR as the clinical system.

Other strategic and vision focused leadership roles in informatics are emerging. It is not uncommon for organizations to have a Chief Medical Informatics Officer (CMIO), Chief Nursing Informatics Officer (CNIO) or even a Chief Health Informatics Officer (CHIO). Clinical leadership is critical. Unlike a Chief Information Officer (CIO) whose focus and background are typically more technical, these more clinically focused informatics roles ensure that not only are systems "up" but they are meeting the needs of the patients, clinicians and the health system.

Broadening the concept of working in a matrix environment, informatics teams also work closely with technical IT teams and key clinical stakeholders as a system is maintained and managed. Building the governance structure to ensure all three areas (informatics, technical and clinical) are involved requires leadership support from the very top of the organization. Again, organizations will structure this governance in a variety of ways depending on the size and geographic disbursement of their system. An organization with one stand-alone hospital may establish an interdisciplinary system review committee consisting of members representing each clinical discipline that uses the system along with informatics and technical specialists. This committee is responsible for reviewing, approving and prioritizing any clinical system changes or enhancements that are requested. In a multi-hospital system, processes and governance will include reviewing, approving and prioritizing at an enterprise level. There may be clinical system review committees at each hospital that report up to a centralized review committee for final approval and prioritization. In some organizations a CIS Review Committee will report to a broader or higher level governing body where decisions are made regarding larger CIS acquisitions and projects that require significant funding. An enterprise level governing body can help with overall decision-making and prioritization that ensures that CIS decisions

are based on the organization's mission, goals and strategic plan, avoiding situations illustrated in this chapter's vignette.

The Governance of Configuration Management

Configuration management for a CIS consists of structures and processes that surround making changes to a clinical system. These may be changes required by the vendor or changes approved by the multidisciplinary review committee in an organization. Regardless of where the change originates it should follow standard processes from idea to production and include the following:

- A place for stakeholders to submit a system change or enhancement request
- A multi-disciplinary committee that routinely reviews the requests for changes. Some organizations call this a Change Control Board. This committee should be comprised of representatives from informatics, information technology and clinical areas
- A standard method that the system change review committee or chance control board uses to review and approve each proposed change
- A method to prioritize approved changes
- A standard process for building, testing, training, communicating and releasing changes into the production environment
- A communication strategy to keep everyone informed on the status of system changes

Figure. 12.3 illustrates one organization's processes for ensuring that system changes follow a standard pathway [18].

Business Continuity and Downtime

Ensuring that an organization's clinical systems are up and running at all times is a significant task. While IT departments strive for uptime of 100 %, the reality is that at some point in time there will be a system interruption or downtime. Oftentimes, these are planned events in order to install vendor or security updates. When planned, communication can go out preemptively to prepare staff, and patient data can be printed and available during the downtime. When unexpected, the potential ramifications can be serious and impact patient safety. Documented potential hazards include an increased risk of medication errors, unavailability of images, and canceled procedures [19]. An organization needs to be prepared for when, not if, downtime occurs. There are three areas that organizations should focus on: Business continuity, downtime preparations and recovering from downtime events.

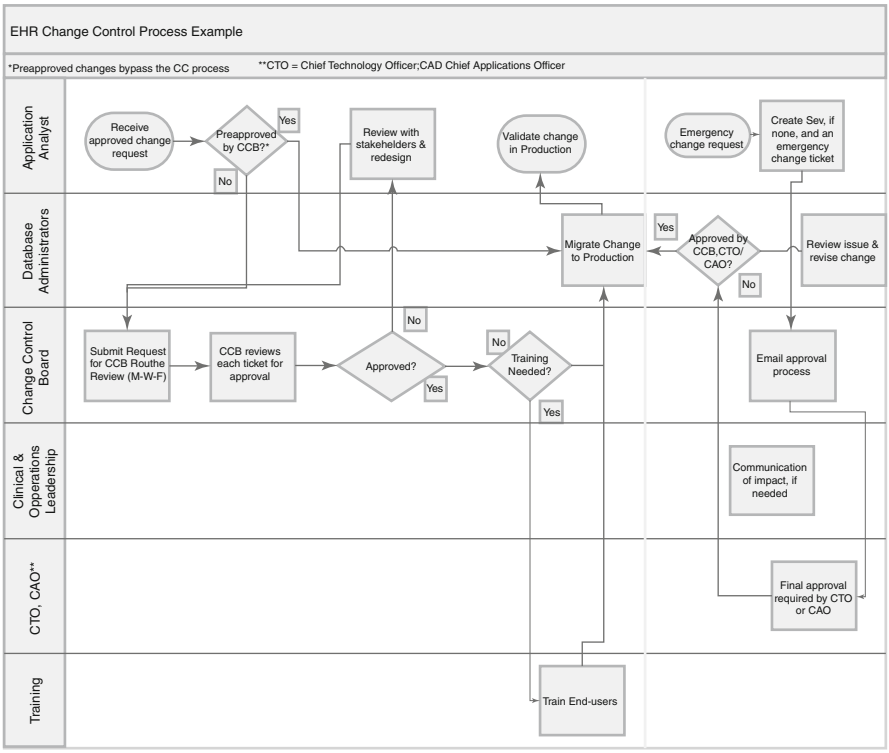

Fig. 12.3 An organizational change control process workflow (Reproduced from Ref. [18] with permission from Honor Society of Nursing Sigma Theta Tau International)

Business Continuity

An organization's disaster recovery plan should provide a level of system backup that minimizes the impact of an outage on the care and safety of the patients whose data it contains. Business continuity must be maintained with a planned and methodical strategy that is well communicated across the organization. There are three broad strategies to back up a system that has unexpectedly crashed [20]:

- Hot Site – a replicate of the production environment that allows for an immediate cutover in case of disaster or unexpected outage. Continuous syncing allows for minimal impact and downtime to business operations. A hot site must be equipped with all the necessary hardware, software, network, and Internet connectivity. It should be located far away from the original site, in order to prevent the disaster affecting the hot site as well. This is the most expensive option.
- Warm Site – A warm site is another backup site, but is not as well equipped as a hot site. It has power, phone, network, etc., but a warm site is not ready for immediate switch over in the case of an unexpected downtime. The time to switch over

from the disaster affected site to a warm site is more than that of a hot site, but less cost makes this choice more attractive to organizations. While the hot site provides a mirror of the production data center and its environment(s), a warm site will contain only servers ready for the installation of production environments.

- Cold Site – A cold site contains even fewer facilities than a warm site. It will take more time than a warm site or hot site to switch operations but it is the cheapest option. The cold site provides power, cooling, and/or office space in the event of a significant outage to the main work site or datacenter. The cold site will require extensive support from engineering and IT personnel to get all necessary servers and equipment migrated and functional.

Preparations for Downtime

Preparation for a system interruption or downtime consists of the mobilization of people using standardized and well disseminated processes. In addition to ensuring the ability to recover from a technological standpoint, there are several things an organization should consider when developing a contingency plan. The Office of the National Coordinator for Health Information Technology (ONC) has developed and made publically available a self-assessment tool that organizations can use to determine if they are adequately prepared in the event of an EHR system interruption. This tool is one of the Safety Assurance Factors for EHR Resilience (SAFER) Guides and includes ten ways where organizations can improve their handling of system downtimes [21]:

1. Hardware that runs applications critical to the organization's operation is duplicated
2. An electric generator and sufficient fuel are available to support the EHR during an extended power outage
3. Paper forms are available to replace key EHR functions during downtimes
4. Patient data and software application configurations critical to the organization's operations are backed up
5. Policies and procedures are in place to ensure accurate patient identification when preparing for, during, and after downtimes
6. Staff are trained and tested on downtime and recovery procedures
7. A communication strategy that does not rely on the computing infrastructure exists for downtime and recovery periods
8. Written policies and procedures on EHR downtimes and recovery processes ensure continuity of operations with regard to safe patient care and critical business operations
9. The user interface of the locally maintained backup, read-only EHR system is clearly differentiated from the live/production EHR system
10. There is a comprehensive testing and monitoring strategy in place to prevent and manage EHR downtime events.

Downtime and Post Downtime Recovery

Throughout the time that the system is unavailable, end-users must have access to the information necessary to continue patient care. Organizations handle this in several ways. Many have developed a read-only version of the production data base that can be accessed and used to review patient history, clinical notes, medication lists and administration schedules. Users need to be reminded that the read-only version may have a gap in time not accounted for if the copy-over from the production database was performed an hour or two prior to the system interruption. Other organizations rely on printouts that have been developed to capture a summary of critical patient information up to the point of the downtime. In either case, it is imperative that care providers are aware of the downtime procedures and follow them. Downtime drills that mimic a system interruption are recommended and can serve as a valuable process improvement practice to reduce potential errors [22].

Once the system becomes available, recovery should include regression testing prior to releasing the system to the end-users. As important as the technical aspects of system recovery are, the processes to recover clinical information are equally as important to ensure continuity and safety of patient care. Coordination and communication between all disciplines during and after a downtime are key to a "successful" system interruption. An example of a tool used by an organization to communicate processes to follow during and after a downtime including recovery processes can be found in Table 12.5. Care providers should clearly understand what needs to be documented into the system during the recovery phase. For example, nurses may have a policy stating that all nursing admission assessments, medications given and blood products are to be entered into the EHR once it comes back up.

Evaluating the Outcomes of Clinical System Use

The acquisition and management of CISs represent a significant portion of an organization's bottom line. Millions of dollars are invested in these systems, not just to meet meaningful use objectives for the financial incentive, but to provide a higher quality of care than paper and pencil ever could. Once implemented, administrators across the nation are asking – "Is our EHR helping us realize our organizational goals"?, "Is it reducing medication errors"?, "Is it eliminating duplicate ordering of diagnostic testing?, "Is it allowing more time for our care providers to spend with the patients?" and "Is it improving the overall health of our patients? With expertise, guidelines and tools still emerging in this area, organizations are beginning to address the evaluation of health IT with primarily trial-and-error methods.

One resource that has emerged to help drive change and make improvements is the Institute of Medicine's Learning Health System series. Knowledge contained in this series provides best practices by our nation's healthcare experts, and the common thread throughout the 15 volumes is the use of technology in driving

Table 12.5 EHR downtime processes – by department

Department (phone numbers)	How to handle routine orders during downtime	How to handle STAT orders during downtime	How to retrieve results	Who will enter orders into EHR post go-live
Laboratory Chemistry 867- xxxx Hematology 867- xxxx Microbiology 867-xxxx	Send copy of downtime order form to Lab via pneumatic tube system	Tube copy of downtime order form to lab and follow up with phone call to department.	**Routine** – Results will be delivered by messenger to units on routine rounds. **STAT** – Unit will be called with result and the hardcopy will be delivered by messenger.	Lab staff
Radiology 867- xxxx	Send copy of downtime order form to Radiology via pneumatic tube system	Tube copy of downtime order form to lab and follow up with phone call to department.	**Routine and STAT** – Clinicians can call the Radiology department or physically go to the department to retrieve results.	MD or RN
Nutrition 867- xxxx	Send copy of downtime order form to Dietary via pneumatic tube system	Tube copy of downtime order form to lab and follow up with phone call to department.	N/A	MD or RN
Pharmacy Unit Dose 867- xxxx IV Meds 867- xxxx	Tube copy of downtime order form to Pharmacy. There is a new downtime TPN (#1234) order form that will be available on all units. For Medication Replacement, make a copy of the order (whether it is from your medical care plan or on a manual form) and tube to the pharmacy.	Tube copy of downtime order form to lab and follow up with phone call to department.	N/A	MD or RN
Blood Bank/DTM 867- xxxx	Tube copy of downtime order form to Blood Bank/DTM	Tube copy of downtime order form to lab and follow up with phone call to department.	N/A	MD or RN

	Value Category (STEPS™) and Subtype	Documented Examples
S	Satisfaction: Patient; Provider; Staff; Other	Improved communication with patients; improved patient satisfaction scores; improved internal communication
T	Treatment / Clinical: Safety; Quality of care: Efficiency	Improved patient safety; reduction in medic errors; reduced readmissions; improved scheduling
E	Electronic information / Data: Evidence Based Medicine: Data Sharing and Reporting	Increased use of evidence-based guidelines increased population health reporting; improved quality measures reporting
P	Prevention and Patient Education: Prevention; Patient Education	Improved disease surveilance; increased immunizations; longitudinal patient analysis; improved patient compliance
S	Savings: Financial / Business; Efficiency Savings: Operational Savings	Increased volume; reduction in days in accounts receivable; reduced patient wait times; improved inventory control

Fig. 12.4 HIMSS Health IT Value STEPS™ (Reproduced with permission from the Healthcare Information and Management Systems Society. ©2013 HIMSS)

clinical transformation [23]. Focusing on the use of technology is one of the largest healthcare IT industry leaders, the Health Information and Management Systems Society (HIMSS). They have assembled the Health IT Value Suite; a comprehensive knowledge repository that classifies, quantifies and articulates the clinical, financial and business impact of healthcare IT investments. This collection of stories and case studies provides a consistent way to learn and communicate the real-world impact of healthcare IT, drawn from numerous value-focused, evidence-based examples of healthcare IT evaluations and uses a common vocabulary referred to as the HIMSS Health IT Value STEPS™ as seen in Fig. 12.4. As of April 2015, the collection contained 310 stories representing 56 unique benefits of healthcare IT across five broad categories. Organizations are encouraged to submit their own outcomes work to the collection so the dissemination of learning continues [24].

The Agency for Healthcare Research and Quality (AHRQ) identifies five categories where outcomes can be measured as they relate to health IT as part of their Health Information Technology Evaluation Toolkit [25]:

- Clinical Outcomes Measures
- Provider Adoption and Attitudes Measures
- Patient Knowledge and Attitudes Measures
- Workflow Impact Measures
- Financial Impact Measures

This toolkit emphasizes the importance of selecting the right measures or metrics and provides several tools to help project owners determine the best and most accessible measures to select for study. Additionally, the appendix contains multiple examples of outcome evaluation studies along with the measures that may be used to evaluate a project [25].

In addition to AHRQ's toolkit is the Guideline for Good Evaluation Practice in Health Informatics or GEP – HI developed by Nykanen et al. [26] 60 areas are identified in these guidelines that are of potential relevance for planning, implementation and execution of an evaluation study in the health informatics domain. These areas cover all phases of an evaluation study: Preliminary outline, study design, operationalization of methods, project planning, execution and completion of the evaluation study. Issues of risk management and project control as well as reporting and publication of the evaluation results are also addressed [26]. Organizations can use this resource throughout the evaluation, from planning to knowledge dissemination.

In *Conducting Quality Healthcare IT Outcome Evaluations: Guidelines and Resources,* Sengstack (2015) provides a step by step guide to walk informatics specialists through an outcome evaluation project including the broad categories below followed by a description of each [27]:

- Identify the area of focus for the evaluation
- Determine the problem under study and the evaluation question
- Review the associated literature
- Identify the appropriate data to be collected
- Determine the type of study
- Determine the data collection method and sample size/date range
- Collect and display the data
- Document and disseminate results

Identify the Area of Focus for the Evaluation

Prioritize a list of potential topics to evaluate as a first step in any evaluation program. Generate initial ideas with the organization's key stakeholders at the table so this important work supports the organization's mission and goals. Brainstorming as a group to generate a potential list of areas to evaluate followed by voting using a nominal group technique can be effective in making decisions regarding where to start.

Determine the Evaluation Question

Determine the question that will lay the foundation for the entire evaluation. A clear, focused question helps the team determine what data will need to be collected and how it ultimately should be reported. Examples of questions that can be asked include:

- Has duplicate ordering of chemistry labs been reduced since duplicate order checking functionality was implemented?
- How many patients have entered blood glucose readings into their patient portal over the last 6 months?
- Do patients who enter their blood glucose readings into their patient portal have better control over their diabetes than patients who do not use a patient portal?

- Has implementation of the sepsis alert in the EHR resulted in improvements in timeliness of antibiotic administration for patients determined to be at risk?
- What is the estimated amount of financial savings if automated report print-outs were reduced by 50 %?
- Have the new admission assessment screens resulted in timesaving and improved support of workflow for nurses?
- Do patients who have scored higher than 20 on the electronic Risk for Readmission tool have a follow-up appointment scheduled with their physician within 72 h of discharge?

Review the Associated Literature

Conduct a literature review. There may be others who have studied this question in the past and evidence may already be published that answers the question. Searches should be conducted in peer reviewed journals by searching available databases such as CINAHL, PubMed and Cochrane Reviews.

Identify the Appropriate Data to Be Collected

Determine the specific data elements to be collected. For example if your question is "how many patients have accessed laboratory results via their patient portal over the last 6 months?" then you will want to collect and/or consider the following:

- Number of unique patients who have accessed results via their patient portal in the identified time frame
- Number of times each individual patient has accessed their lab work via the patient portal
- If a percentage is desired, then a count of all patients who have a patient portal account set up would be needed as the denominator and the numerator would be those who have reviewed labs during the identified time frame
- If a percentage of the organization's entire population is desired, then a count of all patients with an encounter would be needed as the denominator and the numerator would be those who have accessed the portal and reviewed their labs during the identified time frame
- Demographics on the patients who have accessed their lab work (age, gender).

Determine the Type of Study

While the gold standard and most rigorous studies are felt to be randomized controlled trials, these are difficult to conduct in the area of health IT. The majority of studies that evaluate outcomes of health IT are descriptive studies or comparative studies over

time, i.e., pre-post studies. They usually document study limitations and most note that generalizability is not practical due to the heterogeneity of systems. Keeping it simple, clear and straightforward is key to not only ensuring that the evaluation can be conducted, but that the information gleaned from the assessment can easily be disseminated to an audience that can take action on the results. If you want to make comparisons between two similar groups, and are not sure which comparative statistics would be best, it is recommended that a statistician is part of your evaluation team [27].

Determine the Data Collection Method and Sample Size/Date Range

At this point of the evaluation, you may already have an idea of how you will obtain the data. In this step, the exact method to be used to attain the data is clarified. Whichever method is selected, ensure key stakeholder consensus on both the type of data and the collection method. Data can be obtained to answer an outcome question in a number of ways:

- Data may already be available in the EHR (or other database), and you will need the assistance of someone skilled in running a query or developing a report
- Manual chart review
- Observe end-users as they interact with the system
- Conduct a survey
- Convene a focus group

Collect and Display Data

Once data has been collected over the agreed upon time frame, it will need to be presented and displayed in a format that can be comprehended by multiple audiences. Data that represents the results of an outcome evaluation must contain all of the information necessary for interpretation. Data can be displayed in graphs, charts and/or tables. Each of these should include: a title with date range and sample size as appropriate, legends that clearly explain the content and colors, labels on the x and y axis so the numerical value can be understood, and any other descriptors necessary for interpretation.

Document and Disseminate Results

Writing up your evaluation and potentially submitting for publication is the last step in the process. Without comprehensive documentation of your study, the chance that any practice improvements will occur becomes unlikely. Talmon et al. [28] in their

Statement on Reporting of Evaluation Studies in Health Informatics (STARE HI) recommend the following headings in a health IT evaluation report: Title, Abstract, Keywords, Introduction, Study Context, Methods, Results, Discussion, and Conclusion. Utilizing the STARE HI guidelines for each of these sections of a health IT evaluation study will add strength and rigor, improving chances of publication and enhancing the business case for health IT.

As the U.S. federal government's Meaningful Use program begins shifting toward a more outcomes focus in Stage 3, we will not have a choice but to focus on outcomes. Learning how to conduct these types of studies becomes imperative as evidence is created, disseminated, and applied to practice.

Emerging Trends

As clinical organizations adopt new information systems to support care delivery processes, they establish a foundation for a learning health system that supports continuous quality improvement. In the most recent draft of the Federal Health IT Strategic Plan for 2015–2020, the first objective lists the need to increase the adoption and effective use of health IT products, systems, and services [29]. The strategies to meet this goal include expanding the capacity of the workforce to support the use of health IT and identifying and promoting proven practices in the development, design, purchase, tailoring, and deployment of health IT. With less painful implementations and with system usability improving, we'll begin to focus more on the benefits and value proposition of clinical systems than on their installation and management.

Innovative strategies to train the growing health IT workforce are emerging and are moving from the traditional classroom setting to more on-line interactive training. This trend is not only occurring in academic institutions but within healthcare organizations themselves. With many organizations spanning multiple states, the logistics of classroom training is challenging. Use of synchronous and asynchronous training methods using available technology is evolving along with the use of simulation training for more complex healthcare situations. At Oregon Health & Sciences University, an EHR training platform identical to the live, production system, learners review and correct a simulated medical chart for a complex virtual patient with chronic diseases and years of fragmented care [30]. At Bon Secours Health System in Richmond, Virginia, nurses train and assess system usability in a simulation lab complete with a training EHR system and a manikin for the complex task of the administration of blood products [31].

In addition to improving organizational capabilities, and skills in overall system implementation and management, automated tools are emerging for many repetitive health IT related tasks. Applications to conduct various levels of system testing are now available and can be used to conduct regression testing as well as performance testing. Vendors continue to evolve their automated testing tools, making them increasingly user friendly and moving them more into mainstream use [32–34].

Lastly, government and industry leaders are beginning to assemble better tools for organizations to measure health IT's effectiveness. The 2015–2020 Federal Health IT Strategic Plan emphasizes the need to invest, disseminate, and translate research on how health IT can improve health and care delivery. In addition to the HIMSS Health IT Value STEPS™ initiative mentioned above, the Agency for Healthcare Research and Quality has collected and published several quick reference guides for key evaluation areas including the: Impact of Health IT on Nurses' Time Spent on Direct Patient Care; Percentage of Alerts or Reminders That Resulted in Desired Action, and Prescribing Patterns of Cost Effective Drugs [35]. It is hoped that the evaluation methods described in these tools will be adopted as organizations begin establishing strong programs to assess health IT effectiveness. Without strong evaluation programs it will be a challenge to determine if clinical systems are truly improving the health of our nation.

Summary

Clinical information systems large and small are continuing to pervade healthcare. Organizations are counting on these technologies to assist in meeting the Institute for Healthcare Improvement's goals for the triple aim: to improve the patient experience of care; improve the health of populations; and reduce the per capita cost of healthcare [36]. Implementation and management of these systems requires the combination and coordination of people, processes and technology to ensure that organizations can realize the many benefits that are available with an optimized and well managed system. From selecting the right system, through all phases of the SDLC, the expertise with the right skill set, following the right processes is essential to success.

Application Exercise/Questions for Discussion

1. An infection control practitioner approaches you and explains how difficult it is to manage their patients who are on antibiotics. She wants the organization to consider the acquisition of a new infection control/antibiotic stewardship clinical system. What would be your first steps as an informatics specialist in a multi-hospital healthcare system?
2. When developing a Request for Proposal, why is it important to develop a thorough list of functional requirements?
3. During planning for an EHR implementation an organization's informatics and technical teams decide the go-live date will be on October 15th at 12 noon. Would you have any concerns with this? If so, why?
4. When designing end-user training for a new clinical system, the team neglected to include a plan to evaluate the training sessions. Is this component necessary? Why?

5. Your organization just went live with a new EHR yesterday. You are making rounds on the clinical units and visiting physician offices to provide support. Several end-users have requested changes be made immediately. How would you respond?
6. Which type of clinical system testing should include the end-users and why is it so important?
7. Discuss some of the potential issues that may occur without an organizational Change Control Board or standardized processes in place for system changes.
8. A system interruption has resulted in an unexpected downtime. You are asked to make rounds on the patient units to ensure care providers know what to do. What kinds of things will you be assessing as you make your rounds?
9. As part of an evaluation study for a clinical system, you are asked to present the findings and the data to a group of administrators. What will you be sure to include in your data graphics?
10. An organization is concerned that medication errors are on the rise despite the fact that bar coding processes are in place and integrated with the EHR. What are some of the initial questions you should ask as part of the evaluation process?

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Chapter 13
Human Factors Engineering and Human–Computer Interaction: Supporting User Performance and Experience

Richard J. Holden, Stephen Voida, April Savoy, 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 important to the success of clinical informatics.
- Identify models, theories, and principles of HFE and HCI that can be used to design and evaluate a range of 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).

Core Content

- Human factors engineering (HFE)
- Models, theories, and practices HFE and human–computer interaction (HCI) domains
- HFE and HCI principles of design and evaluation for usability

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- HFE and HCI methods of design and evaluation for usability
- The nature and cognitive aspects of human decision making
- Quality and safety issues related to user interface design
- Human and social issues in clinical informatics design and evaluation

Key Terms

- Human–computer interaction (HCI)
- Human factors engineering (HFE)
- Usability
- Usability engineering
- Usability heuristics
- Usability testing
- Use case scenarios
- User-centered design (UCD)
- User experience
- User interface
- Rapid prototyping
- Sociotechnical systems

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 was designed by an artistically gifted graphic designer.

Dr. Davis appreciates a good-looking display but notices a slow-down in her work as she starts to use the EHR 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 graphs but her clinic has disabled printing in an effort to "go fully paperless." Dr. Davis has also stopped using the graphic icons for shortcut commands after having clicked one (a computer with green checkmark) that logged her out of her session and another that looked like a standard web browser

"refresh" button but that actually wiped and restarted her complex clinical note. The buttons are meant to save time, so they lead to actions directly, without a confirm-or-cancel prompt.

When entering orders, Dr. Davis finds herself doing a lot of typing. The auto-complete feature under medication orders is helpful, but 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 '40 mg orally once daily' 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 name 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 will 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 a product can be used by specified users 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. 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 the case vignette of Dr. Davis. 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, there is an emerging literature on how to apply these principles and processes to health IT [6, 8–10].

Putting HFE and HCI in Context

Table 13.1 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 [11].

HFE and HCI Models

A general type of contemporary HFE/HCI conceptual model is a *sociotechnical systems model* or *work system model*, which depicts the interactions between people and other social, technical, and environmental elements. Figure. 13.1 depicts one such model [12]; for others, see Carayon [13]. Four main points regarding technology can be gleaned from the model in Fig. 13.1:

Table 13.1 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" [78]. HFE is systems-oriented, design-driven, and has a dual goal of improving performance and wellbeing [79].
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" [80].
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 [36] decomposes usability into the system's learnability, efficiency, memorability, error avoidance and recovery, and satisfaction of use; others add usefulness, effectiveness, and accessibility [81]. 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, 82]. 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 [15, 54].
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) [30].
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.

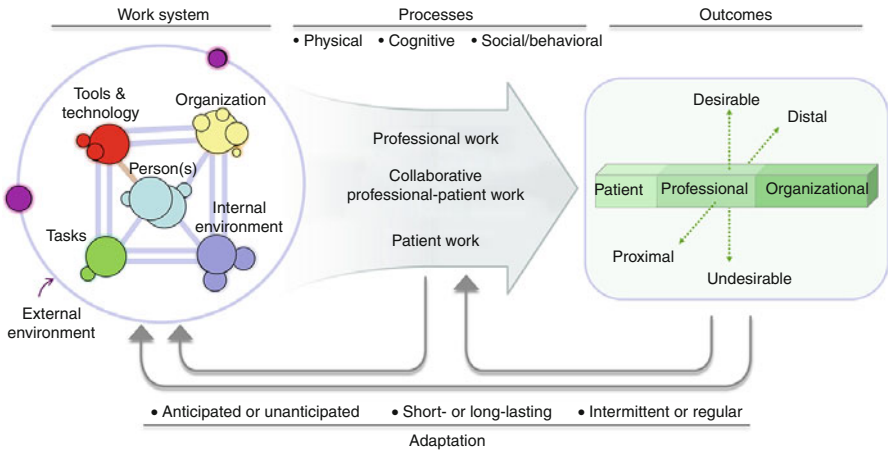

Fig. 13.1 SEIPS 2.0, a sociotechnical systems model developed for healthcare [12]

- **A system is comprised of many components**: technology use occurs in context [14].
- **The elements interact**: the person-technology interaction is key, not 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 [15].

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" its users [16]. 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 [17]. Based on these models, techniques like the keystroke-level model [17] and the GOMS ("Goals, Operators, Methods, and Selection rules") family of analysis techniques [18] were developed to enable usability engineers to decompose a person's use of an interactive system into the smallest possible 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. Evans 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 ways to use a system; the outputs from these techniques can be used to quantitatively compare different use strategies or designs.

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 [19, 20]. 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 [20]. Figure. 13.2 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 that is 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 [20]. Mental models are fairly stable individual people's representations of how the world works or how specific objects in the world work [21]. 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 really are.

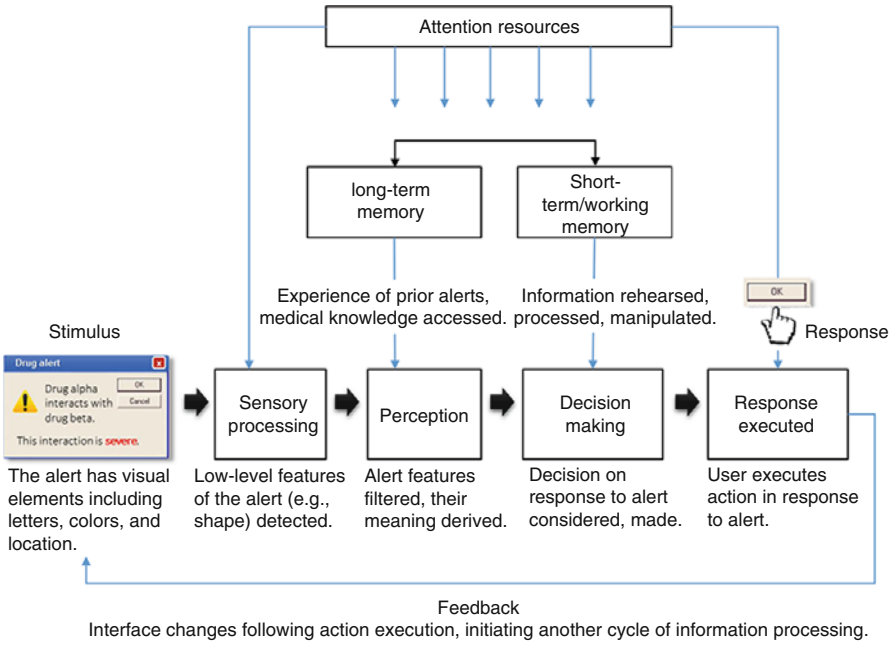

Fig. 13.2 Information processing model applied to clinical informatics [20]

- 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 means that something is "loading/not ready"), confusion ensues and usability suffers [22].
- 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 capacity of the finite and time-limited short-term memory. This can result in errors in cognition and is prevented by presenting familiar information, reducing memory load, or not requiring memory use and instead making more accessible any information that needs to be used. Furthermore, cognitive processes and especially short-term memory are susceptible to failure when attention is drawn away or, in a finite-resource depiction of memory, "depleted."
- The last stage in information processing is usually the execution of a decision through action. Actions can be verbal or physical, with the latter being the most common way to act on health IT. The time it takes to carry out an action in a user interface is described by the Hick-Hyman Law and Fitts's Law. The Hick-Hyman Law states that given the rate of human information processing, the time to decide and act on something (e.g., click on the right link) increases logarithmically with each added object (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. Fitts's Law states that the time to move to an object

(e.g., move a mouse cursor to the button) increases logarithmically as distance to the object increases and the width of the object decreases. 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 [23, 24] *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 successfully bridge a "gulf of execution." 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 [9] TURF framework is grounded in HFE/HCI but created specifically for EHR system usability. It defines EHR system usability as the degree to which an EHR system has the potential to be useful, usable, and satisfying when used for clinical care. Usefulness refers to whether the EHR system has functionality to support the requirements of its users' work. Usability refers to the EHR system's learnability, 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 evaluation 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 user-centered design principles, including:

- Designs are based upon an explicit understanding of users, tasks and environments;
- Users are involved throughout the design and development process;

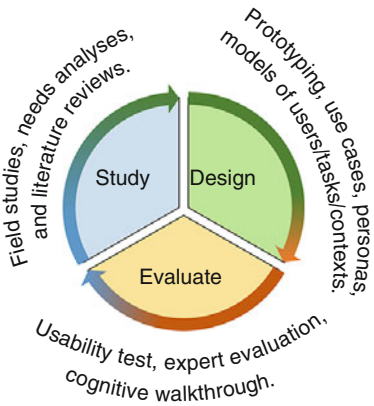

Fig. 13.3 Three broad, iterative phases of user-centered design and specific activities

- 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 serve to define the *process* by which HFE and HCI practitioners structure their work. Other articulations of this process [20, 25–27] characterize the UCD design process as an ongoing cycle (see Fig. 13.3):

- First, 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 [28]. 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" [29], or—in many cases—some combination of these techniques [30].
- 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 [29, 31], to more traditional artifacts, such as sketches, "wireframe" user interface mockups, storyboards, physical prototypes, video walkthroughs, simulations, or early system implementations [32–34]. During 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) [35].

- Finally, practitioners transition to *evaluating* the designs. There is a variety of approaches to evaluation based on objectives, design iteration, participants, and tools. The UCD process encourages the involvement of users at the earliest possible point of the design process. Sometimes, HFE/HCI professionals carry out the evaluations themselves, called "expert review," assessing the usability of the designs based on established heuristics or principles [36]. Experts can also conducting low-level "cognitive walkthroughs" that model users' likely mental goals at each step of a system interaction [37]. In other cases, practitioners show the designs (or, in some cases, deploy the partially- or fully-implemented systems) to people who will be representative of the final system's users, with the goal of eliciting 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 that it takes 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 the one they prefer or would most likely use, then probe about how they arrived at their choice. In tests of interactive systems, usability professionals can track eye movements and key strokes. 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 with respect to scheduling and travel, the remote usability testing option is gaining momentum in healthcare [38]. It allows users to participate in evaluations without leaving their desks and lets them use their own hardware.

Of note, the National Institute of Standards and Technology (NIST) provides a template for reporting the results of EHR usability tests [39], based on the ISO/IEC common industry format [40]. Furthermore, there are several measures for user-reported subjective usability, such as the System Usability Scale [41]. The outcome of the evaluation phase often helps to refine the practitioners' *understanding* about 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 life-cycle, or as early as possible, compared to late in the cycle (e.g., after it has been engineered) [42]. However, a recent 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, and a final third mischaracterized UCD as responding to post-market end-user requests for changes [43].

In some cases, the UCD team involves the end users of a system. This approach, known as *participatory design*, originated in Scandinavia as a way to ensure that users would be empowered in the design, development, and deployment of new workplace technologies [44]. In participatory design, users actively contribute as co-designers of a system, often through a series of 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 to 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 [45], technology-supported standardized nursing documentation [46], web-based observational tool for detecting intravenous medication errors with smart infusion pumps [47], and public health informatics projects [48, 49]. Participatory design is a promising concept whose practices and challenges should be more systematically articulated for clinical informatics [50].

HFE and HCI Principles for Design

HFE and HCI experts have developed several principles or heuristics for good design that apply across products and interfaces. Table 13.2 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. An application of these principles to health IT is illustrated in a recent review of medication safety alerts [51]. Some of the principles are also clearly violated in the case vignette of Dr. Davis, 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 not only violates the principles of how humans think and act but also clinical cognition, or how doctors think and act [52]. Health IT that does not accommodate clinical cognition or workflow can create serious risks and promote workarounds [53–55].

Table 13.2 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 [9, 36, 83–86]

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 [20, 56]. Nevertheless, healthcare delivery involves goals, actors, procedures, and constraints that pose particular design challenges, discussed elsewhere [52, 57]. Healthcare delivery and clinical informatics have its own standards, requirements, terminologies, and regulations, among them 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 that of patient or family member, with multiple professions sometimes using a single system. Users also tend to be professionals and may have trained in different institutions with different IT systems. The working conditions of clinician users are also unique, in that learning is often practice-based, residents' duty hours are restricted, time pressure can be very high in certain settings, and co-workers are often separated by time and space. The same clinical informatics systems are also used for both daily, high-frequency and low-risk activities and in infrequent and high-risk scenarios. Thus, they must be designed to balance efficiency with the prevention, detection, and remediation of 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. 2 and 18) 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 issues of change management, implementation planning, and the interaction between social and technical aspects of usability [58–60].

Additional HFE and HCI Resources

The history of HFE and HCI and its products spans over 70 years and interested readers will find many excellent accounts of the history, science, and practice of these fields [20, 36, 61–63]. Table 13.3 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*. Models of team-based care such as the patient-centered medical home (PCMH), coordinated care, and team-based primary care are widely-promoted but variably applied [64, 65]. 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 [66–68]. However, design and testing for usability usually

Table 13.3 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. [87, 88] and McDonnell et al. [89].
Books and journals
Books on EHR usability [10, 90]
Books with comprehensive content on usability and HCI [83, 91, 92]
"How-to" books to guide usability testing [36, 81]
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 [93]**)**
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) 10x10 Course on Healthcare Interface Design

considers individual needs and involves individual end users, as opposed to teams. Clinical informatics systems are often designed for either physicians *or* nurses *or* pharmacists *or* technicians; future design and evaluation should consider clinical information systems and usability for physicians *and* nurses *and* pharmacists *and* technicians *and* others. This will mean more consideration of *shared* and *collaborative* tasks, workflows, technologies, training, infrastructures, and policies. Challenges include improving communication aspects of health IT, managing changes in user roles, and addressing the issue of responsibility for shared data [54, 69].

The second trend can be called *personal and connected health informatics*. With increasing involvement of patients and families in their own care [70], there has been both a rise in and need for patient and caregiver use of information and

informatics systems [71]. For additional detail on the evolving role of patients in their own health and emerging patient- and caregiver-facing information systems, see Chap. 19. Unfortunately, few technologies of this kind are developed using UCD practices and HFE/HCI principles, which jeopardizes their usability and results in lack of overall use and system abandonment after an initial period of use [72]. 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 [73]. The recently announced alliance between Apple, Epic Systems, and Mayo Clinic notwithstanding, personal technologies are not currently integrated into clinical care. Therefore, a major 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.

The third trend is that of *mobile health (mHealth) and ubiquitous health (uHealth) informatics*. Trends in mHealth, in particular, can have an influence on usability, as clinicians are now using EHRs and other informatics systems on not only laptops but other mobile devices such as smartphones and tablets. Compared to the desktop computers for which many clinical informatics systems were originally designed, mobile technologies have different input modalities, operating systems, connectivity options, and contexts of use, requiring additional usability considerations. The mHealth trend is coincident with a rising "app culture," highlighted by Epic Systems' 2015 announcement of its "app store," App Exchange. 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. At this point, the majority of the concerns with the integration of mobile devices and apps in clinical workflow have focused on infrastructure and security. Beyond those concerns, there are challenges to obtain a better understanding of the impact that 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 speed and accuracy of data entry. 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 fourth 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 the contribution of not only expertise from data sciences but also 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 13.2 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 but humans are responsible for evaluating patterns and making decisions [74]. 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 organizational human factors or "macroergonomics" [75, 76].

Summary

If the purpose of clinical informatics is to improve clinical care, then it must support, be usable, and be satisfying to the individuals who actually 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 [77]. However, various health IT systems, including EHRs, have come under criticism for usability problems, reducing efficiency and productivity, and disrupting established patterns of workflow. 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 UCD to improve the usability of clinical informatics systems and to 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 and that future generation of health IT users will enjoy improved performance and user experience.

Questions for Discussion

- Can usability as defined by HFE and HCI be achieved simply through displays that are pleasing to the eyes, or must goals besides aesthetics be met?
- 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?
- A hospital wants to create a dashboard to track the recommended care that patients have received versus care that is pending our overdue. Apply the three phases of the UCD process, including specific steps, to the design of this system.

- What are the HFE and HCI considerations for a new implementation of a suite of desktop and mobile technologies intended to improve collaboration between nurses, physicians, retail community pharmacists, patients, and their family caregivers, for managing chronic disease?
- Given that UCD requires designers to take into consideration the needs of end users, what are the approaches to ensure that user needs are appropriately understood and addressed?
- Examine a user interface and identify ways in which elements of the interface comply with or violate HFE and HCI principles for good design.
- 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 IV
Leading and Managing Change

Chapter 14
Leadership Models, Processes, and Practices

Robert C. (Bob) Marshall

Objectives

Provide up to date and in-depth information on the following topics to assist prospective candidates to both pass the CI Board Exam, and provide a level of understanding that will allow someone reading the chapter to implement a better level of leadership and management in any CI or CXIO position. Topics covered include:

- Leadership vs Management; Leadership Models;
- Dimensions of effective leadership;
- Strategic, tactical, analytical and innovative thinking for leaders;
- Analytical and critical thinking; Understanding, surviving and changing organizational culture; Governance (e.g., processes; responsibility versus authority);
- Negotiation; Conflict management; Collaboration; Motivation; Decision making and accountability; Communication and leadership; Emerging leadership trends.

Core Content Covered

4.1. Leadership Models, Processes, and Practices
4.1.1. Dimensions of effective leadership
4.1.2. Governance (e.g., processes; responsibility versus authority)

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4.1.3. Negotiation
4.1.4. Conflict management
4.1.5. Collaboration
4.1.6. Motivation
4.1.7. Decision making

Case Vignette

George Linksys has been splitting 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 budget restrictions brought on by changing reimbursement, he has to consolidate his department and reduce staffing to twenty-four. He has also been assigned to develop and implement a governance process that will require all departments to submit new software application requests, as well as 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. In addition, some of the new responsibilities are quite different than what people in his department have done in the past. This will require solid leadership skills to ensure success for everyone, including the organization as a whole.

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 common 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

Table 14.1 Summary table comparing leadership and management traits/behaviors

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

From Ref. [4]. Used with permission from Lee Candy/Educational Business Articles

Leadership vs. Management

Management is a set of well-known, well-defined processes, such as planning, budgeting, structuring and 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 to produce products and services of consistent quality, on budget, day after day, week after week. This is a difficult, complex task, but it is not 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 Table 14.1 for a summary comparing leadership and management traits/behaviors [4].

Leadership Models

Leadership models may be defined as guides that suggest specific leadership behaviors to use in specific environments or situations. There are multiple leadership models in the literature with various levels of research and internal/external validity 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 leader model is the team leader, who is both strong on task and on 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 reach goals as effectively as possible, while also working hard to strengthen 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 more punitive coercive or legitimate power for fear of jeopardizing relationships.

The impoverished leader uses a "delegate and disappear" style, and they show almost no commitment to either task accomplishment or relationship maintenance. They pretty much allow their teams to do whatever they want. Blake and Mouton emphasize that the team leader model is preferred, but allowed that situational use of the other models might be appropriate in specific settings [5].

Situational Leadership

That brings us to the next leadership model, that of Situational Leadership, which was originally developed in 1977 by Paul Hersey and Ken Blanchard. It 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 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 on-going assessments of

the employee's abilities as new tasks are assigned or situations arise. The goal is to provide the needed level of 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 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 direction and support as needed [7].

USE Case Example
George has studied different models of leadership, and he feels that situational leadership best fits for 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 each task. This will allow him to better allocate both his time and personnel resources to successfully 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 by one 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 in order to reach an agreed upon goal, but doesn't 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 the strengths of followers, 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 fulfilment in meaningful work [10].

Use Case

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 both supported and valued by focusing on their success and their personal needs to be successful.

Action-Centered Leadership

The next 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 behaviours that assist/support people or a group perform 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, but adds a results element onto the foundational elements of individual, team and task. The results element is added to emphasize leadership's responsibility for measurable outcomes in healthcare, which includes patient outcomes [12].

Healthcare Quality Professional Leadership Development Model

The National Association for Healthcare Quality published a leadership model in 2008 that is 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 models of healthcare and wellness. 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 those of 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 and 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, there are numerous theories that 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 or risk
5. Managing Energy: sustaining the energy that is the life force of change

Of these five dimensions, McKinsey's research has shown that meaning has the most significant impact on work and life satisfaction. In fact, 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. In this theory, the eight dimensions are pioneering, energizing, affirming, inclusive, humble, deliberate, resolute and commanding [18].

The authors state that all leaders need to be able to stretch beyond their primary leadership dimensions to have their greatest impact, and they need to understand how their individual 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 quite generalizable to other fields, including clinical informatics [19].

One very important 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 be broadened to include complementary dimensions. Reeves argues that leaders need not, in fact cannot, be every dimension themselves. However, the effective leader can and must ensure that every leadership dimension is provided by some member of the leadership team [19].

The leadership dimensions included in this model are visionary, relational, systems, reflective, collaborative, analytical and communicative [19].

While the book goes into great detail and provides the research behind each dimension, most are superficially self-explanatory except for the systems dimension. 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 in a manner that enables each member of the

organization to understand and consistently use these important interconnections. Systems leadership is not just about complexity. The greater challenge is converting that complexity into simplicity for others to understand and act upon [19].

Strategic/Tactical/Analytical/Innovative Thinking

It is important to have a deliberate, systematic process for making decisions and managing work to guide individuals, teams and organizations towards desired outcomes. Those decisions have to 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 [20].

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 long-term development of people. Using strategic thinking allows for systematic and efficient strategic planning for the organization, teams and people [20].

Strategic thinking and strategic planning, while complementary, are not the same thing. F. Graetz created a model that helps to define the differences. She said that the role of strategic thinking is "to seek innovation and imagine new and very different futures that may lead the company to redefine its core strategies and even its industry". Strategic planning's role is "to realize and to support strategies developed through the strategic thinking process and to integrate these back into the business" [21].

Liedtka observed five major attributes of strategic thinking that resemble competencies.

These five attributes/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 incorporates scientific method into strategic thinking.
5. Intelligent opportunism – being responsive to good opportunities and not losing sight of alternative strategies as they present themselves [22]

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 takes into account the preparation/level of effort needed to reach the long-term goals. Tactical thinking is more immediate or "in the moment", often safe and conservative and status quo maintaining. It looks for the immediate payoff and involves automatic and routine execution of a task. It is the immediate "what to do and how to do it" mode of thinking [20].

A number of 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 – fairly rare; this occurs when managers make tactical decisions counter to strategy because they do not accept the strategy and 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 current strategy is a tactical error [23].

Use Case

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 as a whole) is dependent 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 both his departmental mission and that of the organization as a whole. Creating such a plan allows George to work with other department leaders to harmonize their individual department strategic plans by focusing on the organizational mission (shared values).

Analytical/Critical Thinking

Analytical thinking skills are critical because they help one to 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 so one can understand when to think critically and when to think analytically [24].

When thinking critically, one makes the decision 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 [24].

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 [24, 25]:

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 creative 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 as creative thinking and applying them to practical solutions [26].

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 important, communicate those ideas to our consciousness and provide an innovative solution [26, 27].

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 a set of questions, the 5 W's and the 1 H, to help trigger ideas and solve problems. The Problem Statement method is self-explanatory, but not easy to accomplish in many cases. This method works when everyone identifies what the problem is for them and then collaborate/negotiate 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" [26].

There are a number of 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 [26, 28].

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 attribute; and modify the attributes to increase value, reduce negative value or create new value [26, 28].

Brainstorming, also called "Classic Brainstorming", became popular in the 1950s as a way to come up with new ideas. There have been various versions developed since in an effort 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 [28]:

1. Arrange the meeting for four–eight 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 vision works for them as well. Visioning works because humans are an imaginative species and are motivated by what we perceive as a possible and/or desired future [26].

Use Case

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 come up with 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, and 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 and minimize conflict.

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 [29, 30].

The seven characteristics of organizational culture are [29]:

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)

In order to implement change in an organization, which informaticists must do on a regular basis, it is critical to first understand the organizational culture. Here are some basic guidelines to help with that task [30]:

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? This would be things like problems, successes, crises, etc.
   (d) How are decisions made? Are they made by one person, by 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 compared to what is actually seen by others within and outside the organization. This is a common disparity, and can create internal confusion. It is important to discuss this disparity with other, trusted leaders. An ideal time is during strategic planning discussions [30].

Changing the culture of an organization is never easy, but it is possible. The best and most enduring method to change organization culture is to change behavior, not by changing structure. In order to change behavior, one must change the underlying mechanism that drive existing behavioural 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 [31].

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 modelling and emphasizing what's important in terms of desired social values
   (b) Symbolic action – actions speak louder than words; it is the actions of leaders that let the organization know what is valued and what is not. Reward members whose behaviors reflect what is important, and discourage behaviors that do not reflect what is important 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 [30, 31]
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 do 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 [31].

Use Case

While Health IT, clinical workflow analysis and implementation are already components of the organizational culture, governance is not. George is going to 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 both prioritizes and ensures compatibility of the system. 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 process 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.

Governance (e.g., Processes; Responsibility Versus Authority)

Health IT governance can be defined as putting structure around how organizations align Health IT strategy with business strategy, ensuring that they stay on track to achieve their strategies and goals, and implementing good ways to measure Health IT's performance. A Health IT governance framework should answer some key questions, such as how the Health IT (Clinical Informatics) department is functioning overall, what key metrics management needs and what return on investment Health IT is providing to the organization from its investments [32].

Health IT governance is important for the following reasons [32, 33]:

1. Confers legitimacy on decisions
2. Standardizes processes
3. Shapes expectations
4. Ensures benefits are achieved
5. Aligns strategy
6. Provides input to capital budget process
7. Provides Health IT demand management
8. Provides Health IT portfolio management

One of the first steps in creating a functional governance process is to create a governance or steering committee. The governance or steering committee should govern all Health IT or all IT projects. If the latter, it will likely be chaired by the CIO. If the former, it will likely be chaired by the CMIO. Regardless of the Chair, the committee needs to include a senior financial person, a C-Suite level management person, a senior IT person, senior nursing leadership, a building services executive, senior ancillary services representatives (Rads, Pharmacy, Lab), senior medical staff and independent providers. This level of participation provides legitimacy and decision-making authority [33–35].

The governance or steering committee is the ultimate decision authority, but much of the baseline work is performed by area-focused subcommittees or advisory groups. These groups provide an easily identified place for concerns about existing systems. They can also originate projects or ideas for projects. Their most important role, however, is prioritization of projects within their purview. In smaller organizations, there may be a single subcommittee that reviews and prioritizes all project submissions. In that case, the subcommittee/advisory group needs broad representation from across the organization as well as Informatics and IT advisors. For larger organizations, there may be a subcommittee for each of the major areas, such as, providers, nurses, ancillary services, HIM (Health Information Management), patient billing/finance and business intelligence [33–35].

One of the key roles of the governance or steering committee is Health IT portfolio management. This is informed by both the CIO and the CMIO, and the CEO or CFO have the C-Suite responsibility, but the governance/steering committee

makes the decisions. This is a critical role for the governance committee, as portfolio management is needed to balance and prioritize new projects/investments with the operating costs of existing systems, as well as the costs associated with transitioning from existing systems to new systems. [35]

Portfolio management consists of the following components [35]:

1. Establish and maintain a portfolio of new and existing IT/Health IT capabilities needed to achieve business goals
2. Build a portfolio that recognizes the variety of investment categories that differ in complexity and degree of freedom in allocating funds
3. Aligning the portfolio with the strategic direction of the enterprise
4. Have evaluation criteria in place to include:
   (a) Alignment with enterprise strategic objectives
   (b) Financial worth
   (c) Delivery risk and benefits risk
5. Implement a decision-making process to prioritize allocation of resources for operations, maintenance and systems development

Use Case

George is well aware of the pitfalls of governance. The most common being that governance can become an obstruction to innovation and competitive "nimbleness". Governance, in George's mind, should both facilitate innovation and ensure alignment with the organizational strategic plan for any Health IT software or hardware with software interfaces. To best accomplish this, George creates a governance committee comprised of 1–2 senior leadership members (at least one of whom is the governance sponsor) and the department heads from all of the major departments in the organization. He also creates focused subgroups to review and present new submissions to the whole group. It is the whole group that decides what gets prioritized and purchased with an organizational focus and shared goals. The groups to be represented include, but are not limited to, providers, nurses, ancillary services (lab, rad), pharmacy, IT, facilities, HR, Finance and HIM. In some organizations, this group may also be the Informatics Committee. In other organizations, the Informatics Committee is one of the subgroups for the Governance Committee, though the Informatics Committee's scope does not include just governance-related topics.

Negotiation

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 [36].

Barriers to negotiation [37]:

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 [38]:

1. Background homework: before negotiations begin, understand the interests and positions of the other side in relation to your own. Look at things from the other side.
2. During the process, don't negotiate against yourself: especially true if you do not fully know the other side's position. Stay firm on your initial set of 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 a number of negotiating pitfalls to avoid. A list of seven common ones are [39]:

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 fully. 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 have a clear understanding of 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 [40, 41]:

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.

Use Case

As stated above, George is faced with both 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 own 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 to get 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 publicly support the governance model in an attempt to create openings for negotiation with those most opposed to the governance model.

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 [42]

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 [43–45]:

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 mutually and completely 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 [43, 46–48].

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 important 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 offer a quick resolution 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 clear advantage to waiting for conflict resolution. Too often, avoiding results in worsening of the conflict and increasingly strained relationships. If the issue is important, or even moderately important, to either party, avoidance is a poor strategy [43].

Use Case

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 has to let go. 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 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, as 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 in order to successfully manage it. Here again, shared organizational values can help find common ground as a way to overcome conflict.

Collaboration

According to Baggs and Schmitt (1988), collaboration involves coordination of individual actions, cooperation in planning and working together, sharing of goals, planning, problem-solving, decision-making, and responsibility. Collaboration can happen between two people who represent the same or different disciplines, or among small groups of people representing one or a range of disciplines [49].

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 [50].

Leadership is a key ingredient in effective collaboration, be that the leader of a team or the leader of an entire organization. Some of the key leadership skills for effective collaboration include the following [50]:

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 key 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 a variety of reasons, will stay in a collaborative environment where they are challenged (in a good way) to grow both personally and professionally. There are several habits that have been shown to create such an environment of collaboration within an organization [51, 52]:

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

Motivation

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 to make an effort to attain a goal [53].

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 led to the idea that workplaces are social environments, where people are motivated by such things as recognition, security, and a sense of belonging vice purely economic interests or the physical environment [54].

Since the Hawthorne experiments, multiple theories have been developed in an attempt to better characterize motivation. Each has strengths and weaknesses. Each has

limits in generalizability. What is fairly 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 as well as the goals and aspirations of the individual (achievement, possibility for growth, social relationships, etc)
2. Extrinsic factors – depend on the surrounding environment or basic human needs (salary, office space, responsibility, etc) [54]

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 [54, 55].

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 [54]:

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 relies on different assumptions. In this theory, there are factors that increase motivation (motivators) that align with intrinsic factors. There are also factors that 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 [54].

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 [55]:

- 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 achievement itself is an intrinsic factor.

In general, intrinsic factors tend to be much more effective then extrinsic factors in motivating people, at least within the workplace [54].

Use Case

George is faced with the spectre of having to downsize 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 and critical thinking as well as conflict management. Through all the changes, one component that must be maintained is motivation. George has to motivate his people to maintain morale and assume greater roles and responsibilities at the same time they are seeing their co-workers be retired or terminated. It is likely many of his department members 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 both advocacy and negotiation with senior leadership to entice George's people to deliver more with less personnel resources. He will also need to find motivating factors for the other department heads to participate and fully engage in the governance process. Motivating others often requires a needs assessment (what motivators to they desire/what motivates them) and then negotiation to deliver on those needs.

Decision Making/Accountability

Clinical Informaticians 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. In this section, we 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. Clearly, 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) [55].

Both the decisive and flexible decision making styles focus on speed in making the decision, but they differ in that decisive also 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 in these two styles is the final decision process. Hierarchical will challenge others' input to ensure they are valid, will 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 [55].

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 input 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 delegating that to others… hopefully to those who are trusted and have good ideas) [56, 57].

One thing that research has found is 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 marked decrease in the flexible style [55].

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 [58].

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 [58].

Simple and complicated contexts assume an ordered universe. Here, the appropriate actions are to sense, analyse and respond for complicated and sense, categorize and respond for the simple context. Complex and chaotic contexts are unordered. The appropriate responses here are probe, sense and respond for the complex context, and act sense and respond for 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 [58].

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 [59].

Use Case

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 decisions 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 own desires/needs, he can elicit ideas/inputs from the department members and make a unilateral decision or he can engage the group and make a shared decision. Depending on the situation, one of the latter two decision making styles are the most functional from a long term leadership perspective. Given lots of time and full engagement, the shared decision making style is best. With the Governance Committee, George must employ a shared decision making style or face a significant backlash from the other department heads, who are his peers. It takes more time, and it also takes employing all of the tools we have previously discussed: 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).

Communication and Leadership

There are all kinds of models of communication, some basic and some complex. For our purposes communication can be described as CREATING UNDERSTANDING.

Through words, actions, body language, voice tone, and other processes you send many messages about yourself and your organization. This constitutes one-half of the communication process. The second half consists of verifying that the message you intended to send was actually 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 common understanding is by asking the other people what they have heard, and what their reactions are to it [60].

Verbal communication is the most obvious form of communication. Research has shown, however, 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 [61].

Skills acquired and/or knowledge gained about good communication are only valuable to the extent they can be practically applied when called for. 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 messenger; it is however 100 % about meeting the needs and the expectations of those you're communicating with [62].

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 take-aways – 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) [62]

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, your positions or your circumstances. It's about helping others by meeting their needs, understanding their concerns, and adding value to their world [62].

Use Case

It is very easy for people to get the wrong idea about your intentions, and this is even truer with the more impersonal modes of communication we often employ today: e-mail and text messaging. You have to carefully craft e-mail messages to ensure you and your intentions are not mistaken. Whenever possible, it is best to resort to the old style of phone or in-person communication to ensure the message received

is the one you want to send. Even then, if there is 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), then communicating by less personal modes is possible without having to worry too much about misconstrued intent. Phone conversations are an acceptable alternative to F2F communications, but should be intermixed with F2F discussions as long as trust is being built. E-mail and texting are convenient, but they are much less effective modes and much more likely to be misconstrued by the recipient.

Emerging Trends in Leadership

Both the Institute for Leadership and Management (ILM) and the Center for Creative Leadership (CCL) have published papers on future leadership trends [63, 64]. The Center for Creative Leadership has also published a paper on the future of leadership development [65].

The ILM paper describes the future of leadership in its 2020 Vision paper. Its key findings are the following [63]:

1. A flexible workforce – more flexible working arrangements, to include job sharing, teleworking, flexible hours
2. Core competency required – the core leadership functions (communication, delegating, goal-setting and motivating) will be more important but harder to achieve
3. The power of relationships – working relationships will become increasingly important both within teams and with external stakeholders; this is also driven by the flexible workforce

The CCL leadership paper describes ten trends for leadership. These are [64]:

1. The rise of complex challenges – internal organization changes, market dynamics, shortage of talent and continued globalization
2. The innovation revolution – everyone is looking for the next big thing
3. The art of virtual leadership – this extends from the flexible workforce in the ILM paper; the key here is communication skill, specifically frequency and clarity/message effectiveness
4. Collaboration nation – collaboration is becoming much more important to succeed as a leader; this is usually a learned skill, but requires constant practice
5. The world of interruption – most leaders are interrupted about every 30 min, but the range is from five minutes to never; lots of strategies here, from being

uninterruptible (turn off phones, close door, empower assistant) to technologically simplifying one's life
6. Authenticity is the next celebrity – be honest and open; do not compromise your values, beliefs or personality
7. The fallout from the Baby Boom – many millions of senior, experienced people will leave the workforce as Baby Boomers retire; create a plan for leadership succession and train new leaders
8. More from the Baby Boom – find innovative ways to attract and retain experienced workers while preparing the next generation to take over; of note, Millenials are harder workers and better community builders than Boomers
9. Leadership for longevity – improved levels of stress, health, diet and fitness will be even more essential to ensure a sustainable and productive career
10. What's next? – more participative leadership style; employee instant gratification; collaborative technology; work/life balance; internal alignment

The CCL paper on leadership development identifies four future trends [66]:

1. More focus on vertical leadership development (developmental stages) along with continued work on horizontal development (competencies)
2. Transfer of greater developmental ownership to the individual – making people responsible for their own development
3. Greater focus on collective rather than individual leadership – this goes back to collaborative or participative leadership
4. Much greater focus on innovation in leadership development methods – organizations will have to innovate and incorporate new methods and new technologies to develop good leaders in a world with increased complexity

Questions for Discussion

1. Why is leadership an essential skill for a clinical informatician?
2. Describe a leadership model you have observed in practice. Did the leader meet all of 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 conflict was resolved poorly. What lessons from the first scenario could have improved the second?

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Chapter 15
Effective Interdisciplinary Teams

Titus Schleyer, Holly E. Moore, and Kathleen Weaver

Learning Objectives

At the end of this chapter, students 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 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

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Case Study

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 a variety of systems to serve its healthcare information technology needs. Registration, admissions, 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 use in the inpatient and outpatient settings was custom-written by a local software company that has been 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 made the decision 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 complained 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 6 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 of the 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 thereafter. 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, in general the Philadelphia economy is booming. Competition for skilled information technology personnel in healthcare is fierce. What can you do to ensure you can hire enough skilled IT staff?

Human Resources Organization Planning and Development

In the current knowledge era, and especially in the information technology 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.

Personnel have evolved from being "a" resource in production in the industrial economy to "the" resource in the knowledge economy. The ability to manage 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 organizational development and talent recruitment. Do not treat this function as a "service" that is used to "procure" workers when needed. Instead, engage all relevant parties, including your informatics organization and its stakeholders, as well as recruitment 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 feed on themselves which increases capacity and ability to achieve beyond any one person's ability.

Figure 15.1 shows a general overview of the human resources process, which we will use to map our discussion.

- **HR Planning**: Be clear about what your goals, timelines, process and stakeholders are. Once you have a plan, you can go about determining what kind of staffing you need.
- **Staffing**: With your plan in hand, you can set out to staff your organization. Staffing is a set of activities aimed at attracting and selecting individuals for positions in a way that will facilitate the achievement of 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

Fig. 15.1 General overview of the human resources process

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.

- **Evaluation**: While it is common to focus on results and solving problems, and ignore individual contribution of skills and knowledge to this effort, it is very important to periodically perform formal and informal evaluations. You need to identify and share how well each individual applies their knowledge, skills and experience to fulfill the requirements of their position. While many think of evaluations as merely scorecards for merit pay increases and promotions, the most effective evaluation programs focus first and foremost on coaching and development.
- **Compensation**: Initially, compensation is set based on a variety of factors, such as position requirements, candidate qualifications and market value. Market value is determined by supply and demand for the skills required in your geographic location. After that, compensation should track the results of performance evaluations, market trends 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 compensation. 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.
- **Maintaining the workforce**: Maintaining the workforce is a constant process of promotion, reassignment, recruitment and termination to make sure your workforce is supporting your staffing plan.

HR 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 determine its success – as well as yours as a manager. Key to being able to maximize staff contributions to the organizational mission requires a solid human resources plan. Given your goals, what kind of people do you need to achieve them? How do staff roles complement each other for maximum effect? How do expected staff transitions, such as retirement, affect your staffing needs? Having a solid HR plan in place prepares you well for creating jobs and recruiting for them.

Creating Jobs

So, how do you create a job? Start with 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 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 being able to successfully perform the job. Minimum selection criteria should **not** include knowledge, skills and 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 job holders, managers and subordinates
- 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.

Creating Job Descriptions

The 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 transition of workflows and functions, allowing for effective change management in line with the evolving needs of the organization.

Formats vary greatly but typically contain the following elements:

- **Title:** the title often becomes the primary identity for a position. Titles alone can be a very effective management and development tool.
- **Organizational relationship**: title of position the position reports to
- **Position Purpose**: a few sentences describing the primary function of the position
- **Exempt status**: to the extent the organization is treating the position as exempt it is beneficial to include in the job description those duties that support the exempt status. "Exempt" is a federal wage and hour term meaning not eligible for overtime pay over 40 h of work per week. "Nonexempt" means the position IS eligible for overtime pay based on the duties required of the position. Learn more about exempt status by going to www.dol.gov/whd/
- **Position Essential duties and responsibilities**: essential functions and responsibilities of the job. This may also include nonessential functions which are desired but not necessary aspects of the job.
- **Qualifications**: statement of skills, abilities, education, and previous work experience as well as desired skills that would be beneficial
- **Physical Demands and Working conditions**: the environment in which the job is performed, especially any unpleasant (or dangerous) conditions. Lifting and standing requirements are often recognized in this section.

For a sample job description see Box 15.1.

Box 15.1 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 through the creation and maintenance of a common business intelligence (BI) framework, end-user training, and the development of 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 such highly successful outcomes that the institution becomes the benchmark. Instill and inspire accountability and empowerment as part of 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 PhD degree in computer science, information science, big data or a closely related field is required.
- At least 3 years practical experience with management and analysis of 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 a familiarity with 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 are representative of 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 of time.
- 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 are representative of those an employee encounters while performing the essential duties of this job. 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 offers the opportunity to transition tasks within the same job title or career path, and facilitates effective management of internal equity without having to constantly update individual job descriptions.

Staffing

Attracting top talent is a competitive proposition. Top talent working in your organization attracts and breeds more top talent. The goal of your recruitment should be to entice a large pool of qualified candidates. Deciding whether to recruit internally or externally has its advantages and disadvantages (see Table 15.1). How feasible internal recruiting is depends somewhat on your organization (size, job diversity, etc.) and the availability of appropriate talent pools within it. Many experts advocate for a balance of the two.

Table 15.1 Staff recruitment

	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	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. Places 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 adjustment time

Ultimately, the appropriateness of recruiting internally or externally depends on the organization's needs, capacity for training and development, culture and specific demands of it project(s).

Internal Recruiting Sources

Filling job vacancies through promotions and transfers can capitalize on the investment the organization has made in recruitment and development of its existing talent. Effective sources for internal recruitment include job posting, skill tracking systems and employee referrals.

External Recruiting Sources

The use of external labor sources varies with a variety of 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 often can 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
- head hunters/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 organization 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. One word of caution is that the need for diversity in your work groups is sometimes compromised and should be consciously avoided. Also, DO NOT lower your qualifications or write a job description to the person versus the position needed.

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. You should be aware of how labor market characteristics, e.g. a multigenerational labor force that includes groups such as baby boomers, Generation X and millennials, match your organizational culture.

Recruitment Effectiveness

Evaluating the success of an organization's recruitment efforts is crucial. Without the use of metrics and assessment, organizations tend to recruit the way they always have, possibly missing out on improvements they could make. Table 15.2 shows some useful short- and long-term metrics.

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 requirements of the position.

Table 15.2 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 Equal Employment Opportunity (EEO) and Affirmation Action program implications
Long-term	Performance of hires Turnover Absenteeism per hire Training costs

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 veracity of the information. If employees are found to have lied on their application form, they can be terminated for falsification of information.

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. Whenever possible, the organization should keep applicants informed of their status and avoid significant time lapses between communications.

Step 3: Selection Interviews
Selection interviews are intended to allow the interviewer to probe areas of interest in order to determine how well the candidate meets the needs of the position. Unstructured interviews typically have relatively low reproducibility and validity. While structured interviews are better, semi-structured interviews are the most common. In those, the interviewer uses a set of prepared questions as a guide but explores and focuses question as needed.

Situational interview questions are helpful because they do not have canned answers. The applicant therefore must think on the spot. The interviewer asks questions designed to elicit stories and examples that demonstrate the applicant's skills and qualifications. The intent is to try to predict future behavior.

The following are helpful techniques for interviews:

- **Plan for the interview.** Be familiar with the job requirements in order to be able to assess how the candidate matches them.

- **Establish and maintain rapport.** Try to create an environment in a situation where the candidate feels relaxed 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. Eye contact is a key indicator for truthful responses.
- **Ask questions**. Plan ahead and ask open, probing questions that encourage candidates to tell you as much as possible. Make sure that 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.
- **Take notes**. Note taking is strongly recommended to document the qualifications of the candidate. It is not necessary to ask permission.
- **Summarize.** Conclude the interview with a brief 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 don't 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 on the grounds that 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 Civil Rights Act of 1964 and 1991 as well as 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 minority applicants from discriminatory employment procedures.

Pre-employment tests may be broadly categorized in the following manner:

- Cognitive ability tests measure individuals abilities related to verbal and mathematical skills, logic, reasoning and reading comprehension.
- 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 for software applications, programming languages and healthcare terminology.

- Honesty/integrity tests measures 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.
- Substance abuse tests are measures intended to ensure a drug-free workplace.

Step 5: Background Checks

Assuming that the best indicator of future performance is the past performance of an individual, it is important to check references carefully. This step typically takes place once an applicant is considered a good candidate for the open position. For executive level positions, it may make sense to conduct background checks before face-to-face interviews to avoid burdening top management.

The following are common types of background checks:

- **Work reference.** The most informative references are those given by former and current supervisors who are likely to know the candidate's work and who have observed the candidate performing a job that is similar to the one the candidate is applying for. Always obtain permission from the applicant. 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 if there is no business reason to do so.
- **Motor Vehicle Record checks**. Motor vehicle records are maintained by departments of motor vehicles in all 50 states for up to 5 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 use of a company-owned personal vehicle for 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.

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 legal counsel. Set a reasonable acceptance deadline taking into consideration situations involving relocation or with higher level positions.

Development

Hiring and New Employee Training Process

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. Make sure 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. Make sure the employee is set up to receive organization-wide information (e.g. membership in email lists and important directories).

First Month: In order 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
- Organizational 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 3 Months: Micromanagement in the first 3 months is a good thing to facilitate continual 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 resource who is regularly available for questions.

Throughout this training time, it is important to assess whether a good hiring decision was made. Be as open and honest possible as you learn how an individual's skills and past experience match the job expectations. This is a probationary period – use it!

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.
   (d) 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 talent.

Most jobs are not static. Requirements tend to evolve, especially in dynamic, growing organizations. It is very important to grow the employees with the jobs.

Evaluation, Compensation, and Maintaining the Workforce

Performance management is the process of maintaining or improving employee job performance through the use of performance assessment tools, coaching and counseling as well as providing continuous feedback. Individual contribution drives business results that accomplish the goals of the organization. The performance management process provides the opportunity for 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
- Identify opportunities for development and training needs
- Communicate expectations and determine employee aspirations
- Foster commitment and mutual understanding

The most commonly used category rating method is a graphic 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 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. Also, evaluations are trending towards providing feedback on individual contribution to achieving specific results, projects, and/or metrics versus behaviors.

Compensation

Regular evaluation of compensation can ensure:

- Productive talent is financially recognized in an equitable way internally.
- A 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 compensation of talent is a difficult challenge. If available, you should seek guidance from the human resource department in your organization. It is common for human resources to have access to external labor market data. 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 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 number of incumbents. Do not allow pay decisions to occur simply when staff provide 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 work group. 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 clear understanding of new expectations associated with increase in compensation.

Departure of Staff

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 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. Having said that, your goal is to be aware of all team members' aspirations so that those skills can be applied internally with the natural growth of the organization if at all possible. It is a given that you are not going to have opportunities for all, and their departure can open opportunities for others to grow and develop.
- **Involuntary terminations** should involve counsel from your human resource or legal department. You want to steer clear of accusations of wrongful terminations. Employees are protected by a number of 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's 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 is given 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 a number of 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 on the basis of 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 if his or her disability. A qualified individual with a disability is one who can perform the essential functions of the job 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, 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 7 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 12 workweeks of leave in a 12-month period for: the birth of a child and to care for the newborn child within 1 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 1 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 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 to the organization's goals, customer's satisfaction and productivity. High performers outperform their colleagues and demonstrate a strong capacity to grow and success 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 if 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 accomplish, who will be on the team, and how the team's work will be performed.

Task forces, development teams, committees and working groups are just a few of the types of teams that you will be called on to organize and lead. 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 have the potential to solve problems and be innovative in ways that are not feasible for a single individual.

Yet, in spite of their importance and ubiquity, it is not uncommon to find dysfunctional, dormant, and failed teams. A diverse group of people working together can foster greater creativity and innovation, and this often means more work can be completed. However, having a group of people working together can also increase the chances of debilitating conflict, often causing greater coordination and communication

challenges for the team lead. Ignoring these trade-offs during formation and management of teams is an important cause of many problems and failures.

As you lay the groundwork for a team, launch it, and lead the team through the development and the performance of its work, it is essential that you 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 scope, scale and timeframe of the goals. As the team lead, you will need to establish the purpose of the team, which provides direction and expectations. Team members need to be identified, in addition to establishing 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 purpose of the team, 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, bringing forward specific information about how the team will need to function so that they 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 purposes of the team, what it will accomplish and the expected outcomes.
  - **Duration** – The expected timeframe that the team will be in existence 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 disband at the appropriate time, rather than to continue on without a solid ending.
- **Members** – Who is involved in and affected by the team?
  - **Team members** – Each member should be individually listed, including both 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 who have an interest 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 is crucial for everyone to understand and should be documented in the beginning, and also 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 the team should meet, where the meetings need to occur and how that connection will happen should be clearly written 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 that will be 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 does it 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** – Technology is the lifeline of teams these days. Since teams are often distributed geographically, it is imperative that all members 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 as to the best forms of communication for the team. Identifying what technology each member needs will help significantly reduce logistical problems and ensure that all members of the team are able to 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, in addition to allowing the outside supporting member the time and resources expected of them.

A comprehensive Team Charter will lay the foundation for an effective team by clearly documenting the team's purpose and tasks, its composition, its structure and process, and the necessary resources.

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 to develop a shared understanding of the goals and tasks, build the relationships, and understand the structure and the roles within the team. Articulating these with the team during the team's initial meetings will help to provide a needed cohesiveness in the team.

1. Relationships
   As discussed in previous sections, following the necessary steps to gather the right people is key to creating a high-functioning team. The organization of a team will affect the relationships between the team members in terms of responsibility and authority. A team that is well designed will promote good communications between team members, which in turn can help with making the team more productive. In addition, the relationship between the tasks and also the workflow process are affected by the organizational design of the team.

   Although job titles may be duplicated throughout the team, each member will contribute uniquely to the team based on their knowledge and experiences. The more variety the team has, the more views will be articulated. It is very important to have all points of view represented. However, composition is more than just having the right people; it is having 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 faultlines, 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, in addition to having a good organizational design, will create an environment for the team to work effectively with one another.
2. 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 own roles, in addition to others' roles, can help decrease confusion in the future. 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 lead needs to actively manage these external relationships, which should be also documented in the team structure.

   Most 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 the percentage of their time will be dedicated to your team. This is a very important step, as it will determine which tasks will be assigned to team members.

3. 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 how it will 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 activities and timelines of other team members.

Group Management Processes

Working with the members during the initial stages of forming the team create an environment where all members feel comfortable will help the team work smoothly, having a major impact on the goal. The initial interactions of a team are extremely important in establishing motivation and understanding among the team. This helps establish team empowerment, allowing each member to understand how their expertise will contribute to the team and the outcomes. There are some key actions to be taken when initially developing the team character.

- **Kick-off Meeting**
  During initial interactions when the team is forming, it is important for the team members to develop interpersonal relationships among its members. Providing time for the team members to get to know each other will help build this rapport. Gathering team members for an initial kickoff meeting is extremely important for articulating a shared mission and establishing a clear understanding of the goals and activities. This can be an activity where each member shares a success story and a frustrating team experience with the rest of the team. This 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 on a regular basis.
- **Team Expertise**
  In between meetings there are likely to be questions and issues that need to be addressed. Since each member will be bringing their own 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 allow others to 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 this wide variety of expertise is a very positive feature, as it provides a wealth of information, and should be taken advantage of.

- **Problem Solving**
  Establish how problems will be solved. It should be established 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 lead, will need to provide general problem solving rules. To extend this exercise, allow the team members to provide examples of possible problems so that the team can practice addressing the established team problem solving processes.

  Now that the team has been introduced, roles and responsibilities have been clearly 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.

Managing a Team

As you lead the team, you will be responsible for managing the processes and making sure 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 a wide variety of 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. But 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 has an understanding about their tasks and how they fit into the team process. However, there will be incidents when a team member is unable to complete a task by the assigned time. As the team lead, you will need to decide if the task can be delayed, or if another team member should be assigned the task. 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 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 percent-

age of time a team member can contribute to the team as the work progresses. The best way to manage this is to understand their 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 clearly document when each of their assigned tasks need to be completed.

- Resource Changes
  Team resources have been clearly documented in the Team Charter, however most teams undergo a variety of 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 receive information from people outside the team. The process needs to be established and shared with the team so there is no confusion about who will be gathering and distributing the information throughout the team. Often times the team lead 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 the information will be coming from. However, it doesn't always need to be the team lead. It is common to have a designated team member connect with outside contacts. This is often the case when the team is reliant on outside information to successfully complete the process.
- Conflict
  One benefit of having a team is that the diverse composition 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 expression of opposing views, which may be real or perceived. Regardless of whether the opposition is real or perceived, if two or more members disagree, there is conflict. Conflict can range from a disagreement on how to proceed with a task to personality conflicts. As the team lead, you will be responsible for professionally managing the conflicts to keep the team on track.
  - Constructive Conflict
    Conflict that is constructive 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 lead, 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 be willing to embrace change and be willing to 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, rather they can be personality attacks or hostile discussions. Destructive conflict can erupt due to a power struggle, feelings of inequality, or personal vulnerability. As the team lead, you will need to handle destructive conflict very professionally and carefully. If not handled properly, the result can be an imbalance of power or damaged relationships.

When a conflict becomes destructive, the following should be used to work through the situation:

1. Conversations should be halted to allow parties involved to decompress for a period of time.
2. Issues should be acknowledged and an agreement from everyone involved should establish what the real issue is.
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 as moved away from a destructive nature, work to switch the conflict to be constructive in nature, emphasizing that the outcome will benefit the team.

Conflict will occur in every team. With the wide range of personalities gathered in a team, it is inevitable, so be prepared for it. Being professional, keeping the team goals in mind, and keeping the team members focused on the same 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 progressing through the tasks and accomplishing the goal of the team, is an ideal situation and should be strived for within each team. However, you can have a cohesive team, but they are 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 to verify they are a successful team. If you see issues, you need to evaluate if the root cause is the unhappiness of the team

members, there is conflict about the tasks or goals, or one of the other core contributions to the team mentioned earlier.

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 doesn't always mean a better team. If there are resource issues, or if the team is not working towards the designated goals, adding more people can often cause conflict and decrease productivity. Often times, 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 is not always better, it can often be very 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, and managing conflict between members is essential and an important 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. 15.2), they are also among the most reviled activities in businesses.

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. Meetings are one way to support and facilitate these collaborative work processes.

However, meetings are expensive, especially when all factors, such as personnel costs for participants, effort and time expended in preparation and follow-up, and

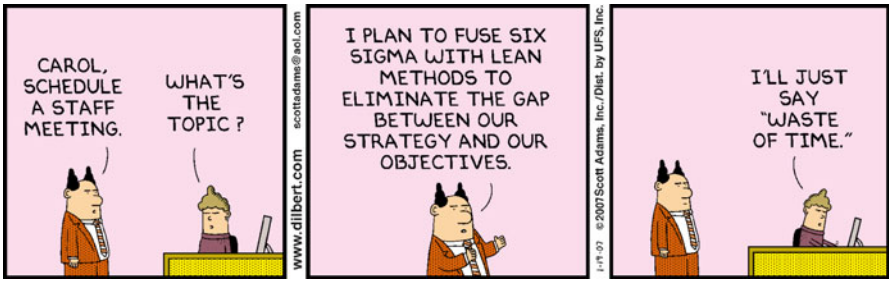

Fig. 15.2 Judging from Dilbert cartoons, meetings are among the most reviled activities in businesses (Dilbert © 2007 Scott Adams. Used by permission of UNIVERSAL UCLICK. All rights reserved)

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 $1,500. A similar meeting among executives will incur a multiple of that cost.

Good meetings do not just happen on their own. They are the result of careful planning, attention to participant needs and follow through [1]. 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 [2]. How you plan, run and follow up on meetings has a lot to do with how useful they are 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, from the project and organizational perspectives, the most value-added. 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 each and 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/she 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 maintains ultimate control of group decisions, even if they are often arrived at in a democratic manner.

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 the meeting 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 not only focus on achieving the objectives of the meeting, but also manage the interactions among participants in order to maximize efficiency and effectiveness. When meetings work, they flow naturally. Questions/problems are understood by everyone. 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 15.3.

However, 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 is constantly dominating the discussion? Or, the fact that no one seems to show up on time? Leaders must be able to 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 end up as the subject of a Dilbert cartoon.

Participants often see themselves as passive victims of whatever is going to transpire 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

Table 15.3 Positive behaviors that both leaders and participants should demonstrate in meetings

Leader	Participant
Be open and encouraging	Decide to make the meeting worthwhile
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 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)

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

In the book "Meetings that Work" Marlene Caroselli suggests a seven-step framework for conducting successful meetings [1]. This framework is an excellent way to think through meetings, starting from whether they are required at all to maximizing the results of a meeting. The framework includes 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 project for an hour or to 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 e-mail?

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 prior to 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 of the meeting. A solid agenda is an important foundation for a successful meeting. Distribute the agenda at least 24 h before the meeting. 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 information such as 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.
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; making sure to keep the group on target when the discussion is straying from the current topic; minimizing distractions; making sure all attendees get to 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 prior to 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 but

can serve as the input for the next meeting. With good meeting minutes in hand, follow up on action items with those to whom tasks were assigned. 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. Some examples:

- **Do meetings always have to last 1 h?** No. The time required for a meeting should be driven by the agenda. If the work of a meeting is done and it can end early, then **end** it early.
- **Why not go outside?** Picking an unconventional location for a meeting (e.g. in a nearby park, on lawn chairs under a tree, in a roof garden) is likely to energize participants and make the meeting more interesting.
- **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 added benefit that latecomers can review 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 the course of a few hours or a day. The strategy has the added 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. One of these tools is x.ai, an artifi-

cial intelligence powered personal assistant that schedules meetings for customers without human intervention.

In summary, group meetings are important tools for achieving organizational objectives. However, meetings work best when they are carefully considered, well-planned and well-executed, and are balanced with other organizational activities.

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Chapter 16
Project Management

Lisa Anne Bove, Ryan D. Kennedy, and Susan M. Houston

Learning Objectives

1. Describe the basic principles of project management.
2. Discuss how to determine resource needs for a project.
3. Analyze three challenges in project management.
4. List the five phases of project management.

Core Content (Competencies)

Project Management

4.4.1. Basic principles
4.4.2. Identifying resources
4.4.3. Resource allocation
4.4.4. Project management tools (non-software specific)

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4.4.5. Informatics project challenges

4.4.5.1. Scope creep
4.4.5.2. Managing expectations
4.4.5.3. Balancing competing priorities

Case Vignette

Good Hope Hospital (GHH) is a 500-bed community facility that implemented an Electronic Health Record (EHR) 4 years ago, complete with computerized prescriber order entry (CPOE), medication reconciliation, interfaced lab results, and full electronic documentation of patient demographics, vital signs, and clinical summaries. The rollout was successful in all areas of the hospital, except the Critical Care Unit (CCU). At the time of the deployment, the 20-bed CCU was overwhelmed with patients and had insufficient staff to handle the project. The department leadership was concerned about a potential negative impact on the patient outcomes, so a decision was made to delay the implementation of electronic documentation in that department. Now that 2 years have passed, the chief executive officer (CEO) of GHH is eager to bring the CCU in line with the rest of the hospital, although staff in that area are hesitant to move forward. The CCU leadership point out that they have been able to deliver superior patient care, despite the lack of CPOE and electronic documentation and medication reconciliation in the EHR, which was plagued with unscheduled downtime during its first year. The CEO counters that patients fall into an electronic "black hole" when they are at their most critical state and the hospital is missing out on funding opportunities through Meaningful Use incentives.

You have been assigned as the project manager to bring the CCU in line with the rest of the hospital's electronic processes. The major objective, as given by the CEO, is clear: Implement full electronic documentation in the CCU using the existing EHR within 1 year and within a $250,000 budget. After meeting with the CCU leadership, you realize he and their staff are not in full support of the project, although they are willing to give it a try, as long as the following additional requirements can be met:

1. Deploy a real-time electronic view that can display clinical data from the EHR system (medications, labs, vitals, and I&O) in the same format as the existing paper flowsheets;
2. Integrate the existing medical devices into the EHR system to reduce data transcription errors, including hemodynamic monitors, ventilators, pumps, and hemodialysis devices; and
3. Deploy new mobile workstations so device availability will never impair patient care.

You immediately realize that a contract for implementation support will be needed with the off-site EHR vendor, to help supplement the already resource-limited, in-house IT department. Despite the request from the CCU leadership, the

CEO remains steadfast with his time and budget expectations. As you would expect, this is not the only project underway at GHH. The CEO is also expecting the hospital to deploy a Barcode Medication Administration solution, a Patient Portal, a Drug Interaction Application, and an upgrade to the EHR within the same year. These projects require many of the same IT and functional resources as your electronic documentation project.

- Given the varied opinions and expectations across GHH, how would you go about conducting a Stakeholder Analysis for this project?
- What skill sets will this project require from your human resources, and what roles would you include on your team?
- What are the most important skills you will need to possess on this project, as the project manager?
- Since the CCU leadership has already added new requirements before the project even starts, how will you manage potential scope creep while still satisfying stakeholder expectations?
- How will you empower your team to perform, given the number of competing priorities?
- How will you manage a team that includes a vendor that will be conducting the majority of their work off-site?

Introduction

Healthcare is changing ever faster and information technology (IT) projects abound. While "failing fast and frugally" may be a good way to achieve innovation, it is not a good way to manage projects [1]. Historically, however, healthcare IT projects have failed at an alarming rate. A project is considered to be a failure when it is late, over budget and/or "has not delivered what was required, in line with expectations" ([2], p. 1). According to a Harvard Business Review study in 2012, over half of all projects fail [3].

Generally, projects fail for three reasons:

- Failure to plan requirements (scope)
- Failure to complete the work (on time) and
- Failure to deliver something that is worthwhile (expectations).

Projects can benefit from project management in order to bring them in on time and on budget while meeting stakeholder expectations. Skills project managers need in order to keep projects on track include the ability to:

- manage change,
- plan,
- communicate,
- analyze risk,
- solve problems, and
- control quality [4].

More and more often, chief medical informatics officers (CMIO), chief nursing informatics officers (CNIO), and informatics clinicians are called upon to lead healthcare projects, such as implementing electronic health records, preparing for meaningful use, or developing analytics projects to improve care. Clinicians and other healthcare providers often make good project managers since they already have many of the skills that make a good project manager, including the ability to plan, communicate, and "generate a spirit of cooperation while coordinating diverse activities" ([5], p. 23). Without some basic project management training, however, clinicians do not necessarily know how to apply these skills to manage projects. This chapter will discuss tools that project managers use to bring projects in on time, on budget and with the ability to meet stakeholder expectations.

Basic Principles of Project Management

The concept of project management has been around for centuries. In fact, there is evidence that the building of ancient structures, like the Giza Pyramid and Greek Parthenon, were among the first efforts that used a tool or process to accomplish a specific goal [6]. Over the years, project management has become more relevant for a larger number of industries, gaining traction as its own discipline by the 1950s [7]. In 1969, a group of project managers founded the Project Management Institute (PMI), which has become the leading association to help define standards, certifications, and practices associated with project management. 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) [8]. For the purposes of this chapter, the majority of the terms, concepts, and descriptions will be based on those that are defined by PMI.

Concepts

To start, project managers need to focus on the most fundamental question: What exactly is a project? In the most basic terms, a project "is a temporary endeavor undertaken to create a unique product, service, or result" in order to meet part of an organization's strategic plan ([9], p. 3). This is an extremely important point to understand because as the term "project" becomes more and more commonplace, the definition can become somewhat muddied with the basic operations of an organization. Work that is ongoing in nature to help support the mission of an organization is not a project. In referencing the definition of a project, the ongoing work

does not create a unique deliverable, nor does it have a defined start and finish (temporary). The major difference between projects and operations is that projects will end "when their objectives have been reached or the project has been terminated" ([10], p. 5). Once this basic difference is understood, project managers can begin to explore what this means for the healthcare industry.

In general, the healthcare industry is growing rapidly, spurred on by new standards of care, technology innovations, and an aging population of patients [11]. In order to keep up with these changes, and ensure timely and efficient implementation of new services and systems, healthcare facilities need to employ good project management principles. Some potential examples of healthcare projects that could benefit from project management may include:

- The implementation of a Barcode Medication Administration tool.
- The implementation of a Provider and Patient Portal.
- The physical move of a healthcare practice from one building to another.
- The implementation of a billing system for third-party reimbursements.
- A hospital center converting from paper records to an Electronic Health Record.

Each of these examples has very different costs, timelines, resources, and levels of complexity, but they all have several common qualities:

- They will create a unique product or service.
- They are temporary and will be considered complete once the objectives are met.
- They will require a specific set of resources, which may include people, technology, or physical assets.
- They have a primary customer.

Given these similarities, any one of these examples could be managed as a project using a defined methodology. There is at least one additional common attribute amongst these efforts; project constraints. Historically, projects were limited by the "triple constraint" of scope (the objectives that will be accomplished during the project), time (the duration of the project work), and cost (the budget of the project) [12] (See Fig. 16.1).

A project could clearly define two of these items, while the third would be dictated or constrained, based on the defined needs of the other two. For example, the implementation of a Barcode Medication Administration tool could be done faster and with less cost, if the scope of work is reduced. Conversely, the tool could meet multiple stakeholder needs throughout the entire hospital, but the time or cost would need to be increased to meet that need. Over time, project managers have learned that there are other areas of impact beyond just those three, including resources, risk, and quality, effectively increasing the number of constraints from three to six [10]. Due to these multiple layers of impacts and constraints, it becomes more apparent that there needs to be a process in place to help manage the work, and that is where project management becomes a critical component for healthcare projects.

Fig. 16.1 The triple constraint of project management

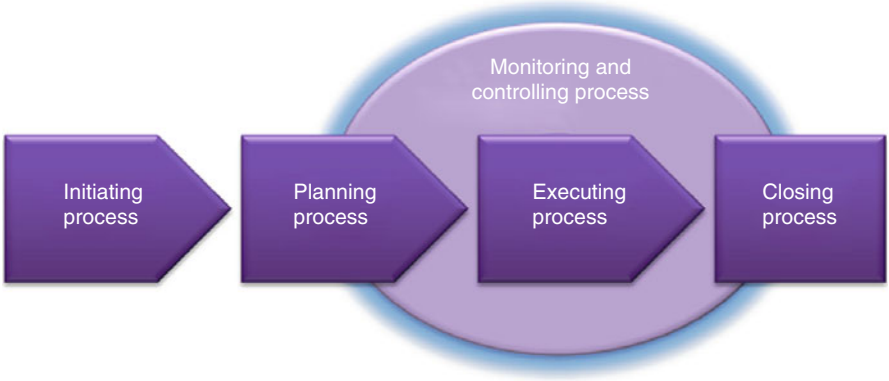

Fig. 16.2 Depiction of the five phases of a project

Phases of a Project

The lifespan of a project can be broken down into different phases. These are described by the Project Management Institute (PMI) in five distinct process groups:

1. Initiating Process,
2. Planning Process,
3. Executing Process,
4. Monitoring and Controlling Process, and
5. Closing Process (See Fig. 16.2).

These phases occur in a natural, linear fashion, with the majority of the staff's workload occurring during the Executing Process. They are referred to as process

groups because they are each contain a series of processes. In fact, the Project Management Institute (PMI) recognizes 47 distinct processes across these groups, which are further categorized into 10 knowledge areas with over 100 unique inputs, outputs, and tools and techniques [9]. For the purposes of this chapter, the concentration will be on the five basic process groups.

The first process group is Initiating. The primary function of this process is to evaluate the proposed project against business need and technical feasibility, and provide sufficient justification for a decision on the project's approval [13]. Generally, the details that are captured during this evaluation process are presented in a project document called the Project Charter. The components of a project charter vary widely across industries and organizations, although at a minimum, they usually include the name of the project and project manager, a description of the unique product or service, a justification as to why it is being done, and milestones, risks, and expected cost and timeline (See Fig. 16.3). A project sponsor, who will serve as the champion of the project, may also be identified at this point and a link between the project manager and the business unit or department and decision-making bodies (e.g., Board, C-Suite). Regardless of the components, an approved project charter signifies the authorization of the project and the project manager. More details about the project charter are included later in the chapter.

Once the project has been approved, planning can begin. The project manager will use the project charter to begin to define a project management plan. Planning represents a significant amount of time and work effort during this phase on the part of the project manager, as many aspects of the project are defined and planned, including the integration, scope, schedule, cost, quality, human and non-human resources, communications, risk, procurements, and stakeholders [10]. Several of these areas are described in more detail later in this chapter. Together, these components help outline the project management plan, as well as the knowledge areas described by the PMI. Once the project plan is finalized and approved, it can be helpful to create a formal project baseline. A baseline serves as a reference point for the project to help stabilize the project during monitoring and controlling. The baseline can also help the project manager to understand any gaps between what was planned and what was actually completed at the end of the project. In any case, there should be no changes to the baselined project plans without following a change control process, as defined by the project manager or the organization's project management office (PMO). Change control and scope creep will also be discussed later in this chapter.

After planning is complete, the Executing process group starts. The responsibility of the project manager during this phase will vary, depending on the complexity of the project and the organization's practices [13]. It is during this time, however, that the majority of work will be conducted to complete the planned objectives and project deliverables. During execution, the project manager will need to ensure that all processes are followed, the schedule, scope, and cost are managed, and risks, issues, and decisions are documented, reviewed, and communicated. This is often referred to as Monitoring and Controlling phase which runs in parallel to the Executing Process. Both sets of processes are considered complete once the objectives of the project have been met.

Project charter template

Project Charter

Project name: ***Project ID:***

Prepared by: ***Preparation date:***

1. Project description:

Business need,justification or benefit:

Expected outcomes:

-

Overview of objectives:

-

Assumptions:

-

Constraints:

-

Dependencies:

-

Risks:

1.

2. Milestones and deliverables:

Milestones

Milestone	*Estimated duration*	*Resources*

Deliverables

-

3. Budget/contracts:

Purpose/vendor	*Cost*	*Funding source*

4. Stakeholders:

Title/role	*Name*	*Department/organization*

5. Project team:

Project role	*Name*	*Department/organization*
Project manager		
Project sponsor		

Fig. 16.3 Example of a project charter highlighting its main elements

After the product or service has been successfully delivered, the project manager needs to archive the work and step away from the project in a process known as Closing. The project manager will review all deliverables against the project plan

and charter to ensure they have been completed. 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. The project manager will also conduct a lessons learned process to highlight areas of the project 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. Upon acceptance, the project manager can release or close all project resources, including human, non-human, and contracts. The product or service should have been transitioned to an ongoing support team, as well, because upon closure of the project, the project manager's responsibilities for this effort are complete, and the project manager will no longer serve as the point of contact for the product or service.

Project Management Tools

As with any other role, project managers need tools to successfully manage projects. These tools focus the project manager, the team and stakeholders on the project outcomes throughout the project in order to complete the project on time and within budget. These tools identify and manage information in order to address why this project needs to be done (business case), what needs to be done (project charter), which stakeholders need to be involved in the project (stakeholder analysis), when the project will be done (WBS or timeline), how information about the project will be communicated (communication plan) and how issues and risks will be managed (risk management plan). These are key tools that should be included in every project, no matter how big or small. 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.

There are also a number of charts and graphics that can assist with the project especially during the planning phase. An Ishikawa or fishbone diagram is a graphic tool used to explore and display opinions about sources of variation in a process. This is a good way for the project manager to include the team and stakeholders in the project planning. 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. 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 (see Fig. 16.4). A mind map is another planning tool that supports team brainstorming activities (See Fig. 16.5).

A Program Evaluation Review Technique (PERT) chart is a project management tool used to schedule, organize, and coordinate tasks within a project. PERT is a methodology originally developed by the U.S. Navy in the 1950s to manage the Polaris submarine missile program. A similar methodology Critical Path Method

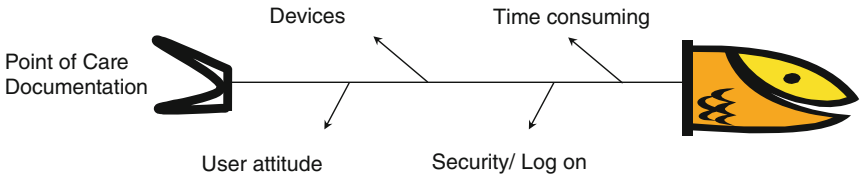

Fig. 16.4 Example of a fishbone diagram used to identify sources of variation in a process

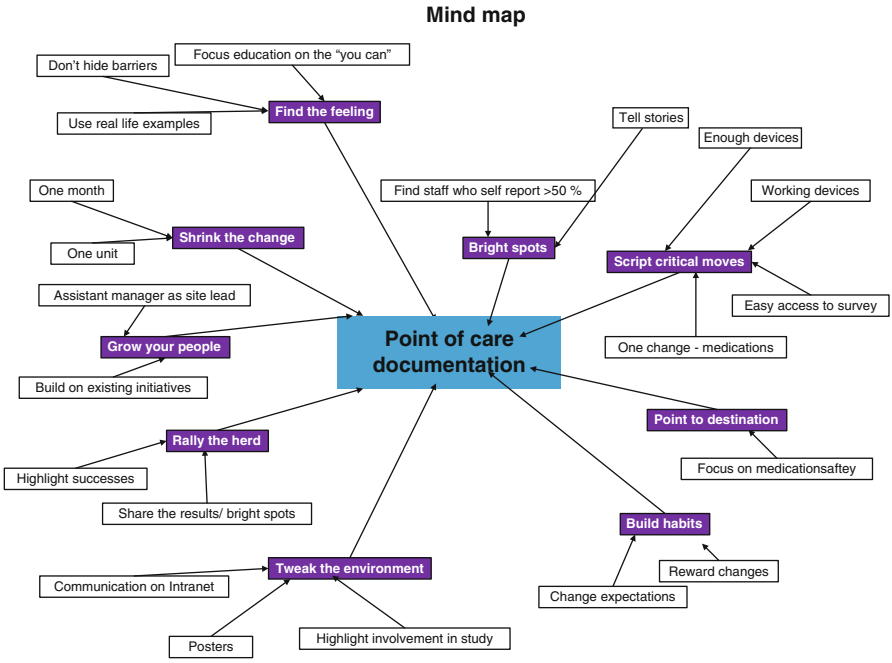

Fig. 16.5 Example of a mind map planning tool

(CPM) was developed about the same time for private sector project management. The PERT chart is sometimes preferred over the Gantt chart, another popular project management charting method, because it clearly illustrates task dependencies. On the other hand, the PERT chart can be much more difficult to interpret, especially on complex projects. Frequently, project managers use both techniques.

A Gantt chart is a horizontal bar chart developed as a production control tool in 1917 by Henry L. Gantt, an American engineer and social scientist. Frequently used in project management, a Gantt chart provides a graphical illustration of a schedule that helps to 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 (See Fig. 16.6). Additional information on PERT and Gantt charts as it relates to finding a project's critical path can be found in the "work breakdown structure (WBS)" section of this chapter.

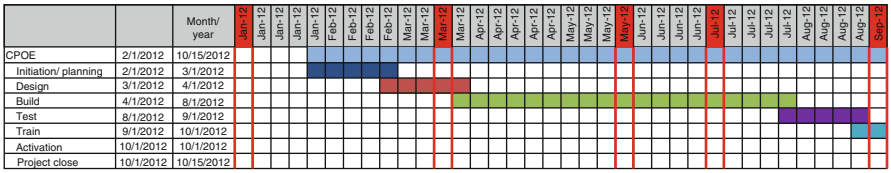

Fig. 16.6 Gantt chart example created using a spreadsheet program

Business Case

In order to get a project funded, many facilities require a business case. According to Dawes, et al., a business case includes a "plain language statement of the problem to be solved, with key data to illustrate its significance, as well as its severity and complexity" ([14], p. 34). A business case should also identify stakeholders and how they will be affected if the project is done or not done. It states assumptions, estimated costs and resources. In addition, the business case includes options by comparing the current state and the potential future state if the project is completed. With limited funds, many projects compete against each other, and decision making committees need to understand the value of a project in order to approve funding and resources. A business case will help to present the value of the project to the funding committee. A well-written business case can increase a project's chance of approval.

Business cases should be written in terms the stakeholder and approving authority will understand and support. Starting with a problem statement that shows the potential positive impact sets the tone for the business case. The problem statement should be tied to the strategic plan of the facility and show how the proposed project can support that plan. Problem statements should include quantification where possible such as 'reduce errors by 5 %' or 'increase compliance by 10 %'. For example, data should then be presented to support the potential positive outcome including information that demonstrates what will occur if no change is made. General information about the potential costs – both the financial and resource costs – should then be described.

Once the potential project is described along with the estimated costs, the business case should include a timeline with major milestones. Decision makers need to understand how long it will take to achieve the potential results and how this project can fit into the other projects scheduled for that reporting period. The timeline can be high level and just include major phases such as planning, implementation, training if applicable, and the projected go live period.

Including an executive summary as part of the business case will also help the decision makers focus on what's important. Key elements of the business case that should be included in the executive summary include the problem statement, scope of the proposed project, and both the business and financial impact of the project.

Project Charter

Once a project is approved, a project charter "formally authorizes the existence of a project and provides the project manager with the authority to apply organizational resources to project activities" ([9], p. 68). The charter documents the project and is a method to obtain sign-off and agreement from the stakeholders. Lowenhaupt & Friedman further described the purpose of the project charter to do the following:

- "Document agreement between client organization, team sponsor, project team, team leader, and project manager.
- Provide a clear statement of purpose of the implementation project and what the team is committed to deliver.
- Define the project roles and responsibilities.
- Provide the baseline for scope and expectation management" ([15]: p. 137).

The charter is a way to get all the stakeholders on the project to agree on the overall project and the methodology that will be used to complete the project. Charters should be succinct statements of the plan, the resources and their roles, the milestones and how the project will be managed. The content of the charter should include all the following:

- Project description, purpose and goals: This section should include a paragraph or two describing what the project expected to accomplish. In addition to the project purpose, a list of specific goals or outcomes should be included.
- Project scope: This section describes what is and is not part of the project. In addition, all the departments or units that are included or excluded from the project's scope should be listed.
- Project assumptions: Assumptions guide decisions throughout the project. Including the expectations that guide the project effort help to standardize the decision making processes throughout the process. Assumptions can include resource duration, prerequisites, software functionality, building codes, and other constructs for the project plan.
- Project approach: This section includes a description of how the project will be implemented and the high level milestones, such as planning, analysis, build, testing, training, and go-live activities. In addition, the approach should describe how risks and costs will be managed.
- Project reporting structure: A reporting structure is important in any project. Since many of the team members of most projects do not directly report to the project manager, describing the hierarchy of responsibility and project organization structure is necessary. Including a description of who is part of the project including teams, stakeholders, leaders, and third-party vendors is also part of this section.

The charter drives the project and is used for the duration of the project to guide team members and stakeholders. It is a living document to be updated throughout the project as teams change or as the project changes. Stakeholders should sign-off on the initial charter at the beginning of the project. Any future changes should follow a change management process with approval and documentation.

Stakeholder Analysis

A project stakeholder is anyone who is impacted by the project, including those involved in the actual project work such as the project team. Stakeholders can have influence on the project deliverables or outcomes. 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" ([9], p. 30). Identifying stakeholders should occur as early as possible. A 'savvy project manager' should evaluate the political climate surrounding the project ([16], p. 74). There are several documents that can assist with this task. Lessons learned from similar projects and the business case can provide some good information regarding who was or will be impacted as well as their interest in the current project. Anyone the project manager, or project team, will need support or assistance from should be added to the list. Once a project sponsor is identified, they can assist with the identification. Project team members, the decision making committee and even vendors can assist with the identification of possible stakeholders. Depending on the project, potential stakeholders include:

- Organizational Leadership,
- Project Sponsor,
- End Users,
- Vendors,
- Project Manager,
- Project Team Members,
- Resource Managers,
- Marketing/Sales,
- Quality Assurance/Quality Control,
- Legal,
- Finance or Funding Source,
- Contracting Office,
- Patients,
- Visitors/Customers,
- Business Partners,
- Government Regulators,
- Consultants,
- Payors, and
- Providers.

Once stakeholders are identified, understanding everyone's stake in the project includes identifying who stands to gain or lose if the project is success or unsuccessful [16].

This can be completed through a Stakeholder Analysis which begins once the initial stakeholders are identified and then is repeated for all new stakeholders. This analysis evaluates each stakeholder's expectations, needs, perspective and objectives for the project. The outcome of the analysis should be reviewed often as the results will change over time as their views, their priorities or the project changes. There are various tools available to use for this analysis and they are all very similar.

One tool looks at key information regarding each stakeholder, using a table where each stakeholder or group of stakeholders are on each row. The analysis concepts are in each column (See Table 16.1).

Different organizations look at different concepts for the analysis, but the intent is the same, understanding each stakeholder to help define how to manage their expectations. Stakeholder Analysis concepts include:

- Stakeholder – the stakeholder role or name, such as project team or end users.
- Involvement – the stakeholder's level of involvement in the project: Will they be active participants providing requirements, testing, or will they be inactive but impacted by the deliverables?
- Interest – the stakeholder's level of interest in the project: Are they looking forward to the project and deliverables, or not happy with the impending change?
- Influence – the stakeholder's level of influence within the organization or the project.
- Power – the stakeholder's authority within the organization or within the project.
- Impact – the impact of the project or deliverables on the stakeholder or their department.
- Expectations – the stakeholder's expectations for the project, project manager, deliverables, and other outcomes.
- Communication – the stakeholder's expectation for communication, including form, frequency, and method.
- Support – the type of support the stakeholder can or will provide to the project and project team.
- Role – whether the stakeholder has a defined role on the project beyond stakeholder.

Once this analysis is complete, the project manager can determine the best method of managing each stakeholder, or group of stakeholders. Additional columns could be added to the above spreadsheet to define the method of communication and method of managing expectations. Another option is to use a tool with two rows and two columns to plot each stakeholder based on comparison criteria (see Fig. 16.7). There are variations on this tool as well and it would depend on what two criteria are important to evaluate or you could utilize multiple versions to provide differing viewpoints. The main criteria used for this tool include influence/ power and importance/ interest. Any stakeholders who are high for both criteria are key people and should be actively involved in the project. Stakeholders who are high for only one criterion should be closely managed to meet the specific needs. For example a stakeholder who has a high interest, but a low influence should be kept informed of the project progress. The ones who are low for both criteria should be monitored, but should take the least amount of effort from the project manager.

The project manager can find themselves caught in the middle between multiple stakeholders as it is rare that all will have the same perception, goals or expectations in the project. Differing views can come from internal factors such as organizational leadership or clinicians, or from external factors such as, government regulations,

Table 16.1 Stakeholder analysis

Stakeholder Analysis								
Stakeholder	Role	Involvement	Interest	Power	Impact	Expectation	Communication	Support

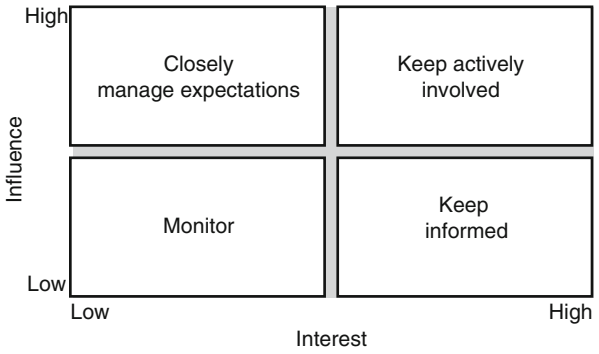

Fig. 16.7 Example of a 2×2 table for performing stakeholder analysis

the vendor or third party consultants. The stakeholder analysis can provide assistance with who may have the power or influence to assist when the disagreements go beyond what the project manager can negotiate. The project manager represents the organization when managing conflicting expectations from external sources. While vendors or consultants come in with much experience with implementing the specific project, the project manager and team, know the culture of the organization. In addition, the project sponsor is a great resource when issues need to be escalated as they represent the organization for the project.

Once the stakeholder analysis is complete, regular review is needed throughout the project since opinions change over time, especially if there are requests to change the scope. This task is typically completed by the project manager although anyone can provide input or assistance. An ongoing effort should be exerted to building and maintaining relationships with stakeholders.

Work Breakdown Structure (WBS)

PMI defines the Work Breakdown Structure (WBS) as "the process of subdividing project deliverables and project work into smaller, more manageable components" ([9], p. 63). PMI further explains, the WBS is a "hierarchical decomposition of the total scope of work to be carried out by the project team to accomplish the project objectives and create the required deliverables" ([9], p. 63). The purpose of the WBS is to create a structure for the work that will be delivered; that is to identify what must be done. Lewis considers the WBS the most valuable tool a project manager has because it ties the whole project together [17]. Even a small, short project can benefit from a WBS since the WBS:

- defines all the work to be done,
- creates a graphical representation of the scope and magnitude of the work,
- provides the basis for the resource assignments,
- allows the project manager to estimate the time for each task, and
- helps the project manager to calculate resource costs for the project [17].

By using a WBS, the project manager can organize tasks that will complete all the work required by the project's scope. The first step in creating a WBS is to identify the major tasks needed to complete the scope. For example, these tasks could include major activities such as "analyze existing data", "create reports", "test reports", "go live with new reports", etc. The purpose of this first step is only to identify the steps, not to organize them. By identifying all the steps first, the project manager can better organize and create a schedule that includes all the steps.

Once the first step is completed, then the project manager begins breaking the major tasks down into further details. For example, the step of "creating reports" may be further detailed into sub tasks such as "complete report requests", "develop template", "create development database", etc. Including team members or other subject matter experts (SMEs) in this step can be very useful as they often bring a different view of the work. The project manager continues to further define all the major tasks until all the subtasks are identified.

Once all the tasks and subtasks are identified, the WBS is complete. Next, the project manager assigns resources to each task and subtask and identifies how long each subtask will take. These are almost always estimates and can be based on previous projects. Often, at this phase, resources are not yet assigned to the project. Instead, the project manager may need to identify the resources needed based on the tasks and duration. Most IT projects will need similar resources, including at a minimum, a champion or sponsor, an analyst, a builder, someone to coordinate testing, to coordinate training, and resources from the unit or department impacted. For smaller projects, some of these tasks may be done by the same person; in larger projects more people are needed. The project manager should identify resources based on the tasks and durations, as well as the skills needed, rather than specific individuals. For some projects, the team is identified in advance of the project based on how previous projects were staffed. There is no formula to identify the right number of resources; teams should stay as small as the work allows to keep the project costs down. In addition, there are times when adding more resources does not get the work done any faster or more efficiently, but instead can add more complexity to a project.

Once identified, team members can help identify how long a task would have taken them in similar projects and them the project manager can then add or subtract time as needed for the current project. The next step is to identify how to determine when the task is complete. This includes identifying any deliverables or outputs for each task. Not all tasks will have an output; some tasks are just an activity to complete in order to do other tasks. For example, status meetings should be tasks in the project plan in order to account for the time spent on the tasks, but do not have any specific deliverables as a result of the activity. The project plan should not be a to-do list of every activity needed, nor should tasks last much more than 2 weeks in duration. The level and number of tasks is guided by the project manager's style and the degree of control needed to effectively manage the project.

Once tasks with resources and duration are listed, the project manager needs to identify any predecessors and/ or links between tasks. For example, usually software needs to be loaded before specific project or site modifications can be made.

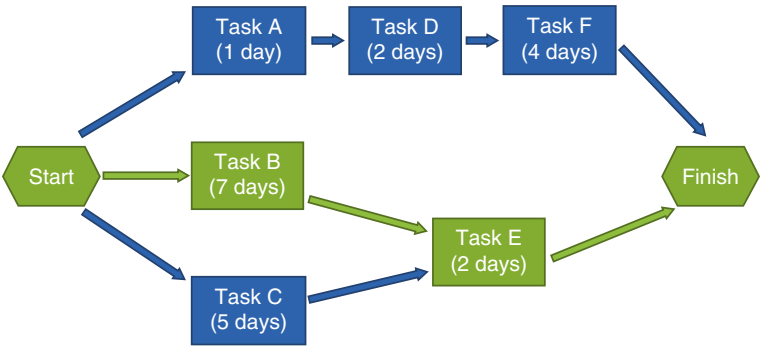

Fig. 16.8 Example of a PERT chart used to determine the critical path, which determines the shortest possible duration for a given project

This would make loading the software task a predecessor of the modify software task. Some tasks can be done simultaneously, that is, they are not dependent on each other to be completed. For example, training preparation tasks can be worked during the same time as testing tasks.

When tasks with known durations are aligned in a project plan with specific predecessors, it is possible to determine the shortest possible duration of the entire project. To find this duration, the project manager can review each series of sequential tasks and find the series with the longest overall duration, which is also known as the critical path. In the example PERT chart (See Fig. 16.8), the project has a total of 6 tasks (A, B, C, D, E, and F). Each task has a fixed duration, but it's possible for some tasks to occur concurrently. For example, Tasks A, B, and C can start at the same time. However, other tasks cannot start until others finish, as indicated by the arrows. In the path A-D-F, Task D cannot be started until Task A is complete, and Task F cannot be started until Task D is complete. By counting up the total duration of these tasks (1 + 2 + 4), the project manager can determine that this particular series of tasks will take 7 days to complete. However, there are other paths through the project, including B-E and C-E. By adding up those paths, the project manager finds that B-E will take 9 days (7 + 2), and C-E will take 7 days (5 + 2). The critical path for the project is the longest of these series, or the B-E path. If either Task B or Task E take longer than expected, the entire duration of the project will be extended. Conversely, tasks that are not on the critical path may have more flexibility. For example, if Task A takes 2 days to complete, it will have no impact on the overall duration of the project because Task F will still finish a day before Task E. If, however, Task A takes 5 days to complete, the critical path shifts to the A-D-F series (5 + 2 + 4 = 11 days).

Another way to demonstrate these linked tasks is by developing a Gantt chart. A Gantt chart displays the same information as the PERT chart, but in a more linear fashion, aligned against a timeline (see Fig. 16.9). In this view, it can be much easier to find tasks occurring concurrently on a day-to-day basis. The Gantt chart also shows the predecessor/successor relationship between each of the tasks. Gantt

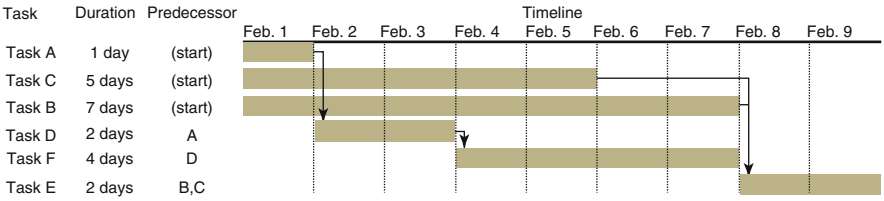

Fig. 16.9 Example of a Gantt chart highlighting dependencies and the critical path

charts can be quickly created, viewed, and analyzed via various types of project management software.

Project management software can help to add and manage these types of links. At the most basic level, project management products will help manage projects from start to finish, help keep costs down, especially in large, complex project and allow employees at different levels to have an input into the process. Project management applications can also help with task scheduling, cost control and budget management, resource allocation, collaboration, communication, quality management and documentation or administration. Once all the tasks and resources are added to the project plan, the project should be baselined. Baselining a project creates a view of the project before the work starts so that it can be compared throughout the project and help determine where any issues may occur.

Many project managers view the project plan as the most difficult part of project management. Although some of the tools available are complicated, a simple timeline with activities, due dates, and person responsible may be sufficient to run many projects. Using software specifically developed for managing projects, however, can help manage tasks that are linked together, generate reports and identify the critical path of a project. A critical path is the longest path or set of tasks through the project. This path or set of tasks drive the project duration; that is, the project cannot be completed any sooner than the last task in the critical path. Understanding and carefully tracking the tasks in the critical path will increase the likelihood of an on time project. Project management software can also help to adjust a project plan if needed due to delays or changes in scope. Tasks can be linked to start one after another or at the same time when using predecessors and links. By linking tasks together, the project manager can more easily see how a change to one task can impact others. For example, if testing is a predecessor to training users, and a delay occurs with testing, there also needs to be a delay in training tasks.

Project Management Office

To help navigate a project through all the process groups, a project manager may rely on the standards set forth from their organization's Project Management Office. According to PMI, "a project management office (PMO) is a management structure that standardizes the project-related governance processes and facilitates the

sharing of resources, methodologies, tools and techniques" ([9], p. 9). While PMOs have been around for a while in other industries, they are still fairly new in healthcare. In addition, to creating a standard methodology, the PMO mission and objectives usually includes consulting, mentoring, and training project team members and organizational leadership [18]. Having experienced project managers who follow standard processes and use consistent tools to set expectations on how a project will be managed serves the ongoing success of organization. The focus of a PMO is to have "centralized and coordinated management of an organization's projects, programs or a combination of both" ([19], p. 11).

Utilizing standard tools within the PMO helps to monitor work across all projects. For example, using a standard tool such as Microsoft Project Enterprise (Redmond, WA, USA) or Solution Q Project Portfolio Management (Toronto, ON, Canada) to define the project work and required resources could allow the project manager to understand the resource availability. Evaluating the demand for resources against their capacity for projects helps with planning individual projects and identifying resource related risks across the portfolio of projects. This is also beneficial when reviewing and scheduling new project requests while ensuring the right resources are available. Standard project portfolio tools provide the ability to review all project requests along with ongoing projects and their associated details. This allows for the ability to look at the inter-project dependencies and risks as well as providing early clues to potential issues that may cause delays in other projects.

In healthcare organizations, there are a variety of options for the reporting structure of the PMO. Since many of the activities identified as projects are related to IT, the PMO often reports to the CIO and focuses on IT projects. In other organizations, the PMO reports to clinical or business leadership or the CEO. In larger organizations, there may be an overarching PMO at the corporate level with project managers or remote PMOs at the local level. The location of the PMO does not impact the value it provides to the organization as long as standards are created and followed.

Communication Plan

Once the project planning (project charter, WBS, etc.) is complete, the project manager will spend most of their time during the project communicating with the team and the stakeholders. The main purpose of communication is to get the right information to the right people at the right time and in a useful format. In many ways communication is selling and reselling the project throughout its duration. The project manager needs to determine who needs what information in order to continue to support the project and complete the required tasks. Good communication can increase the chances of project success, whereas limited or bad communication can lead to project failure. The basic assumption in any communication plan should start with 'no surprises'. Communication should flow from the team to the project manager, from the project manager to the team and from the project manager to the

sponsor or committee overseeing the work and the stakeholders. Team members should provide the project manager with detailed status which the project manager can then roll-up into status for the stakeholders. The project sponsor and stakeholders do not need every detail about the project; rather they need to know about issues and risks that will impact the timeline, scope, resources or deliverables.

The duration of the project often drives the frequency of communication, but no matter the duration, communication should be regular and scheduled. For example, during long projects (more than 6 months) it may be enough to report status monthly. For shorter projects and during major milestone events or issues in larger projects, weekly or even daily status may be needed. For example, during the training phase of a project, daily reports on the number of users trained can help to focus leadership on getting all the users to a scheduled training class prior to the end of the phase. Basic status reports include information about:

- What was accomplished since the last reporting period?
- What are the planned activities by the next reporting period?
- Are there any priority issues and risks that need to be escalated?

Stakeholder status reports should include more information about the project's well-being. For formal communication with stakeholders, using a dashboard style report is often very well received by stakeholders to enhance the details. Dashboards can include the following:

- Project progress toward milestone completion (% complete)
- Overall status (using red-yellow-green highlights)
- Key issues
- Key risks with any available mitigation plans
- Upcoming milestones

Keeping the team and stakeholders up to date on the project timeline, risks and likelihood of successful completion will assist the project manager to complete the project as planned.

Risk Management Plan

Assessing risk is another key task that the project manager needs to focus on throughout the project. Most of the team members and stakeholders are focused on the 'now' during the project; that is, the tasks that are currently in progress. The project manager, however, needs to also focus on the next planned tasks or milestones to determine the probability of those occurring as planned. PMI defines risk as "project risk is an uncertain event or condition that, if it occurs, has a positive or negative effect on one or more project objectives such as scope, schedule, cost, and quality ([9], p. 314). Lewis further describes a risk as "something that can happen" ([17], p. 197). Issues, on the other hand, are something that has happened and need to be managed.

Table 16.2 Risk assessment

Risk table			
Risk	Probability	Severity	Total
Limited number of training rooms	5	5	10
Severe weather (snow) preventing scheduled attendees for training class	3	5	8
Delayed testing may impact start of training	3	4	7
JCAHO visit may occur during training and may impact training.	2	4	6

Once identified, risks can be mitigated, avoided or transferred to another party. Risks can be prevented if identified and managed early enough in the project. Risks should be assessed throughout the project, but two key times to focus on risks is while the business case and project management plan for the project is created and key milestones during the implementation of the project. When creating the business case, risks can be identified based on the maturity of the proposed solution. New software, for example, is more risky than using established software. This is also true with inexperienced staff or the use of new contractors. Identifying these risks during the business case can help to reduce the likelihood of their occurrence or avoid their negative impact to the project. For example, if new software is being developed as part of the project, extending the expected timeline and adding additional tasks to test the software may mitigate the risks.

During the implementation phase of the project, reviewing the progress of the project and issues can help the project manager identify risks and potentially avoid them. Questions the project should ask to identify risks include:

- What could go wrong?
- What kinds of threats exist?
- What other competing initiatives may impact this project?

Once risks are identified, they should be assigned a probability and severity ranking. This will help to prioritize a strategy to prevent the risk from occurring. Probability ranking is a simple assessment of the likelihood of the risk from becoming an issue, from not likely to very likely. Creating a numeric probably ranking from 1 to 5, with 5 being the most likely will help to rank the risks. Risk severity takes into account the impact to the project if the risk were to occur. Again, a 1–5 risk severity scale can be used with 5 describing a risk that could have a major impact to the project schedule, costs, and/or deliverables. Adding together each risk's probably and severity score will help to determine which risks have the potential to most adversely impact the project (See Table 16.2). Risks with high scores (i.e. 7, 8, 9 or 10) should have a detailed mitigation plan reviewed and approved by the stakeholders. In addition, these risks should be included in status reports and dashboards so the decision makers are aware of them throughout the project.

Resource Allocation

Human resources are often the most costly and difficult to manage on a project. Project staff and stakeholders usually come from various departments, business (or clinical) units, or companies and need to quickly come together as a team. In addition, stakeholders to whom the team members report have competing priorities that may impact the ability of the team member to fully commit to the project tasks and timeline. Estimating the time it takes to complete complex tasks on a project is often dependent on the skill of the team member, their understanding of the complexity of tasks that are assigned to them and their knowledge of and belief in the project outcomes. During the business case process, it is necessary to identify resource skills and estimates of the number and type of resources needed. Assumptions are made about the availability and skill set of each team member expected on the team prior to the project approval. These assumptions are often carried into the project and can impact project success as estimates become reality. Task completion estimates are often done by skilled individuals or subject matter experts, but the tasks may not be completed by these same experts. This may cause durations to be underestimated and may adversely impact the project.

Project managers must manage and skillfully allocate resources to successfully complete the project as planned. Often this takes some knowledge of the team members' skills and work style, as well as the culture of the organization. From a project perspective, team members are expected to complete tasks on time and with excellent quality. It is possible, however, that other important activities may take precedence over the project's tasks, especially if the team member does not directly report to the project manager. In addition, team members may not fully understand the urgency of the tasks they have been assigned and may allow them to get behind unless correctly managed.

Projects are made up of people doing tasks. In order to successfully complete the project, however, individuals must become a team with a common goal; that is, success of the project including completing tasks on time and budget while meeting agreed upon expectations. Katzenbach & Smith investigated what made some teams high performing and discovered that teams are not just groups working together, but are groups with individual and mutual accountability and discipline [20]. The most significant step to achieve this mutual accountability and discipline in a project is a common purpose that the team has helped to shape [20]. This common purpose should be the project goal, which in turn should be tied to the organization's strategic objective. The team members need to understand how their activities on the project will help to meet or not meet that goal. Having team members articulate their role in the project goal can help with their commitment. For example, a report writer that does not participate in patient care may not see him or herself as being able to directly impact a goal of reducing medication errors on a project. Reminding team members of their contribution to the overall project goal throughout the project and looking at issues and successes based on how their individual successes or failures impact the project will guide their behavior within the project.

Identifying Human Resources

Often, projects are planned with specific individuals in mind. These individuals are, however, often are not fully available to the project at the time the project needs them due to the nature of projects. Instead of identifying individuals during the planning process, the project manager should instead identify the skills required to successfully complete the project. Perhaps multiple people have those skills or can partially contribute to the project. In addition, since most projects are made up of temporary teams, team members need to be able to work together, so work style is also important to assess. For a project creating reports to reduce medication errors, analytical skills and the ability to mine data are needed. For a project to improve physician adoption of a new order set, some medical experience and informal authority may be needed in addition to technical build abilities. Teams rarely have all the required skills at the onset, but can learn them through the project with as they determine exactly what is needed.

As the project progresses and more work is identified or work is behind, many project managers will add additional team members in order to meet the planned deadlines. A principle called Brook's Law states that 'adding people to an already late project may only make it later" so careful consideration of the impact to adding new people to a project needs to be assessed ([17], p. 20). There are times when two people can get twice as much work done at the same time and others when they will just get in each other's way. The project manager needs to assess this prior to adding additional resources to the project. Often, team members who are assigned to the project for a specific amount of time are not actually working on the project for the expected time. This may be due to competing activities, time off, and/ or other duties as assigned. Project management tools such as Microsoft Project (Redmond, WA, USA) help to define the amount of time an individual is working on a task (i.e. full time, 20 %, etc.), but this is often not used during estimating and not always used to its fullest during a project. A simple way to estimate is to assume that a full time resource will only dedicate 30–35 h to a project rather 40 h as they will have other tasks they are responsible for. In addition, identifying holidays and time off at the beginning of a project can also help to correctly estimate resource time commitment to a project.

Identifying Non-human Resources

In addition to human resources, project resources include inputs to the project like software, construction or machinery. Estimates and assumptions on the availability of these non-human resources is also part of the project manager's task before and during a project. Teams may need workspace or tools to support virtual team activities. Often resources need access to new software, issues management tools or collaboration tools such as Microsoft SharePoint (Redmond, WA, USA). During the

business case and planning phase these additional resource needs should be identified.

Some standard questions can help the project manager identify non-human resources. These questions include, but are not limited to:

- Where will the team work?
- How will the team share documents and knowledge objects?
- Is the software available or does it need to be purchased or developed?
- If additional software is needed, what hardware is required to support it?
- If a new application is being implemented, do end-users require additional tools (i.e. laptops, tablets, etc.) to access it?
- Is there sufficient storage, bandwidth or power available for the project deliverables or application?
- Is construction needed to accommodate new technology or staff?
- Are any services needed to support the project (i.e. computer assisted training development, technical writers, contractors, etc.)?

Not all of this information may be known during the business case planning, but adding time and tasks to identify the details and estimates on costs is necessary. Specific details can be added during the planning phase.

Identifying Financial Impacts

Once task duration and the resources needed on a project have been identified, the project manager can create the project budget. Starting at the lowest level of the WBS or project plan and estimating the costs for each category including personnel, equipment, software, travel, training, supplies, space, construction, etc. and working through each level of tasks until all the tasks are estimated, will create the most complete budget possible. Many facilities add a contingency to project budgets to plan for changes in scope, projects that span multiple fiscal years and other unplanned costs. This contingency can be 5–20 % of the total estimated costs, for example, although few healthcare projects allow for high contingencies.

Budgets, however, are still just 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 take a project beyond budget quickly [17]. In addition to tracking task and milestone completion, the project manager will also need to track resource hours and time reported to the project. Many healthcare project managers need to track both employees (owned resources) and contractor hours, but are rarely responsible for the actual contracting. In addition, owned resources don't always report time per project. In order to manage a project budget, however, owned resources should be expected to report hours work on the project to the project manager with every status report. Contractors usually report their billable hours monthly and the project manager needs to review their budgeted hours against their reported hours and expected

milestones. Reporting on the project budget should include comparing planned value (budgeted hours) against actual cost of work performed along with any non-human resource costs. Any actual or expected overages should be included in the project managers 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

Even the best project manager with the most comprehensive project management plan and in the most efficient organization with the highest-caliber employees will run into issues on a project. Issues and risks are bound to happen on any size project, and a project manager should be prepared to meet these challenges head-on to be successful. This section will describe several areas to be monitored at the project level, organization level, and external to the project and organization.

Issues, Risks and Resources

At the project level, issues are more prevalent, but fortunately, are usually better anticipated and certainly more under the project manager's control. One particular area of concern is based on the project work activities, and the information gathered during project initiating and planning. The majority of project managers acknowledge that unclear requirements are a top challenge for their projects [21]. Oftentimes, it can be difficult for a stakeholder to adequately describe what they really need, sight-unseen, and it can take a specialized skill set to be able to elicit clear requirements. To help mitigate this challenge, assumptions, constraints, and risks should be clearly documented and communicated to the team and stakeholder. The entire team should provide input to these areas to ensure a comprehensive analysis of requirements. Even with clear requirements, it's possible that critical requirements are still missed. Since every requirement takes time, effort, and money to complete, it's important to stress to stakeholders that if something is not documented, it's not going to be done. Completing work that was not part of an approved plan not only may add unnecessary time and cost to a project, but it may also introduce legal and contractual violations, as well.

If requirements are clear and complete, other challenges around work effort may still cause problems, such as incorrect and insufficient work assignments, or poor cost and schedule estimations. Obtaining the correct human resources on a project is crucial to success. After all, 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 project manager should monitor resources for issues in these areas and take appropriate action, which may include escalation to the individual's supervisor or removal from the project team. Additionally, it's important for team members to 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 project manager 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 could introduce other challenges around procurement, communication, and legal matters. The project manager must stay engaged with the team to ensure they are staying on schedule with their tasks and action items and remain on contract.

Organization Attributes

When analyzing potential risks and issues beyond the project itself, a project manager should be cognizant of organizational attributes that could impact the project. The growth in the healthcare industry has generated a large number of supporting IT systems for every aspect of patient care and research. There is a need to ensure that disparate systems are integrated or interfaced with each other, which introduces a new level of dependency between applications, and thereby, projects. 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. If an organization is fortunate enough to have a PMO, that group can assist with documenting dependencies between systems. Otherwise, the project manager will need to collaborate with other managers and system owners to define dependencies [21].

Other organizational attributes that could 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. In competitive industries, the challenge to get a product to market is even more intense. If deadlines are not met, there is a risk that stakeholders will look elsewhere for products and services or skip needed projects because they do not get the job done [13].

External Factors

If a project manager is able to successfully navigate the challenges within the project and organization, there are still external factors to consider. These usually have less predictability and control, such as natural disasters or power outages, but ensuring that backups and alternate plans are available is still the responsibility of the project manager. Other areas to consider include local, state, and federal

constraints. Healthcare IT solutions are often governed by legal and regulatory constraints, which may specify certain types of permits or registrations that are required to operate a given product. Or, the product itself may be subject to policies, such as IT accessibility, as defined by Section 508 of the Rehabilitation Act (29 U.S.C. 794d). Since the number of challenges an informatics project may face are 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.

Healthcare project management is also challenging because project managers are not only managing projects within their facility's policies, business processes and culture, but also within the larger, quickly changing healthcare landscape subject to federal and state regulations. Government 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 even the Affordable Care Act impact healthcare projects. Software vendors are responsible for keeping their software up-to-date with any government requirements, and so their priorities are also driven by these regulations. Project managers need to understand these and other regulations to help both prioritize and manage projects. Refer to Chap. 3 for additional discussion about these policies.

Scope Creep

One challenge that seems to present itself on any given project is the concept of scope creep. Scope creep is a term that is generally given to increasing amounts of work that was not in an original plan. However, more specifically, scope creep is the unauthorized addition of tasks, objectives, or requirements to a project plan. Scope creep should never occur and is "directly related to requirements and their mismanagement" ([22], p. 82). Once the project management plan is finalized, it is never acceptable for a project manager to allow work to be done against the project that was not defined to be done. Oftentimes, scope creep has its roots in small tweaks and changes to requirements, requested by the stakeholder, either because they were unclear or missing at the start. To satisfy the needs of the stakeholder, the project manager may consider allowing the work to proceed as a good gesture. However, these requests may grow in number and complexity, and by the time a project manager tries to stop the flow of unauthorized changes, it may be too late, and the stakeholder may just expect the work to continue to be added, not understanding the impact to the project plan of even small changes. Therefore, it is critical to establish good change control processes at the start of the project. It does not mean a change to scope or requirements cannot proceed; it simply means it must be evaluated and approved first. A good change control process must be in place and communicated at the start of every project. Change control involves "developing and maintaining processes that define each step required to perform an activity correctly and

efficiently" before it is done ([13], p. 243). The primary purpose of this change control is to:

- gather data,
- define the need for the change,
- identify all impacted resources, timelines, systems, and other projects,
- propose the change to stakeholders, and
- ensure validation and authorization.

These items should be documented in a change request form and presented to an authorizing body to approve. In larger projects, a steering committee is usually formed to help make decisions on these efforts with the project sponsor as the chair, and in smaller projects, the project sponsor would make final determinations. If a change is authorized to proceed, the project manager should make sure the change is communicated to all impacted parties, which may include stakeholders beyond the project team, such as other project managers, who may have to wait before starting an activity on their project, or system owners, who may need to make a change to their application to accommodate the change request. Finally, once the change has been approved, it should be added to the project plan, which should then be re-baselined to serve as the new master plan.

Managing Expectations

The expectations of a sponsor or stakeholder may vary from project to project, although there are several common expectations across all stakeholders. Common expectations, include easy access to services and team members, first-time resolution to requests for assistance, evidence that the organization, project manager, and team cares about the project, and perhaps most importantly, no unpleasant surprises [23]. 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 in the project during the planning phase. Conversations around project assumptions, constraints, risks, and issues should be ongoing, with status reports to demonstrate that the project manager is working to complete the objectives of the originally defined project. Setting expectations beyond what was originally planned is dangerous and may fall into the area of scope creep as previously discussed.

Project managers need to be cautious in these communications, however. It may not be necessary for stakeholders to be aware of every issue on a project, else they will risk that the stakeholder may become frustrated by a seemingly never-ending list of problems. This could lead to early project cancellations or a loss of confidence and support from leadership. Thus, while it is important to convey the status of the project, a project manager should be judicial in determining the items, both positive and negative, that are most likely going to impact the stakeholder.

Although the project manager will make every effort to meet the needs of stakeholders, there is still a possibility that expectations will not be met. Thus, a project manager 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, but 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. It is easy for a project manager to become defensive, reiterating that the project met all requirements, although there must also be some level of compassion. Project managers can use reflective listening skills to paraphrase issues back to the stakeholder, providing evidence that the situation was understood [23]. The project manager can also offer to escalate the issue through his or her chain of command, or provide comparable alternative options, perhaps via a separate project or changes to the existing system through the organization's configuration management practices. And in some cases, a simple apology without accepting blame may be sufficient, with promises to document the issue as part of lessons learned to help reduce the possibility of future occurrences.

Balancing Competing Priorities

Every project manager will need to balance competing priorities, whether that involves multiple assigned projects, or working amongst other manager's competing projects and operations work. Just because these varying priorities exist does not necessarily indicate a problem in an organization. For example, if one project manager is deploying a Patient Portal, while another is implementing Barcode Medication Administration using some of the same human resources, it's difficult to argue that one solution is better than the other. Rather, it's important to understand that these priorities exist and determine strategies for managing them.

To help determine the most appropriate strategy, a project manager should understand where the competition exists. For example, if the situation is with overallocated human resources, the project manager should assess whether any work can be rescheduled or reassigned without impacting the project timeline or if any work being duplicated across projects could be consolidated.

If there is no way to avoid the conflict, and it is going to impact one or more projects, a decision will need to be made on which item has the higher priority. One effective way to determine priority is by creating an urgent-important matrix across projects. This matrix can divide projects and operation work into one of four categories:

1. Urgent and important,
2. Not urgent but important,
3. Urgent but not important, or
4. Not urgent and not important.

This matrix will help bring to light where different projects fall across this spectrum [24].

If there are still competing priorities, however, the project manager can elect to create a decision or options document for a project sponsor to review, which should present the trade-offs, as well as the positive and negative consequences of a given decision. From there, the sponsor, in collaboration with other business stakeholders, can make an informed decision on how to best prioritize work. Some organizations may also benefit from having a project governance body that can help set project priorities, either by a voting or scoring technique.

Regardless of the competing priority, it remains the project manager's responsibility to ensure project objectives and requirements are met in accordance with the defined processes and procedures documented in the project management plan, and the organization's project management practices.

Implementation vs. Development Projects

Oftentimes, healthcare projects will involve the implementation of IT components, such as software and hardware. As healthcare projects have increased, so have the number of options available for commercial off-the-shelf (COTS) products that can be procured from external vendors. However, the unique circumstances of an organization may require the implementation of a custom-developed solution, either in-house or via a third party contractor. Either solution may serve to benefit the organization, but each also has unique challenges that must be considered by the project manager and stakeholders.

If the requirements of the organization can be met with an existing product, the implementation of a COTS solution may appear to be beneficial for several reasons:

1. Other similar organizations may have already deployed the product, so the project manager and organization may be able to acquire the lessons learned of other implementations.
2. Since the solution already exists in some capacity, it may be able to be implemented faster using experiences staff or pre-defined project plans.
3. The work to maintain and support the system could be outsourced directly to the software's vendor in the form of a maintenance agreement.

Implementing a COTS system, however, has several drawbacks, particularly as it relates to meeting any unique needs of the organization. In order to keep the system as standardized as possible, the implementation of new requirements or feature requests will usually be analyzed across all of the vendor's clients. If the request does not benefit the overall business of the vendor or the product itself, it may be difficult or impossible for an organization's unique needs to be met. Or, if the software allows for minor customizations, they could be time-intensive and costly with little support in future software versions. Additionally, as a COTS system grows in size and

complexity, an organization has fewer options for future replacement. The replacement of an EHR, for example, could cost millions, if not billions of dollars and take several years to complete. Thus, it's critical that during the procurement process, all of an organization's requirements are well-defined and communicated early.

If a project manager is assigned a COTS implementation, the following should be reviewed during project planning:

1. Required training for the staff that will use or configure the system, and who will provide that training.
2. The gap analysis between the COTS product and organizational process workflows and requirements.
3. Software testing and criteria for software acceptance.
4. Roles and responsibilities between the organization and the vendor, particularly for installation, configuration, implementation, and ongoing maintenance.

For some organizations, given the limitations of a COTS product, it may seem that a custom solution may provide a greater benefit for unique requirements. Some benefits of custom development include:

1. A product that meets the specific objectives of the organization.
2. The flexibility to add or remove specific features in the future in shorter time intervals, based on the changing needs of the organization.
3. Direct access to the human resources that developed the software.
4. Ability to control the software related to when and how to update the system.

However, custom developed software may also incur larger short-term costs with fewer of the 'bells and whistles' that may be pre-packaged in a COTS product. The most important consideration of a custom developed product is the collection of complete and comprehensive requirements from stakeholders. Business analysts, system designers, and programmers are critical roles to include on the project, as they will work together to develop the software [25]. The work may be outsourced to a software development contractor, but these roles will still be needed at some level. Some of the tasks involved with custom development include:

1. Development of specific and testable software requirements and business rules.
2. Design of the software, which may include prototypes and mockups for a stakeholder to review. It's possible that the stakeholder may want to add additional features upon first seeing the system, but it's important for the project manager to maintain strict change control, just as with any other project. Changes can always be deferred until future versions.
3. Development of a comprehensive testing plan against every stated requirement. Given that the software was developed fresh, the emphasis on testing and quality is even more critical than on COTS systems.
4. Determination of allocation of build resources for post-project support. It's possible that the human resources that developed the tool may be the same resources to provide post-live operations and maintenance, but this should be determined early, especially if the work was completed by a contractor.

Regardless of the implementation of a COTS or custom development solution, upon closure of the project, the project manager is no longer the point of contact for the software, so a complete transition to a support team should be part of any project plan.

Emerging Trends

A 2014 PMI research study finds that project managers are facing an increasingly complex and challenging environment [26]. Organizations will need to be more innovative and more efficient to be competitive. The emerging trends in project management all have the goal of helping project managers meet the challenges of today and to deliver successful projects meeting the expectations of the diverse stakeholders.

Distributed Project Teams

Project teams are spreading out and usually do not work or meet face to face regularly. They are becoming more dispersed within different buildings in the same organization, or different states, or across multiple countries and have increased availability of teleworking. As this trend continues there may be ongoing challenges with time zones as well as keeping the team engaged [27]. This trend will also test project managers to find creative solutions to keep stakeholders involved and informed. As communication tools become more widely available, connecting with team members and other stakeholders will become less of a challenge. New audio, video and instant messaging tools continue to decrease the need for email and provide more synchronous communication. These varied communication methods need to be incorporated into the communication plan. The project manager needs to define when each type of communication can be used as well as how often, if at all, the team should meet face to face.

Cloud Based Collaboration Tools

One tool that assists with diversified teams is the emergence of the Cloud. The cloud is revolutionizing the way documents and schedules are shared [28]. Keeping project documentation in a centralized location is not new, but expanding access beyond the use of shared server drives expands accessibility. Cloud collaboration can allow team members to work on a single document, or comment on others' work, simultaneously [27]. These tools also provide improved communication with stakeholders. Teams need to understand and participate in these tools, rather than keep data on their personal hard drives. Depending on the tool, project sponsors, and other stakeholders, may be able view the status of any project in real-time. This could provide a method to augment or complement the regular weekly or monthly status reports.

The increased use of mobile technology, such as smartphones or tablets, can also give team members the flexibility they crave [29]. Many cloud-based tools provide access through mobile applications and more will be providing this access as the use of these devices continue to increase. Cloud storage improves sharing and communication across devices and locations [28]. One concern with Cloud based tools, however, is data security and privacy. While this is beginning to be addressed, many organizations continue to be cautious about putting project documentation being stored in the cloud where it can be hacked or they have no control over the security controls. Cloud-based tool vendors will need to continue working on demonstrating the security of their products for adoption by some organizations.

Compressed Project Work Cycles

Organizations are becoming more aware of return on investment and want to see the outcome from their expenditures sooner. This leads to an increased demand to compress the project work cycle and produce deliverables quicker. There are multiple techniques for this purpose, but many are focused on applications that are custom developed rather than purchased from a vendor. Iterative prototyping and agile approaches will have an increasing important role in reducing time to market for the custom developed applications [27]. These tend to be more difficult to use for projects that include COTS applications.

Healthcare organizations tend to focus on implementing COTS applications since the government is providing incentives for meaningful use of Electronic Medical Records Systems (EMRs) and the emergence of Personal Health Records (PHRs). Few healthcare organizations have the skill set or the desire to build their own EMR or PHR system. For these projects, there are fewer opportunities for a compressed work cycles. Implementing in phases, when possible, allows the functionality to be delivered in smaller 'pieces' and with shorter turnaround time for the stakeholders to see a return on their investment. Using a vendor developed model can also help to reduce cycle time.

Whatever method the organization adopts to help compress the schedule, having a defined process that is consistently followed will continue to be key to successful projects. The majority of organizations create their own project management methodology to match their unique needs and culture [30].

Project Management Skills

With the changes occurring in how projects are managed, the skills of the project manager will need to change as well. There will continue to be a need for soft skills and with some of the expected trends, these may become more important. The project manager will need to adjust their communication styles to include new tools and to adjust to the distributed teams or the use of outsourcing. They will also have to learn

new ways to coach, mentor and motivate project team members. Project managers will need to run projects and manage the teams and to have more leadership skills than ever before [28]. Refer to Chap. 14 for additional discussion on leadership skills.

With the changing role of project management employers are looking for project managers who have project management experience, making it difficult to enter the profession [27]. Many are requiring project management certification for any open position as proof of experience. Being able to manage multiple projects at the same time is a skill that will be setting project managers apart and will be highly valued for future employers [28]. Project managers need to continuously learn as trends change. Only 52 % of organizations have a formal process for developing the competencies of project managers. These organizations report a significantly higher percent of projects meeting project goals, business intent and completing on budget and on time [30]. The use of virtual learning is will become more valuable as they are less likely to be able to get away to attend offsite education or have budget constraints. Skills will need to grow and expand as the role changes and organizations need to be able to provide support, and time, for this to occur.

Governance

A study by PMI shows that only 42 % of organizations have high alignment of their projects and their organizational strategies [26]. This lack of alignment contributes to the report that 44 % of strategic initiatives are unsuccessful [26]. It is important that projects are evaluated based on defined criteria, one of which is alignment with the organization's goals and strategic plan. The development of a governance committee to review project requests is one method of verifying the projects that move forward are those that deliver the most benefit to the organization. Defined criteria that are applied consistently across all requests ensure priorities are set not only for project approvals but also in what order they should be started. This helps to avoid the impression of favoritism and ensures the right projects are approved expending the available resources in the right place.

Emerging trends can be just what is needed to mature an organization, but they can also be a distraction. Effective project managers should focus on the skills and tools to deliver successful projects. Stakeholders value the deliverables and final outcome. Each new trend, concept, or tool should be evaluated with an eye to improving your processes and situation.

Summary

Healthcare will continue to change and projects are everywhere. Strong project management processes can help reduce the risk of project failure. The defined process groups, from the Project Management Institute, can be used to help define the specific steps that are best practices for a project to go through from Initiation to Closure.

Each step has defined activities and deliverables that feed into the next. Many tools were also discussed along with how they fit into the project management process. These tools, such as the project charter, WBS and communication plan, all help define the project and how it will be completed. Each of these tools can be tailored to meet the specific need or organization, but their purpose and benefit will stay the same.

Managing resources, human and non-human is a skill that all project managers should have. They are often called upon to manage the competing priorities of the project team to ensure the project schedule is not delayed. The future trend of distributed teams will require the project manager to look deep into their toolkit to find new ways to manage the project team and ensure solid communication. Stakeholder expectations are always a challenge, but taking the time to complete a stakeholder analysis will help to define how to manage the different groups. A strong project management process, with defined tools and experienced project managers, can help to ensure project is completed successfully, on time, on budget, meeting requirements and stakeholder expectations.

Clinical Informaticists are often called upon to fill many roles during a project from end user, to team member or even project sponsor depending on their position within the organization. They may even be called upon to be the project manager whether they have prior experience or not. This chapter touches on the skills, tools and expectations of a project manager from planning, facilitation, communication and management.

Questions for Discussion

1. Have you been involved with any projects that have gone particularly well (or not so well), and what do you think was the underlying reason as to why?
2. Identify at least five potential projects that may be undertaken by a healthcare organization, and define what work may be undertaken in each of the project process groups.
3. What are some common challenges that may be faced on Healthcare IT projects?
4. What is the purpose of a project charter?
5. How does a work breakdown structure (WBS) help to create the project plan?
6. As a project manager, how can you best keep a stakeholder happy that has continually changing requirements, without sacrificing the scope of the project and risking scope creep?
7. If you were the sponsor of a project to implement a new system, but the end product did not meet expectations, what recourse would you expect from the project manager?
8. Identify at least three different potential collaboration tools that could be used with a distributed project team, and how they can improve communication.
9. What are the reasons why project managers need to expand their leadership skills more than ever before?

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Chapter 17
Strategic and Financial Planning for Clinical Information Systems

Scott Mankowitz and Alan D. Snell

Learning Objectives

1. Identify the role of the Mission Statement, Vision Statement, Guiding Principles in Strategic Planning.
2. Learn how environmental scanning and SWOT analysis help organizations define their objectives
3. Describe different methods of technology appraisal and acquisition
4. Utilize standard metrics of managerial accounting to rank investment choices

Core Content

4.5 Strategic and Financial Planning for Clinical Information Systems

- 4.5.1 Establishing mission and objectives
- 4.5.2 Environmental scanning
- 4.5.3 Strategy formulation
- 4.5.4 Action planning and strategy implementation
- 4.5.5 Capital and operating budgeting
- 4.5.6 Principles of managerial accounting
- 4.5.7 Evaluation of planning process

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Case Vignette

Carlie is a newly minted CIO at Universal Healthcare, a conglomerate of seven for-profit hospitals in Northern Kentucky. She has extensive experience in Information Technology, but is relatively new to management. She is full of great ideas and new projects for her hospital system, and can't wait to get started.

In preparation for her first board meeting, she reviews the company's annual report. She is gratified to see that her own personal goals for her department mesh nicely with the company's mission and vision. Unfortunately, the financial section of the report leaves her confused. It seems like the company is making a good profit overall, but she can't tell how or where the IT budget is being spent. Moreover, there is very little indication what resources are going to be available for future projects.

Seeking help, she calls Mark, the company's financial accountant who prepared the report. "I'm afraid, I'm not the person you're looking for," says Mark, "You need to talk to Dave, our managerial accountant. He's the one who can help you with budgeting and planning."

She quickly calls Dave and he walks her through the company's strategy for the next few years. He explains that Mark's annual report is for external stakeholders and is not nearly specific enough for her needs. Instead, he shows her the company's internal reports which are sorted by hospital, department and product type. Using these, she can identify the more profitable parts of the organization, and where she should direct her energies. She makes some calculated adjustments to her list of budget proposals and is now ready to meet the Board of Directors.

Thanks, *Dave*!

Introduction

Information systems can comprise up to 30 % of a healthcare institution's capital budget and 3 % of its yearly operating expenses [1]. As the size of the organization grows, this expenditure can easily reach into 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 very basic questions, such as:

- 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 and Vision

Strategic planning begins with developing a **strategy**: a set of rules and priorities to help guide decisions. These ideas are usually encapsulated into mission and vision statements which keep the team focused and motivated. The strategy may apply to a project, a department or even an entire organization.

Creating these statements is relatively straightforward.

- The first priority is to define the goal of the project or the department. (In project management, this document is commonly called a Project Charter; please see Chap. 16 for more information on Project Management.) For example, a project goal may be to install a new Electronic Health Record (EHR) for the hospital, or to streamline database operations. The goal for an IT department may be broader, such as to support and extend an existing information infrastructure.
- The next step is to clarify the goal by defining performance indicators and expected milestones. For example, "to install a new EMR in the hospital within the next 12 months without exceeding the budget and achieving significant efficiency gains in radiology and surgery." A departmental goal may be "to maintain current applications and hardware and prevent unscheduled downtime, to answer customer support tickets in less than 24 h" and so on.
- The **mission statement** should combine these ideas into a brief yet clear statement of purpose. The statement should be simple but inspiring. Technical language and jargon should be avoided. For example, "to implement the best available Electronic Medical Record system for the hospital while minimizing cost, improving safety and maximizing efficiency." A departmental mission statement would be more broad, such as "to provide world-class support to the host facility with best-of-breed software, reliable hardware and responsive technicians"
- The **vision statement** is a bit more aspirational. To compose a vision statement, look at the mission statement and try to extract the human value in that mission. For example, how does the organization change people's lives? How does it make the world a better place? Consolidate these ideas into the values that the organization has (or should have). This statement should describe the organization in a perfect world. Hyperbole is expected. This is a statement that should not only motivate people within the organization, but should entice people outside the organization to join in. For example, "we hope to improve the care of the sick and injured by giving our providers reliable and powerful tools to diagnose and safely treat our fellow humans." In this case, the vision statement might apply equally to the IT department and the EHR project.

It is important to note that even when the mission changes, the vision usually stays the same.

Guiding Principles

Another staple of strategic planning is **Guiding Principles**. These are a set of rules to bear in mind when making decisions for any project, department, or organization. In many ways, this is similar to the Constitution of the United States of America. In order for Congress to pass a law, the law must comply with the goals and ideals of the Constitution. If it does not, the law is considered unconstitutional and must be withdrawn. Similarly, when an organization puts forth guiding principles, it uses those principles as a foundation upon which all short and long-term decisions are made. By adhering to these rules, the organization can ensure that projects don't conflict with one another and will help the organization to achieve its mission and vision. Guiding principles can be broad or very specific, depending on organizational needs. See Box 17.1 for examples of guiding principles from the Joint Commission [2] and the Association of Nurse Executives [3].

Box 17.1: Guiding Principles from Aone and the Joint Commission

Joint Commission Principles to Guide Technology Adoption

- Establish the business case and sustainable funding sources to support the widespread adoption of health information technology
- Redesign business and care processes in tandem with health information technology to ensure benefit accrual
- Use digital technology to support patient centered hospital care and extend that care beyond the hospital walls
- Establish reliable authorities to provide technology assessment and investment guidance for hospitals
- Adopt technologies that are labor-saving and integrative across the hospital

(From Health Care at the Crossroads: Guiding Principles for the Development of the Hospital of the Future, © The Joint Commission, 2015. Reprinted with permission.)

Aone Guiding Principles for the Nurse Executive to Enhance Clinical Outcomes by Leveraging Technology

- The current health care work/practice environment must be redesigned to enhance quality, safety and healthfulness for today and for the future."
- Individuals involved in health care delivery—both from clinical and technology/industry perspectives—are motivated to fix problems and to redesign systems."
- It is clear that integrated technology is required in order to achieve work redesign for today and for the future."

- There is no single transformational technology; this is a complex, multi-year journey that requires a co-designed roadmap to the future." Environments and organizations are complex and already engaged in sometimes chaotic redesign and the implementation of multiple technology systems and products. We will not have the luxury of a fresh, clean slate from which to continue redesign work."
- The environment and organizations within it will continue to be challenged with regulatory demands."
- Human and capital resources will remain constrained

(From: Guiding Principles, © 2009, by the American Organization of Nurse Executives [AONE]. All rights reserved. All rights reserved. Used with permission from AONE.)

Environmental Scanning

With the mission and vision in mind, the next step is to begin **environmental scanning**. This is a process where executives continuously monitor the environment, looking for early signs of changes that could affect current or future plans.

The goals of scanning are:

- To detect scientific, economic, social, political, regulatory or technological trends that are relevant to the organization.
- To predict how these trends may impact the areas where the organization is lagging behind and to identify areas where a line of business may be endangered.
- To alert management to trends that are speeding up, slowing down, emerging and disappearing.

Environmental scanning is usually broken down into **internal scanning** which looks for issues within the organization and **external scanning** which looks at larger trends in the marketplace. External scanning also recognizes what the organization's competitors are doing as well.

Environmental scanning is sometimes mandated by law. For example, the Affordable Care Act of 2010 declared that non-profit hospitals are required to perform a Community Health Needs Assessment (CHNA) every 3 years. This is a very specialized form of external scanning, but can be very useful for a hospital to identify ways in which it can improve its community.

The data collected from an environmental scan are usually presented in a 2×2 table called a **SWOT analysis**. SWOT stands for Strengths, Weaknesses, Opportunities and Threats. Strengths and weaknesses are derived from internal scans while opportunities and threats come from external scans. Box 17.2 shows an example SWOT analysis.

Box 17.2: Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis

Summary of environmental scan:

- The clinic does not earn as much money as it did 2 years ago. Possible reasons include decreased volume of patients and a charge master that has not been updated in 5 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, the **strategic formulation** begins. The organization reviews each of its threats and develops programs to prevent or attenuate them. Opportunities are reviewed and a decision is made which ones to pursue. There are a variety of factors that are important in selecting projects. In general, projects that satisfy governmental regulations and maintenance of commonly used equipment take priority over new ventures. We will discuss this further in Budgeting, which is outlined below.

A useful mnemonic for strategic planning is VMOSA, which stands for Vision, Mission, Objectives, Strategy and Actions. These activities progress from the most abstract to concrete (see Fig. 17.1).

- **Vision** – the dream. Like the vision statement, this is an uplifting statement of hope about the future.
- **Mission** – the what and the why. Like the mission statement, this briefly describes what the organization is trying to achieve and why it is important.

Fig. 17.1 The vision, mission, objectives, strategy and action (VMOSA) pyramid

Table 17.1 Guiding principles from AONE and the joint commission

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 6 AM 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 two above; four technicians	Interruption of radiology procedures	Dr. Barco to arrange gaps in schedule to permit installation

- **Objectives** – how much and when. This is where concrete goals are listed along with appropriate timelines and expectations. This section is more specific and includes definitions of success and failure for each phase of the project.
- **Strategies** – the how. This includes the various methods and procedures that need to be done in order to achieve the objectives.
- **Action plan** – the complete roadmap. This section is the cook book which gives managers and workers clear instructions on how to complete tasks. The action plan divides the objectives into individual action steps. Each step includes a responsible entity, an expected timeline, the resources needed for implementation, anticipated barriers and potential collaborators and remedies. For example, the following might be part of an action plan for an EHR implementation (see Table 17.1)

Whether setting goals for a project or a department, it is vital to ensure that the goals of the larger structure are aligned with the goals of the smaller units. Put simply, a CIO is much more likely to have his projects funded when his mission and vision statements echo those of the larger organization.

Organization and it Capacity and Capability

Technology as a Tool

One of the great temptations in today's fast-moving world is to invest in the latest or greatest "bleeding-edge" technology. While this is a great way to keep the IT staff engaged, it creates the fear of unreliability and instability for the end user. To the healthcare provider, the **technology is only a tool** to facilitate care for patients, and not an endpoint. There are many other important factors that determine health care quality. For example, a great IT system will never make up for sloppy doctors, inept scheduling, low-quality medications or poor administrators. However, a careful doctor with a reliable schedule and potent medications overseen by a top-notch administrator will succeed regardless of the IT system used.

Technology is only successful when it leverages existing strengths of an organization. For example, a regional cancer center has several famous doctors and researchers on its staff. In a marketing effort, it creates a web site that publishes articles about new treatments and therapies that it provides. Patients are drawn to the web site because of the prestige of the authors. In this case, the technology (the web site) is leveraging the existing strength (the reputation of the authors) to create success.

Application Portfolio

The set of technology tools that an organization possesses is often referred to as an **application portfolio**. Since a large percentage of IT budgets involve maintenance of applications, removal of redundant technology can result in significant cost savings.

There are two common ways to manage an application portfolio. In the "top-down" approach, an IT director makes a list of all the software programs used by the institution, along with their functionalities and cost. When a new technology need is identified, the IT director consults the current inventory to see if any of the required functionality can be provided by existing systems. If not, a new purchase is considered. From time to time, the IT director will also review the inventory to remove unneeded items and to suggest better or less expensive alternatives.

Another way to maintain the portfolio is the "bottom-up" approach. In this model, all of the source code for each application is stored in a large database. A computer program searches the code for similarities and makes suggestions about what can be removed. By definition, this process requires access to source code, which is not routinely available for commercial software. For this reason, the "bottom-up" approach is much more commonly used in organizations that develop their own software applications.

Technical Architecture

An institution's **technical architecture** is the hardware, network connections, software and tools that it uses on a daily basis. Certain applications require specific architecture to run. These costs can spiral exponentially when applications require special hardware or networking capacity. In addition to the acquisition and installation costs, the IT department now has to support the new hardware in addition to the current portfolio. For this reason, most IT departments are unwilling to expand their technical architecture unless it is completely unavoidable.

For example, consider a hospital with a technical architecture shown in Box 17.3. Suppose the helpdesk wants to implement a new ticketing system. There are two available options: one is an Apple Macintosh (MacOS) based product which costs $1000 per year; the other option is a Microsoft Windows based product which costs $2500 per year. A quick review of the technical architecture shows that the existing network and database capacity are sufficient for either system. However, the IT staff has had no training in MacOS and is unsure if it can provide reasonable local support. Even though the price is higher, it may make more sense to choose the Windows product because the total cost of ownership is lower.

Box 17.3: Example Technical Architecture for a Hospital

1. Networking
   (a) Internet: six separate T1 lines. For redundancy, two separate vendors are utilized.
      (i) Two of the six T1 lines are specifically allocated for the Electronic Medical Record (EMR) and are connected to the Application Service Provider (ASP) by Virtual Private Network (VPN)
      (ii) Four general purpose T1 lines for all other hospital applications. All four lines pass through hardware firewall.
   (b) Internal network
      (i) Wired: the hospital and all outbuildings are connected via gigabit Ethernet with the exception of 4-West and 4-East which are still using 100 Mbps Ethernet. Each nursing unit has its own switch. There are never more than three switches between any terminal and the hospital backbone.
      (ii) Staff Wireless: the hospital and outbuildings are equipped with 802.11n wireless routers with a maximum distance between transmitters of 90 ft. All staff wifi traffic is encrypted with WPA2

(iii) Public Wireless: Free wireless is available upon request from the helpdesk. Wireless speeds are throttled to 100 kbs and are isolated from hospital networks. Encryption is not available.

2. Telephones
   (a) Voice Over Internet Protocol (VOIP) server with capacity for 192 outside lines and 360 extensions
   (b) Two hundred forty one extensions in use
   (c) Hundred outside lines in the format of 201–555–84××
3. Data Center
   (a) Located in hospital ground floor, climate controlled and guarded 24 h per day
   (b) Six server racks, providing total of 252 rack units (RU) of space; currently, 84 RU available
      (i) Twelve database servers, with 16 terabytes (TB) storage total
      (ii) Sixteen remote access servers, providing remote desktop (RDP) and VPN access
      (iii) Four Radiology Information System (RIS) servers with 100 TB storage
      (iv) Forty six other servers
4. Workstations
   (a) One hundred twenty-five deployed multipurpose windows-based PCs
      (i) Minimum specification: Core i3 processor; 4 GB RAM; Gigabit Ethernet; 19″ flat-panel monitor
   (b) Fourteen Workstations on wheels, windows-based
      (i) Minimum specification: celeron processor; 4 GB RAM; Gigabit Ethernet; 15″ flat-panel monitor; 4 h battery life
   (c) Four radiology workstations
      (i) Each workstation has four high-definition five megapixel displays
   (d) Sixteen high capacity departmental monochrome laser printers
   (e) Forty-four assorted personal printers (color laser, inkjet, other)

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 in much more detail and brief synopsis is presented here.

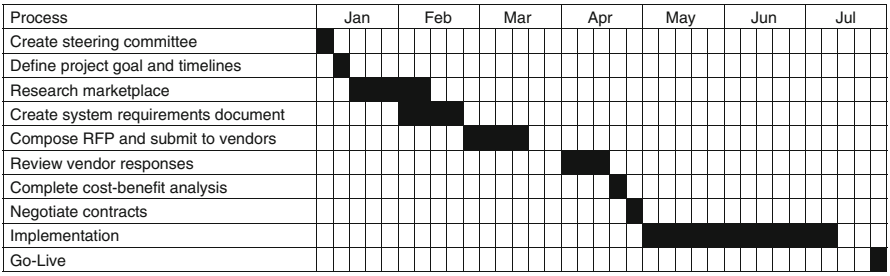

Fig. 17.2 Example of project management timeline (gantt chart)

The general framework for SDLC includes four phases: (1) planning and analysis; (2) design; (3) implementation; (4) support and evaluation [4]. The process begins when the organization identifies a need for a new system and continues until that need resolves or the costs of maintaining the system become prohibitive. At that point, the cycle begins again.

Planning

The SDLC begins with planning. During this phase, the operational needs are defined. What functions or tasks is the system supposed to accomplish? What is the business need of the organization? What is the best set of tools to meet 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. In order to make these decisions, an IT **steering committee** or **governance council** is formed, consisting of the major stakeholders and knowledge experts in the organization. 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 search of the academic literature for best practices as well as a survey of the vendor landscape to find out what products are appropriate for the organization's needs. It also can involve an evaluation of current vendor installations at other institutions. When the choices have been narrowed down, the top contenders will be invited to give demonstrations to the committee. After a cost-benefit analysis, a system is selected. An example timeline is shown in Fig. 17.2.

When determining the 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 include the additional annual cost of the software and predictable future upgrades. In some cases, training or hiring of new staff with expertise in a new operating system is necessary. Construction of a new facility to house the information system may be required. In some cases, the infrastructure costs are so high that the organizations will outsource the application to another vendor. This enables the organization to focus efforts on its core missions, while allowing the vendor's experts to maintain the system. The downside to the outsourced model is that the organization loses

control over its technology and is considerably less nimble in the face of changes. Also, since the application will be supported remotely, the vendor's staff will not be as intimately familiar with the organization's operational peculiarities as a local IT support staff.

There are two common models for outsourced software. The older, 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 *instance* of the software program. In most cases, each user is provided with a *virtual machine*, or a share of storage space and processor time on the server. In some cases, the application cannot be virtualized, and the application requires its own dedicated server. The problem with this approach is that it does not scale very 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 application 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 has to run only one instance, which has a dramatically lower computational cost. In some cases, the vendor may opt to provide individual instances of the application to different customers in order 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 17.2 for a comparison of traditional Client/Server applications with ASP and SaaS.

Design

The design phase can be fairly complicated. It involves analyzing the current (or ideal) workflows of the organization and modeling them into data processes. This information can be gathered in several ways, such as management decisions, open forums, user surveys and/or appointed spokespersons for the various functional groups or departments.

When purchasing a software package from a vendor, much of the design has already been completed; making customized changes can be quite expensive or even impossible. In this case, the design phase may be limited to small modifications or selecting various add-in modules to meet business needs. On the other end of the spectrum, the organization may opt to develop an entirely new application. Although this option is considerably more expensive, it allows the organization to customize the system precisely to its needs.

Table 17.2 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

Once system requirements are defined, the organization creates a **request for proposal** (RFP), which is a document submitted to various vendors to determine if their products meet the needs of the organization. When the vendors returns the RFPs, the committee can make realistic comparisons between the different systems. A small section of an RFP is shown in Table 17.3.

Table 17.3 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	

Implementation

Implementation involves installing the system, training staff and generally preparing the organization for the **go-live** date. In many cases, this phase will require transferring information from the old system to the new. If the data cannot be brought over, they are often kept in an archive that can be accessed if needed.

There are two common methods of implementation. In the **big bang approach**, the entire organization is converted to the new system at once. In the **staged approach**, the new 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 small "bugs" to be recognized and resolved before creating any major service interruptions. However, the benefits of whole-system connectivity and efficiencies cannot be realized until conversion is complete.

In order to have a successful implementation, it is important to create an implementation team. This team is usually composed of many of the same members as the project steering committee from the planning phase. One important 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 common scenario is when a hospital institutes Computerized Physician Order Entry (CPOE) and enlists a physician champion to train and inspire other physicians to use the system [5]. In order for a system to gain traction, the users have to believe that the new system is in some way an improvement over what they had before. Even with current, state-of-the-art technology, this can be a difficult sell. For example, in a paper-only system, most physicians can write admitting orders in 1–2 min. With CPOE systems, it will take much longer, and the user will be interrupted with password requests, clinical decision support warnings and other technical hurdles. Physician champions must

therefore understand the physician concerns and demonstrate the value in the new system to encourage their colleagues to utilize it.

Training is a key component of successful implementation. Higher quality initial training diminishes the need for support after implementation. Training involves many logistical challenges, such as navigating clinical schedules and making sure that the correct knowledge experts are available. Matching the clinical skill set of the instructor to the students is crucially important. For example, a pharmacist should not be teaching physicians about clinical documentation.

Support and Evaluation

Even well-designed systems will eventually have unscheduled downtime as unanticipated problems arise, and the IT department is often called upon to make the system function in new and interesting ways. Invariably, as the environment changes, there will be bug-fixes, major and minor upgrades, new modules and significant overhauls. Up to 80 % of the IT budget can be spent on support, since this is by far the longest of the four phases.

Continuous analysis (sometimes called the **ongoing process of planning**) is important to establish the continuing business need for the system. At some point, the system will have diminishing value and it will be time to begin the SDLC again.

Planning and the Budget

Accounting is defined as recording, synthesizing and reporting of financial and operational data. **Financial Accounting** is the process by which companies report financial information to external parties, such as regulators, stockholders, creditors and the public. **Managerial Accounting** is concerned with providing actionable information to managers within the organization. Financial accounting is a much more formal approach because it has to comply with the Generally Accepted Accounting Principles (GAAP) or other international rules, while managerial accounting can be represented in any format useful to the manger. While financial accounting usually reports information for the company as a whole, managerial accountants are segment specific [6]. See Table 17.4 for a comparison between the two types of accounting.

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 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.

Table 17.4 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

- legal or regulatory requirements
- requirements to maintain 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 come from different sources. Operating expenses come out of the organization's daily cash flow and budgeting process. Capital expenses may come from retained earnings, but more frequently come from debt or equity. In many nonprofit hospitals, fundraising and governmental grants are the largest sources of capital. For example, between May 2011 and January 2015, the Center for Medicare and Medicaid Services (CMS) paid over $19 billion to doctors and hospitals who attested to Meaningful Use of certified electronic health records [7].

Capital budgeting is often called **investment appraisal** because it guides the organization on how to invest or when to borrow money. There are many ways to calculate the value of an investment.

Consider the following example:

A hospital purchases a CT scanner for $1,000,000. After 5 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 17.5 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, expressed as a percentage. Since the total return (i.e. profit) is $450,000 over 5 years, the annual return is $90,000. The **total cost of ownership** of the scanner (i.e. the

Table 17.5 Summary of yearly profit and loss for a hypothetical CT scanner

	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 17.6 Calculating the payback period for the hypothetical CT scanner

	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

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), which is 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 is. In our example above, the CT scanner becomes profitable sometime during year 4 (see Table 17.6)

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 that is 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 invested in another project.

One method to correct for this decreasing value is to calculate what the **present value** (PV) of all future returns are at the time of investment. In order 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 poor credit rating has to pay more interest to borrow the same amount of money, and therefore has a higher WACC [8].

Using a hypothetical WACC of 5 %, $100 invested today would be worth about $121 in 5 years, so the PV of $121 at 5 years is $100.

Using this methodology, we can re-create our table for the CT example, as seen in Table 17.7.

Table 17.7 Calculating present value for the hypothetical CT scanner

	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 17.8 Calculating profitability index for the hypothetical CT scanner

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

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.

$$NPV = PV\ of\ revenue - Investment\ cost$$

Another way to express this value is the **profitability index** (PI) which reflects the ratio of 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.

$$PI = \frac{PV\ of\ Revenue}{Investment\ cost}$$

These two measures complement each other, but can be misleading when applied to projects of different scale. Consider the following two projects, shown in Table 17.8.

The PI for the CT scanner is almost double the PI for the new building, which makes it seem a better investment. When the investment has matured, however, the new building will reward the investor with almost three times as much return. While these financial metrics are important to fuel decision making, it is important to know their strengths and limitations.

Emerging Trends

In 1997, the Balanced Budget Act created the **Sustainable Growth Rate** (SGR), a formula used by Medicare to reimburse physician services. The basic premise was that Medicare spending should never increase faster than the Gross Domestic Product (GDP). Unfortunately, the SGR frequently provided a negative growth rate for physician services. Fearing that Medicare beneficiaries would not be able to find physicians willing to accept this discounted fee schedule, Congress passed numerous

temporary corrections to the SGR. Nearly every major medical specialty depends at least partly on Medicare payments, and physician groups spent heavily on lobbying efforts to "fix" the SGR. While this may have enriched lobbyists, it never resulted in a long-term solution to the problem. As of the time of this writing [9], the U.S. House of Representatives had just passed an SGR fix (H.R. 2, Medicare Access and CHIP Reauthorization Act of 2015), but it has yet to be ratified by the U.S. Senate.

The SGR and its associated drama represents an example in strategic planning. In this case, physician groups performed an *external scan* and detected the *threat* of decreased reimbursement associated with the downward *trend* of the SGR. They recognized that the only way to address this threat was by paying for lobbyists. For the most part, their decision proved correct. After 11 years and 16 patches, Medicare physician reimbursement has stayed relatively stable [10].

Moving forward, if the SGR is repealed, it will be replaced with a new Merit-based Incentive Payment System (MIPS). MIPS represents a consolidation of three other incentive payment programs: the Physician Quality Reporting System (PQRS); Value-Based Modifier (VBM); and Meaningful Use (MU). MIPS will have four basic components: Quality; Resource Use; Meaningful Use; and Clinical Practice Improvement Activities. Strategic planning in IT for the next decade will likely involve developing technologies to encourage, assist, measure, report and create value in one or more of these areas.

Summary

Mission and vision statements help define an organization's culture while guiding principles help direct its actions. Environmental scanning is used to define the strengths, weaknesses, opportunities and threats relevant to an organization.

Information technology should be seen as a tool to assist in the provision of healthcare. The collection of hardware and software that the organization owns is called the technical architecture and application portfolio, respectively. The process for 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 within the organization to assist in planning, budgeting and decision making.

An organization with a limited budget has to decide which opportunities it wants to pursue. There are a variety of financial metrics which can be used to appraise different kinds of investments. The Accounting Rate of Return 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 take into account the time value of money. The Net Present Value reflects the future value of an investment in terms of what it is worth today.

Questions for Discussion

1. The mission statements for most healthcare institutions are similar and nearly always involve caring for sick people. Why do you think it needs to be spelled out for each organization? How might different institutions change their statements to reflect their individual goals?
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 had to implement a new project, would you use the big bang approach or the staged approach? Why?
4. Assuming the salary was the same, would you rather be a financial accountant or a managerial accountant? How large a salary differential would have to exist to make you switch?
5. If the ARR does not take into account the time value of money, why do people still use it? Is there any circumstance in which it is just as good as another option?
6. If you wanted to persuade a budgeting committee to purchase a new barcoding system, which financial metric would you use to quantify its benefit? Would your opinion change if you were trying to convince them to buy a new building?

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Chapter 18
Change Management for the Successful Adoption of Clinical Information Systems

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Learning Objectives

- Describe the process to assess organizational culture and behavior.
- Identify the non-technical factors that influence the adoption of clinical information systems by clinicians and others in the organization.
- Describe strategies for promoting effective use of clinical information systems.
- Describe key success factors that need to be included in an implementation strategy.
- Describe the role of diffusion in an organization for adoption of a new system—technical and non-technical.

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Core Content

- Assessment of organizational culture and behavior
- Social-psychology theories that directly affect change management and adoption
- Change management strategies
- Strategies for promoting adoption and effective use of clinical information systems

Key Terms

- Change management
- People-Process side of change
- Adoption
- Organizational culture
- User needs
- Workflow
- Communication
- Champions

Case Studies

Chemosabe Case Study: Designing for Success

Oncology Hematology Specialists (OHS) is a provider of medical care 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).

Prior to the implementation, the leadership of OHS conducted a search across 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 a 1-year period. 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. Use of chemoSABE was mandated by the OHS leadership, with all physicians using the system for chemotherapy orders by the roll out 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.

Laboratory Result Pager Case Study: Designing for Failure

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.

One of the faculty, without consulting with the house staff, designed and implemented an automatic laboratory result pager using a Coldfusion server with a connection to the institution's EHR. Every 5 min an automatic task would scan the EHR for all new laboratory results for NICU infants, and if a result was abnormal, a page was initiated to a pager that was 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 a number of 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 feedback of the residents. 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 % or more worse than previous results. The modified system was reintroduced with some moderate effect on provider behavior [1].

Lessons drawn from the failure of the introduction of the initial paging system included that inclusion of end users in the design process is critical, work flow and information needs of end users must be studied and analyzed, and the effect of the new intervention must be modeled on work flow, new work demands, interruption of other tasks, and local culture and conditions.

Introduction

In 2014, the US government launched HealthCare.gov, a new consumer-facing website designed as a health insurance marketplace for US residents. The launch was one of the most public failures of a software project, resulting in significant embarrassment for the Department of Health and Human Services as well as the Obama administration and directed public attention to the fact that large software projects frequently fail.

The Standish Group International has been tracking failure rates of software projects for over a decade. Table 18.1 shows rates of success, failure, and challenges (cost and time overruns, failure to deliver to expectation, etc.) of software implementations in international companies [2].

Table 18.1 Standish Group International IT implementation success and failure rates

	2004	2006	2008	2010	2012
Successful (%)	29	35	32	37	39
Failed (%)	18	19	24	21	18
Challenged (%)	53	46	44	42	43

While health IT failures are multifactorial, an often underappreciated aspect in the implementation of clinical informatics systems is the human behavioral changes required for impact on clinical outcomes. Humans - end users, clients, or any other individuals, who use an IT system in the course of their clinical work - and their behaviors are essential for the ultimate 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" not only predisposes that system to failure, but also creates a culture among users of anticipation of future technological failures and resistance to change in general [3]. As organizations scrutinize and incentivize information systems, implementation failure with its high costs (on finances, morale, employee satisfaction, patient care) will not be an option for health systems. This chapter describes many aspects of change management that 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 [4]. Additionally, most studies describing new systems do not include the implementation plans. Those that do describe implementation, seldom include more than a project timeline [5]. As a result, the case-report literature creates difficulty in ascertaining the important dynamics among people, organizations, infrastructures, and software and factors of successful adoption.

Many non-technical factors influence the adoption of clinical informatics systems [6]. Organizational culture and behavior can be misaligned resulting in failure of 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 literally be life threatening [7]. These non-technical factors occur not only during the initial implementation period, but also continually over the life cycle of the system, with the result that different factors can dominate different stages of technological diffusion. Challenges at initial adoption might not be the reason a project cannot cross the implementation chasm to achieve full adoption. Successful change management not only includes initial awareness of these different factors, but accounts for them throughout the life cycle of an informatics intervention. Table 18.2

Several studies have investigated the role of technological change, mostly electronic health record (EHR) implementation, on work efficiency and time spent on training, completion of work tasks, and documentation [8]. Most likely, because EHRs vary significantly in design and functionality, the results of these studies are mixed without a conclusive effect of technology on efficiency [4, 9, 10]. The experienced efficiency tradeoff for many providers creates a perception of low personal benefit of the implementation to their work. Additionally, the change in roles or workflow by implementing a clinical information system can create new demands on healthcare personnel that can provoke resistance to the system.

Table 18.2 Factors influencing resistance to change [8, 36]

Systemic	Organizational	Individual
Healthcare regulations	Competing goals among organizational members	Perceived low personal benefit
Lack of competition	Previous failed implementations	Changes in roles
Lack of outcomes data	Organizational inertia	Perceived loss of status
Rising costs	Low organizational morale	Perceived lack of ownership

Success in implementing clinical information systems is increasingly important. The clinical benefit of many technologies has prompted championing of HIT as improving healthcare and making it more efficient [11].

Many health systems spend significant amounts of money purchasing clinical information systems and associated infrastructure, making investment in these systems equal in scale to building a new hospital wing or laboratory building. New regulatory mandates prompted by the 2009 Health Information Technology for Economic and Clinical Health (HITECH) act have created financial incentives for adoption and "meaningful use" of electronic medical records [12]. Funding for this program totaled $37 billion and created new metrics by which clinical information systems were evaluated [13]. For providers and healthcare organizations to qualify for payments for EHR implementation (or to avoid penalties), they must demonstrate that their EHRs meet functional requirements and that they are being used "meaningfully" [14]. As such, the HITECH act and future regulatory policies add additional incentives for successful adoption of clinical information systems [15].

The value of clinical information systems in healthcare makes successful adoption important in healthcare. Ensuring success relies not only on the design of the product [16], but also on the workflow, organization, implementation plan, and personal dynamics. 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 [17], but the foundations for success involve the quality of the technology and the preparation to implement the technology. First, the technology itself must work as intended, with a high degree of reliability and stability [18]. Frequent downtime events and major ongoing changes to user interface design and functionality pose significant challenges to achieving successful implementation. Software failures in initial implementation phases create a reputation for poor performance that is difficult, if not impossible, to overcome later and creates risks to patient safety [19]. 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. However, the analysis and explanation of benefits need to extend across organizational levels, including the intended end users of the technology [20]. Too often, technology design or purchase decisions are made without 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, the technology must deliver tangible benefits to the intended end users [21–23]. While benefits such as "improving care" are laudable, 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. A more tangible benefit would be "decreasing the time it takes to complete documentation." The end users of a technology are sometimes not the main beneficiaries of the new technology but frequently carry some of the added burdens [24]. Finding ways to deliver at least some tangible benefits to the users in this situation is a requirement.

Finally with respect to 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 [25]. 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 rate of success in healthcare contexts. Balancing customization and standardization is an important success factor for implementing health IT.

Getting Ready

Preparing for implementation of a new health IT system must begin well in advance of the actual implementation date. The implementation team needs to assess the current state of the organization, to understand readiness for implementation of new technology across the organizational landscape, and to formulate plans. Part of 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 current state of the organization, the team should develop implementation plans, strategies, and options specific to the local context [26].

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 [27]. A clinical champion for a health IT project need not be a technology-oriented clinician; in fact, someone who is 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 have access to 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 [28]. An initial loss of productivity after installation of new technology is a well-known phenomenon [29]. Implementation teams need to be aware of this potential for productivity loss, and assist with plans for accommodating this initial, and hopefully temporary, change. For example, in a clinic implementing a new electronic health record, 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 to 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 [30, 31]. This iterative process will allow the team to adjust the implementation based on knowledge gained in earlier implementation phases and locations. 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 [32]. This reassessment and evaluation should continue well past the "go live" date for a new technology, to ensure problems that emerge over days and weeks of use can be addressed.

Toward Adoption: The Organization

It is often easy to forget about the organization as a whole when we are contemplating a new or changes to an information system. With 'organization' we are not talking about the organizational chart and reporting structures, but rather the people who work in the organization as a group and who together can drive success or failure.

We have become so focused on the product or the implementation schedule that we forget that people in organizations have vital signs as a group and past memories of both successes and failures. If you want to explore the extent of this, 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, 2, 5, or 10 years earlier.

This section focuses on the organization as a whole and the steps that are critical to gain adoption throughout the organization from the senior leaders to the person on the front line.

Know your Organization and Its Culture

There are multiple techniques for assessing and knowing the current organization and its culture. The following are a sampling of the techniques. However the key in your role is to know which technique is the needed or most appropriate at any given time.

General Assessment: This effort is comparable to "taking" a history and physical of the organization. Ideally this phase of the 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 process. The second part involves collecting information from those involved in the change through the use of both surveys and interviews. The survey instrument could be sent to randomly selected members of the affected group(s). In 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 the people are telling and to assess their positive and negative feelings about the current organization and the proposed technology changes. An alternative or supplement to the one-on-one interviews is conducting focus-group sessions. These allow anywhere from five to seven people from across the organization to share their feelings and ideas about the current system and new system [33].

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, attack that problem directly through the use of organizational development techniques. Installing information technology system—no matter how good it may be—will not solve a negative organizational climate. In fact, the system may be doomed by it.

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, and the informatics department, etc. This team could analyze the operations and recommended process improvements.

Current and Emerging Political Trends

Power Assessment: Whatever your organization there are sources of power. Some power is easy to detect through the organizational chart, but other forms of power are more subtle. Understanding power is important, because power can aid or derail any change process. Thus, understanding of power structures can aid in the prediction of impediments and anticipatory interventions.

There are several types of power [34]:

- *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 the abilities to negotiate, influence, sell, persuade, etc. Also, variables such as perceived bravery, integrity, and morality can affect interpersonal power.
- *Knowledge-expertise power* derives from one's abilities in a recognized skill area—typically a technical one. The skilled nurse, physician, or systems analysts all have definite power, especially among their professional peers.
- *Knowledge-information 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 can be seen as a source of power even if it is negative for the organization.
- *Positional power* derives from the organizational role or position that one occupies and is often thought of as "formal" power. The organization confers the authority to reward, punish, allocate resources, approve, disapprove, delegate, etc. This form of power is important but is easy to overrate.
- *Derived power* is a form of second-hand power that arises when one person appears to have the ear of, or even the right to speak for, a powerful person. 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 do" form of power. Referent power is created when people model their behaviors on the behaviors of someone they admire.

Prepare the Organization for Change

Organizations usually have statements about the importance of their employees, but then act in completely contrary ways when it comes to their employees. As health care organizations strive for higher productivity in this very competitive market, it will be the health care systems that most effectively manage their human resources 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 improve everything in the organization. If the people are oversold on what the new system will do, the system will inevitably be regarded as at least a partial failure. "Technological mysticism" is a term applied to the belief that technology will magically fix everything; while "technological nihilism" is the belief that it will fix nothing—striking a balance between these when setting expectations is important. Setting realistic expectations for the impact on *initial productivity* during the early implementation stages is critical, since it is almost inevitable that productivity will initially decline, no matter how good the system is or the preparations made for its implementation.

To deal effectively with this competitive reality, it is important that people are involved in any change processes that an organization undertakes. Today's workforce has changing demographics. It is becoming older and more diverse. Some portions are less well trained and educated than others. Thus, it is imperative that healthcare organizations develop and retain better trained and more highly valued workers. Organizational leadership needs to directly involve the workers in the change process and train them not only to handle the new technology, but also in basic core values. Peter Drucker has 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" [35].

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, unmotivated—or even worse, negatively motivated—people can bring the best system to its knees. Which situation will we have? How well we carry out the steps outlined above will often answer that question. Profound change initiatives come in many shapes and sizes. They can be as simple as a series of meeting on a crucial business objective or as complex as a corporate-wide "transformation" [35].

Champions—as stated previously, an informatics system needs champions. The optimal approach is to identify several *clinically-respected* physicians 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 [36].

General ownership—developing respected champions is only the first step in building general ownership in the system. The primary twin tools for general 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, there is an important issue that arises in medical areas: in systems of any size, the participation often has to be representative rather than total.

Increasing ownership—the danger is that the participation process often attracts the "amateur techies" in the organization, either by self-selection or by appointment. However, these people may not be high-clout nor persuasive people in the organization. It is critical to have some participation from key people in power. In health care organizations, this often translates as people who are highly respected *clinically*.

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 particular 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 *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, who are used to functioning under another paradigm of human/computer interface.

Feedback processes—any aggressive change management strategy should 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 return feedback must be provided. Not every issue can be resolved to everyone's satisfaction. Still, people must feel that both they and their concerns are heard and regarded as important [35].

Organizational Resources – People

The organizational leadership—CEO, president, vice presidents, deans, department chairs, etc.—must be *committed* to supporting the change process, not merely involved [37]. They must ensure that there is broad and constant support for the process and the resulting projects. They must also "stay" with the change process in the sense of ensuring that all their decisions and actions are consistent with the values of the organization and the change process. The way for top leadership to destroy a change process is for them to establish a vision, send some person or group off to implement that vision, and then proceed to make decisions not in accord with that vision.

It is critical that top management continuously integrates information planning into the overall organizational planning process rather than treating information issues as occasional problems to be solved on a crisis basis. Since health care organizations are complex and constantly changing, the top organizational leaders are involved in the decision to implement major new technology systems. They then normally charge the person managing this effort with completing the implementation. At this point, top management turns its attention to other problems. The information systems people proceed to buy or build the system that was approved. Major systems are not implemented overnight. By the time of actual implementation, the system that was envisioned may not be the system that is currently needed [38].

The end users are key stakeholders in the implementation of any health informatics system. There are five key areas of concern involving these customers for the information system:

1. The end users must know and comprehend what the system will be realistically capable of doing.
2. The end users must be included in the communications and information regarding changes that are being considered and/or developed.

3. The end users must believe that key people are committed to the success of the system.
4. The gatekeepers and opinion leaders must support the system and push or pull through various times of success or failure. The gatekeepers and opinion leaders need not be the formal organizational leadership.
5. End users must "see and know" the results of their inputs as rapidly as possible. This is true whether it is helping the residency recruitment program, creating a discharge summary statement, clearly identifying all the drugs that a patient is taking, or identifying past medical problems. It is important that changes be seen immediately and not in 3–5 years after end-user participation in the process.

Key Factors to Success

Much has been written about key factors to successful implementation of new information systems in health care and modification of existing systems. In this section we explore some of the key factors to successful change.

Strong Organizational Commitment

One of the key factors to success is a strong organizational commitment that is reflected in the behaviors and messages from organizational and local leaders. A health system constitutes a micro-cosmos with many varying 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" [39]. Unless organizational commitment has permeated through all levels from leadership to clinicians any implementation initiatives are likely to fail [40]. Organizational commitment or buy-in from individuals may change over time. Factors influencing the commitment include experienced outcomes such as changes in workload, competition with other efforts, changes or lack thereof in outcomes, relationship to existing workflows, and opinion of peers [41].

Good Communication

A critical tool to improve organizational commitment is effective communication of a project's anticipated goals and benefits. There are various types of messaging that will motivate. Using messages that force 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 [42].

For the success of the implementation, it is critical that the message, which includes the rationale and the plans for change, reaches all users and staff. Thus repeating the message to assure that they reach all shifts, all locations, all levels of the institutional hierarchy, and all type of providers and support staff is important. Besides choosing the right message types to motivate users and create organizational buy-in, the delivery of the messages is critical to success. Repeated messaging using various channels and modalities targeted at how and when individuals want to receive their new news are crucial. Channels may include mass emails, print and web publications, letters, hospital television pieces, social media (twitter, facebook, etc.) messages, fliers, informational events, and posters [43].

Implementation Planning

Change requires careful and deliberate planning to assure success of an implementation and to avoid undesired consequences. Current processes and workflows need to be identified and analyzed, and future ones must be proposed and evaluated for risks (see Chap. 7 for more detail). Collaboration between end-users and stakeholders, IT staff, leadership, and the implementation team are critical to define and prioritize vulnerabilities, propose and develop the new workflows and interfaces. Planning must further include an implementation plan, 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 [44].

Leadership & Champions

As discussed elsewhere in this chapter organizational leadership is a critical key factor to success. Unless end users know that the leadership both on the highest level as well as the local level is 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 implementation and roll out, are also a key factor to success. Selecting champions should focus on individuals respected by their peers, perceived as thought leaders with great communication skills, and who have the ability to rally others to achieve the best results.

User Needs/Incentives

The design of any health information technology must consider the users' needs including workflow and preferences. The ability to identify the salient features that will satisfy the user and lead to reduction of 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 applications benefits so effectively that they will recruit additional users. As an example, when an online parenteral nutrition calculator was introduced in a NICU, users quickly realized that it not only resulted in less ordering errors, but also reduced the time required from 10 to 2 min. 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 [45]. Building perceived benefits for the user into health information technology reduces efforts required in the training of user since novices will seek out experienced users on their own to be trained.

Functioning Software

Another key factor to successful change is the usability of the implemented health information technology. Usability can be measured by evaluating efficiency, effectiveness, and user satisfaction [46]. Critical for efficiency is that the new system must be thoroughly tested against all possible use cases with the appropriate load (number of users and processes) and must have been shown to be reliable and bug free. Efficiency also demands that the change either not increase the effort by the user or reduce the amount of time and effort required and that the user can produce results in a quick, effective, and economical manner. Effectiveness is determined by the system producing the results it portrays to deliver and the "accuracy and completeness with which specified users achieve specified goals" [47]. Satisfaction describes the user's content with the application and is dependent on efficiency and effectiveness as well as other points such as user preferences. Refer to Chap. 13, which focuses on human factors including usability, for further in-depth discussion.

Training

Implementation of large scale systems such a provider order entry or electronic health records pose significant logistical challenges in regards to 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. 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 work forces have to be trained, earliest trainees may be offered 'refreshers' immediately preceding go-live. A key success factor is to engage the users in the 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.

Implementation Support

During implementation, access to knowledgeable trainers, superusers, 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 support (this usually translates for 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 are critical. Implementation support must record and analyze issues brought to them in an effort to detect systemic problems that require changes to software design or implementation.

Addressing Problems in a Rapid Cycle Approach

Implementation may generate hundreds or thousands of problems reported by users [48]. Addressing these issues during the implementation period followed by reports to users about the progress is a key factor to success since it validates the users and their concerns and improves satisfaction and builds ownership. Allowing problems to persist will result in user disillusion with the product, create frustration, and may result in users harboring resentment towards the product and leadership resulting in a productivity drop off.

Emerging Trends

Multiple factors such as changes in healthcare policy and emerging trends in the technology marketplace shape the healthcare context, influencing implementation and adoption of health IT. The Meaningful Use mandate is perhaps the most significant healthcare policy change directly impacting health IT adoption in the United States over the last several years. Although the Meaningful Use mandate has

successfully encouraged many organizations to expand the degree of health IT use within their organizations, the final impacts of the financial incentives on long-term adoption and use of health IT remain to be seen [49]. Meaningful Use provided incentives for widespread technology adoption [50], but did not directly address the organizational factors that we have discussed throughout this chapter [51, 52]. Concerns remain about the ability of organizations to sustain health IT use when the incentives present in the mandate are reduced. In some cases, the mandated use of technology has produced a degree of backlash against the technology, or more specifically, against poorly designed, poorly implemented technology features. The rapid pace of technology implementation required to receive the highest level of Meaningful Use reimbursement was, in many ways, incompatible with the methodical and structured approach to implementation discussed in this chapter. It further exhausted organizational resources for information technology change resulting in many needed and desired projects to be delayed or cancelled [53].

One unintended consequence of the Meaningful Use mandate has been the increasing consolidation of the health IT marketplace from many smaller vendors towards fewer larger vendors [54]. Marketplace consolidation when paired with other economic factors has fueled an existing trend in health IT adoption and implementation: replacement of "best of breed" software components from multiple different vendors with single vendor monolithic health IT solutions. While monolithic systems present economic advantages to organizations and have potential positive implications for end users related to consistent user interface experiences, they also raise questions about the fit between technology applications and the many unique work environments in healthcare organizations and about customization to meet organizational needs.

A final emerging trend in health IT adoption is the movement away from fee-for-service reimbursement models towards alternative payment models, such as bundled care reimbursement. In early 2015, Medicare announced a goal of shifting at least 30 % of Medicare payments towards these alternate payment models by the end of 2016 [55, 56]. Achieving the quality focused goals of these new payment structures requires a degree of coordination in healthcare delivery, and has multiple implications for the design, implementation, adoption, and use of health IT, especially related to health information exchange and use of data across organizational boundaries. These new care models will require a degree of care coordination and team work that has been unprecedented, with significant implications on how tools used in health care support collaboration and sharing of information as well as hand-offs and task assignment, tracking, and completion features.

Investing in Change

This chapter discussed seven critical macro building blocks of an entire implementation system (Table 18.3). 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.

Table 18.3 Seven building blocks for a successful implementation system

7. Global/Environmental Identify what is occurring in the global environment. For example, recently the issues surrounding Meaningful Use and the requirements within this national program have a direct relationship to information based systems and time requirements. Bundled payments represent another emerging trend		
4. Early Implementation Examples of what is included in this component include: Early implementation planning, assessment of the current workflow, involving the champions, realistic expectations, assess potential impact, planning for implementation (staff, process, materials, etc.)	5. Actual Implementation Examples of what is included in this component include: materials for the end users, training the end users, address problems quickly, etc.	6. Recovery What happens when there appear unintended consequences and how to address them
3. Socio-technical Examples of items in this component include: communication, involvement, building ownership, adoption, champions, keys to success, etc.		
2. Organizational Examples of items in this component include: understanding the current organization (climate, what else is happening, etc.), power issues, preparing the people for change (communication), strategies for working with organizational leaders		
1. Foundational Examples of items in this component include: The technology (hardware and effective functioning software), setting the stage for change (the organizing overall leadership team)		

Implementation is expensive and every organization shys away from costs. However, every organization can decide not if they will pay but only when they want to pay. A past television commercial featured an auto mechanic, who holding up a dirty-corrosive looking automobile part says, "You can pay me now or pay me later. Pay me you will". This commercial speaks to the point (http://www.youtube.com/watch?v=Ij1yDpfZI8Q). Just as money and time spent on 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, but 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.

Summary

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 selection or design of the information technology solution. In preparation for implementations users must be informed through a

variety of 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.

Discussion Questions

(a) You become responsible to implement a major clinical informatics change in your hospital system. What are the first two "to do lists" tasks will you do?
(b) What types of resistance might you encounter?
(c) What do you think are the most successful strategies for the successful adoption of a new clinical information system?
(d) How much time do you really think needs to be spent on the cultural/behavioral issues of clinical informatics system adoption?
(e) If people say that everything related to implementation planning sounds like common sense or generalities, what would be your response?
(f) What are three characteristics of a clinical champion, and why are they important?
(g) What do you need to plan for in order to perform rapid cycle improvement during implementation?
(h) What might be some of your options if you start to think that support from the organization's overall leader is beginning to decrease?
(i) Given that even with the best of plans something unforeseen might occur that would derail your implementation, what are your thoughts on "implementation recovery" strategy?
(j) You have been alerted to problems of interactions between one of your implementation team members and a number of the end-users. How would you address this issue?

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Part V
Beyond Clinical Informatics

Chapter 19
Consumer Health Informatics: Engaging and Empowering Patients and Families

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Learning Objectives

- Define the field of Consumer Health Informatics as a critical domain of biomedical informatics and describe the elements that comprise a sociotechnical perspective
- Identify major drivers that are changing the role of the patient in contemporary health care
- Explain key Consumer Health Informatics functions and describe representative technologies; differentiate between different types of personal health records

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- Describe the factors that influence the adoption and use of Consumer Health Informatics tools, and describe strategies for assessing impact
- Identify significant emerging trends in the field of Consumer Health Informatics

Core Content

- Personal health
- The flow of data, information, and knowledge within the health system
- Policy & regulatory framework
- Forces shaping health care delivery
- Fundamental knowledge in the effective use of biomedical data, information, and knowledge in the field of personal health: patient, consumer, provider, families, health promotion, personal health records
- Procedural knowledge and skills: apply, analyze, evaluate and create systems approaches to the solution of substantive problems in biomedical informatics in terms of people, organizations, and socio-technical systems
- Awareness of forces shaping health care delivery

Key Terms

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 consumers can download a single electronic file that contains their available health data.

Computer 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 as they use healthcare services.

eHealth a field of research and practice focused on the use of 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 the degree to which individuals have the capacity to obtain, process and understand basic health information needed to make appropriate health decisions and services needed to prevent or treat illness.

Information and Communication Technologies an overarching term used to refer to technology that supports communication and/or the gathering, sharing, and use of information.

OpenNotes 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 in which the locus of control and decision-making is centered upon the patient and aligned with the patient's 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, symptoms, lifestyle choices, etc.

Patient Portal a secure online website that gives patients convenient 24-hour access to personal health information from anywhere with an Internet connection in order to enable them to interact with their medical information via the Internet.

Personal Health Information Management the activities that support individuals' access, organization, and use of information pertaining to their own health.

Personal Health Record a private, secure application through which an individual may access, manage, and share his or her health information, including information that is 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 the idea that to fully understand information and communication technologies, it is necessary to examine the interrelation between the technology and its social environment.

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, and can view information from her medical record including visit notes, test results and medications.

After Mary confided to her son about having several weeks of fatigue, he logged into the portal to view available appointments. Unable to see her usual doctor for 2 weeks, he scheduled an appointment for her 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 1 year ago, he searched the portal's education library to learn more 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 that Mary was scheduled to see, along with her usual primary care doctor. At the visit, the doctor seeing Mary 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, have created a new era of consumer engagement, empowerment, and activation. This transformation has striking implications and opportunities for all the major stakeholders groups engaged in the delivery and receipt of health care – patients, providers, purchasers, payors, 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.

Consumer Health Informatics is a critical domain of biomedical informatics, focusing on informatics from consumer or patient perspectives [1]. 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, in accordance with their needs and preferences. Clinical informaticians must apply knowledge in the field of personal health as well as procedural knowledge and skills in order to effectively design, develop, and evaluate systems approaches to improve consumer health and management of their conditions [2, 3]. 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 [4]. By the 1970s, the economic and moral problems of American healthcare were drawing public attention, including increased focus on the imbalance of power in the structuring of medicine, the dynamics of the physician-patient relationship, and patient rights [5]. 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 [6]. The paradigmatic shift towards more "patient-centered" care [7, 8] also set the stage for the emergence of a new era of consumer empowerment [9, 10].

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 [11–13]. 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" ([14], 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' ([14], 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 [15]. Inherent in these aims was a new approach to health care design, including the fostering of continuous healing relationships between patients and providers, and the provision of tools to help patients become more active participants in their care. More than a decade later, significant progress has been made, yet there is still much 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.

In this chapter we examine 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 which influence consumer adoption and use of ICTs, and key elements and strategies associated with implementation. Finally, we provide an overview of evidence in the literature and methods for assessing impact, concluding with a brief discussion of emerging trends.

Fundamentals

Similar to the broader field of clinical informatics, Consumer Health Informatics has come to embrace the notion that a wide range of factors at different ecological levels (e.g., the individual, interpersonal, organizational, and community) can influence the

Table 19.1 Sociotechnical dimensions for understanding ICTs in healthcare settings [17]

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

adoption and use of ICTs. Perspectives that once focused narrowly on technology alone have given way to more encompassing approaches aimed at understanding how consumers and technology interact, and the kinds of impacts that they can have on one another. The term "sociotechnical" is commonly used to express the idea that to fully understand ICTs, it is necessary to examine the interrelation between the technology and the social environment [16]. 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 [17]. Table 19.1 presents a series of eight dimensions that proponents argue are critical to understanding the design, implementation, and evaluation of ICTs in health care [17]. As suggested by Table 19.1, in such complex contexts, interactions among people, processes, and technologies combine to create powerful forces that have implications for consumer adoption and use of ICTs. In this section, we examine the people, processes, and technologies that are the focus of much of the contemporary work in Consumer Health Informatics.

People: The Experiences of Patients and Informal Caregivers

The onset of any health condition introduces challenges. In most cases, these challenges are not strictly limited to management of the condition, but extend outward, impacting many aspects of an individual's life. The need to respond to the

progression of a condition, manage symptoms and treatments, cope with changes in family dynamics, and coordinate resources are critical activities, the responsibility for which falls not only to the patient, but also to their family members and other informal caregivers. The majority of these activities are performed outside of healthcare facilities – in homes, workplaces, and other everyday life settings. Researchers have used the concept of a "trajectory" to describe both the physiological unfolding of a health condition and the activities performed by patients and their informal caregivers to manage it [18, 19].

The trajectory concept is important to Consumer Health Informatics for three reasons. First, it highlights the importance of collaboration between patients and informal caregivers; second, it recognizes that many health conditions are managed mostly outside of formal healthcare settings; and third, it emphasizes that as circumstances change, so too do the activities and resources associated with managing one's health. These three points have direct implications for how ICTs are designed, the functionalities and content that they provide, and the ways in which they are used by consumers. Finally, in its careful accounting of the perspectives of patients and informal caregivers, the trajectory concept also offers a foundation for the emerging paradigm of patient-centered care; the goal of which is to optimize health by shifting away from traditional, paternalistic, provider-driven, disease-focused approaches towards healthcare systems that ensure the patient—including his or her unique circumstances, attitudes, perceptions, needs and experiences—is fully integrated into every phase of medical consultation, treatment and follow-up [7, 20].

Processes: The Work of Managing Health

Information has long been understood as an important resource for individuals who are confronted with a health condition. Social scientists have argued that information can lessen a person's fears and misunderstandings, help individuals develop practical coping strategies, and effectively manage treatments [21]. Just as important as recognizing information as a resource, however, is appreciating that the many health-related processes in which consumers engage 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 a substantial literature spanning psychology, sociology, and the information and communication sciences regarding consumer health information-seeking behavior. Much of this research follows from the premise that when confronted with information needs pertaining to their health, individuals respond by gathering and using information. 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 [22]. Overlooked is the considerable evidence that health information seeking is also often collaborative, and that in many cases, individuals seek health information not only for themselves but on behalf of others – an activity sometimes referred to as surrogate seeking [23]. 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 information pertaining to their own health [24, 25]. Sharing or "exchanging" information to support health-related tasks is an important aspect of personal health information management that commonly involves individuals' informal caregivers as well as their healthcare providers. Research has shown that health information is often gathered and organized with sharing in mind, and that information sharing is performed through various means, including both paper-based and electronic systems [26]. As indicated elsewhere in this section, the seeking and sharing of health information is also important to consumer education initiatives and the realization of 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 in which healthcare providers take responsibility for treatment decisions on the basis of their clinical expertise, and patients are expected to adhere to designated management plans [27, 28]. While perhaps fitting for acute conditions where treatment is mostly confined to medical settings, such models do not accurately represent the experiences of consumers faced with conditions where the majority of management happens in the course of 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 the management of his or her own health and has been framed as an alternative to more established, provider-driven models of care [28, 29]. 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 [30]. 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.

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 a variety of behavior change principles and theories available to inform the design, implementation, and evaluation of behavior change interventions [31]. As we describe further below, ICTs including personal health records, 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" [32]. Health communication refers to the study and use of communication strategies to inform and influence individual and community decisions that enhance health [33, 34]. As described in the landmark *Healthy People 2010* report [35], 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. These are the settings in which 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 and aims to strengthen patient-provider partnerships through a focus 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 understandings of health conditions and treatments [36, 37]. Patient-centered communication is continually influenced by overlapping factors pertaining to 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 (IOM) [15] described coordination across patient conditions, services, and settings as one of the most formidable challenges facing our nation's healthcare system, and included care coordination as one of 20 national priorities to improve healthcare quality [38]. 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 in an effort to facilitate the appropriate delivery and receipt of healthcare services [39]. Integral to this organization of activities is effective sharing of health information across settings (e.g., clinic to clinic; home to 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 a 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 [40, 41]. 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 in a convenient way 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 [42]. As argued by the IOM [15], 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 to 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 [43]. In this section, we briefly describe some of the major representative technologies at the core of such functional groupings, with the caveat that the technologies themselves continue to rapidly evolve.

Personal Health Records (PHRs)

The concept of a PHR is not new; patients and their informal caregivers have always used paper-based systems – lists, diaries, calendars, and other jottings – 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 systems (e.g., an electronic health record), and offer a range of associated functionality [46]. The joint PHR Task Force of the Medical Library Association and the National Library of Medicine [47] 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 his or her health information. The PHR can include information that is 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) that is 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."

Examples of PHR features supporting various health-related tasks and activities are shown in Table 19.2.

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 also 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 [48]. Some portals may also have a means by which consumers can identify a proxy or set of proxy users and delegate access to their

Table 19.2 Health-related tasks and supporting PHR features

Health-related tasks	Examples of supporting PHR features
Accessing and sharing personal health information	Blue Button®, OpenNotes, consumer mediated health information exchange
Educating oneself about his or her health and making informed decisions	Consumer-oriented online health education libraries, personalized education, decision support tools
Tracking personal health information	Journals, logs, diaries, 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

personal health information and use of 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 [48]. Networked PHRs of this kind inherently require interoperability across systems and 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, the messages that patients and healthcare providers exchange automatically become part of the healthcare system's EHR. In addition to serving as a convenient, protected channel for non-urgent communication [49–51], secure electronic messaging also has the potential to strengthen patient/provider relationships [50, 52, 53]. 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. However, 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 [54]. These are questions that the field of Consumer Health Informatics will have to address moving forward, and 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 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 who are seeking health-related assistance [55]. Regardless of 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 a variety of 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 skills-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 [56], previous analyses have revealed improved outcomes for individuals using web-based interventions to achieve desired knowledge or health behaviors, as compared to non-web-based interventions [57]. More so than interventions delivered through other channels, web-based interventions have tremendous potential to reach large numbers of consumers, and can be used at the time, place, and pace most suitable for the individual.

The experiences of consumers, the healthcare processes in which they engage, and the technologies that they use to support those processes will continue to evolve with changes in healthcare and advances in technology. As we emphasize in this fundamentals section, clinical informaticists have an important responsibility to foreground the interactions among these elements and to understand the kinds of forces that influence those interactions. These drivers are the subject of the next section.

Major Drivers

As described at the outset of this chapter, 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, is 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 will explore current drivers of Consumer Health Informatics, including current trends in technology availability and use; increased focus on consumer information needs, consumer desire for engagement, and 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

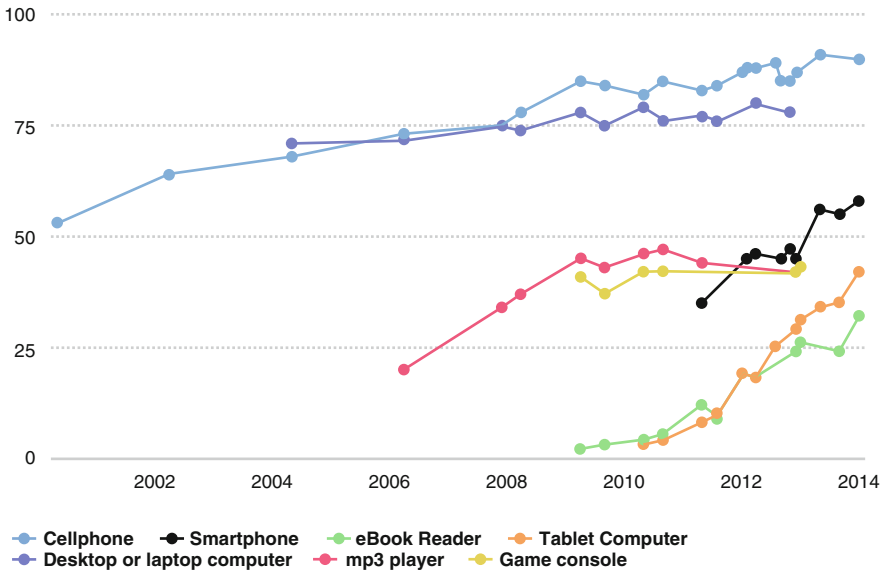

Fig. 19.1 Device Ownership Over Time (Reproduced from Ref. [58] with permission from Pew Research Center)

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 65 and older or with a lower level of education, rates of use continue to rise within these subgroups as well. 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 changes in mobile device availability and usage. Desktop and laptop computers are giving way to greater use of mobile devices. Presently, 91 % of adults own cell phones, and more than half of these are smart phones (**see** Fig. 19.1). 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 to 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 to search on behalf of someone else [60]. Today, many consumers are active in gathering and sharing health-related information, both online and offline, so that they can 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 a wide variety of 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 fully embrace such technologies, 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]. Believing such care to be expensive and inefficient, he advocated for health care to empower consumers, including the development of 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 [63]. 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 better with fatigue and other generic features of chronic disease such as role limitation, and reduce disability and their dependence on hospital care [65].

Financial Incentives and Meaningful Use of Health IT

An equally important factor currently driving Consumer Health Informatics is the transformation happening inside the medical community. As noted in Chap. 3, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 accelerated the investment in and use of EHRs as a way of improving care and enhancing patient outcomes [66]. The $30 billion program, regulated by the National Coordinator for Health Information Technology and administered by the Centers 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 which demonstrate the meaningful use of HIT, with the aim of improving the quality of care while reducing costs. While many of these measures focus on how electronic records are to be used within health systems, several call for HIT functions which impact patients directly. 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;

and (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 [43]. 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 [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 models of care and to 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 both 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.

Major Factors Influencing Adoption and Use

Despite the influence of major drivers and the increasing availability of a variety of 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 [53, 72, 73]. In this section we discuss some of the major factors which 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 the use of

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 use of consumer ICTs can include lack of computer and/or Internet access; although as previously noted, these trends have been changing as access to broadband networks increase and consumers adopt portable Internet-enabled devices. However, a more nuanced understanding of access also includes the concepts of computer and health literacy [74] to ensure that users have the ability and necessary functional and cognitive skills to enable effective use [75]. As ICTs are increasingly provided to enable consumer access to healthcare resources and services, care must be taken to ensure that they do not inadvertently create or exacerbate disparities, especially among vulnerable segments of the population [76].

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 [77, 78], racial and ethnic minorities [49, 79–83], non-English speaking patients, the uninsured [84], and patients without broadband Internet access or with lower income [83], computer abilities [84], health literacy [85], and education [81, 83]. However, if carefully designed and implemented based on user needs, abilities, and preferences; consumer ICTs may also have the potential to eliminate disparities [86]. Unfortunately, however, many existing patient portals are limited in their usability [87–89], particularly for vulnerable populations [90, 91]. 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 contained [92]. Usability improvements that are needed include the ability to easily import, export, and trend information [93]. Importantly, mobile health approaches, such as text messaging outreach that requires only a basic-feature phone, are showing particular promise in some of these populations [94]. As portal features are further tailored and consumer access to mobile devices and the Internet continues to increase, use of portal services may also grow in vulnerable populations. Clinical informaticists must remember, however, 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 ICTs, lack of awareness among consumers continues to be a significant factor inhibiting use [79, 95, 96]. An assessment in 2011 revealed that more than half of consumers were still not familiar with the concept of a PHR [97]. More recent data demonstrate that lack of awareness of portals and their features continues to be a major factor in inhibiting use [90, 98, 99]. As emphasized by prominent implementation theorists, having adequate knowledge of a technology and its features is a prerequisite for adoption and assimilation [100]. 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 being 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 [101].

Like other technologies, motivation to utilize consumer ICTs is also dependent upon perceived relevance and value [100], including the relative advantages of use among available alternatives. To facilitate ongoing use, portals need to be seen as reliable tools that are characterized by quality interactions. Among the different services available through patient portals, patients most commonly use and report highest satisfaction with exchanging secure electronic messages with providers, ordering medication refills and viewing the results of medical tests [102–105]. However, adoption of patient portals also appears to depend on providing a constellation of convenient and functional services rather than selected functionality [102]. In healthcare systems which 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, 106]. Offering portal services also appears to be important to retention of patients by providers and health plans [107, 108]. While the evidence about use of patient portals by specific patient populations remains mixed [109], 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 [77, 103, 110].

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 [53, 111]. Additionally, clinician engagement with portals and PHRs may be required to achieve and sustain anticipated positive outcomes [97, 112]. Although there has been a prominent focus on portals

and PHRs as tools to support consumers, much of the value that consumers derive from the use of 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, 83] or, alternatively, further impede use by actively discouraging or passively failing to address patient assumptions about provider engagement, interruptions or reimbursement [113]. As patients continue to see healthcare providers as a source of expert information, encouraging and also demonstrating use of consumer ICTs will be crucial [48].

Research also reveals that patients are more likely to use portals if they had a primary care provider, or switched to one, who more regularly used secure messaging to communicate with patients [77, 78]. Patients have also been more likely to use a portal when they trust their primary care provider, and report better communication with their provider [114], and when a provider is female and younger [83, 109]. The role that providers play in influencing patient adoption and use of portals highlights the importance of the portal as an environment for ongoing collaboration in the processes of care [115].

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 lack of reimbursement [116]. Electronic communications with patients are not regularly reimbursed in the fee-for-service environment. This barrier has been partly addressed recently by financial incentives through meaningful use attestation and in the patient-centered medical home by coupling secure messaging with care coordination [117]. 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 [118, 119]. 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 the secure electronic messaging features of patient portals. 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 the design of 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 patterns of activity, practice, and behavior. Drawing upon implementation science, specific strategies can be employed to thoughtfully plan and execute programs of implementation for consumer ICTs that are 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" [120]. 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 [121], and to meet patient's actual needs and capabilities [122]. User-centered design (UCD) is a design philosophy which focuses on the end user's needs, preferences, and limitations at all stages within the design process and development lifecycle [123]. The emphasis is on understanding the end user's tasks and goals, and optimizing the product for the user to fulfill these, rather than having to adapt to the designer's preferences [124]. 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 the perspectives of healthcare professionals.

Integration with Existing Activities, Practices, and Workflow

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 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 achieve 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 [125–127]. Implementing technology in healthcare settings must take into account 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 [128]. 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 [129].

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 [130]. Workflow represents a commonly understood set of procedures for and sequence of work tasks, along with the assignment of 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 in order for its use 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. As an 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 Champions

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 which influence the implementation and use of the technology [131–133]. An ecological perspective that emphasizes the interactions between people, processes, and technology [134] 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 also consider their perspectives, professional values, and local practice patterns. Ensuring visible leadership support and engaging clinical champions is an important strategy for effective implementation [135, 136].

Drawing upon diffusion of innovation theory [100], 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 make effective use of the technology [137]. In the past, Consumer Health Informatics initiatives have often focused on the provision of 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 the encouragement of a trusted health professional and concordant support from administrative and clinical staff [138]. 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 a 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 at 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 either financial (e.g., reimbursement for specific activity) or non-financial (e.g., workload credit for activity). Whereas fee-for-service models incentivize quantity of workload, pay-for-performance models incentivize 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 aforementioned strategies can be effective at furthering implementation of consumer ICTs, it is also important to recognize that a variety of 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, however, 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 [109, 139, 140]. In this section, we begin 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 now 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 use of both qualitative and quantitative approaches. Studies that focus either on the technical aspects or anticipated outcomes may fail to take into account social, organizational, professional, and other contextual considerations [141]. Ethnographic approaches to studying consumer ICTs as they are actually used in healthcare settings is crucial [142], avoiding a limited focus on pre-determined outcome measures, and further enabling the identification of unanticipated consequences or "emergent effects that may be enduring" ([141], p 41). Indeed, we advocate for 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 an examination of processes of care and associated health behaviors [42], employing participatory research approaches to engage both consumers and health care professionals [143]. Informaticists will play an important role in constructing a bridge between the technology and its use, ensuring that the analysis and mapping of processes engages 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 the advancement of patient centered outcomes research (PCOR) [144]. 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" [145]. 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 has the potential to inform the research and also 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 use of specific features. However, simply enrolling (or being enrolled) in a patient portal may itself have positive outcomes, on the basis of 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 which offer secure electronic messaging can improve access to care [146], patient satisfaction [102, 103] and chronic care outcomes [103] for many patients. Patient portals may be particularly valuable when combined with new models of primary care, such as the patient-centered medical home (PCMH) [147, 148]. Patients using portals which provide access to electronic health records report better understanding of health conditions and the plan of care [99]. Better patient adherence has also been reported among those using a portal-based medication refill function [149] and accessing their provider's clinical notes [99, 107].

To date, evidence remains mixed on the impact of patient portals on traditional forms of healthcare utilization. Some studies suggest that use of a patient portal increases utilization of in-person outpatient visits, emergency room visits and hospitalizations; while other studies suggest it leads to less outpatient and urgent care utilization [103, 150]. Most studies of utilization have thus far been observational and challenged by the difficulties of being able to compare healthcare use among those who sign up and use portals with those who do not.

In terms of effects of patient portal enrollment, a 2011 systematic review [151] 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 [152, 153]. In the third RCT, use of the patient portal had no effect on indicators of patient engagement [154]. More recently, four additional RCTs published in

2012–2013 further evaluated the effects of patient portals on health outcomes [155–158]. These studies also showed heterogeneity in their results; while 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 [155], another study showed no effect of a patient portal on rates of adverse drug events [159]. 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 of depression in patients recently starting antidepressants, and improved receipt of preventive care services [109]. As more interventions that utilize patient portals and other consumer health technologies are developed and adopted over the next 5–10 years, the evidence base assessing 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, increasingly health systems and researchers have 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) [160]. 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 [161]. 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 [162], improving immunization rates [163], and improving medication adherence [164].

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

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 [165], 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 [166]. Primarily these entail effectively striking the balance between enabling ease of information exchange and protecting patients' privacy rights, concerns, and preferences. Unintended consequences that can result from the tension between patient desire for access to and control of health information and providers' needs for full information about the patient include patients inadvertently or purposefully restricting access to information that may be needed by healthcare providers for clinical decision-making, and the introduction of uncurated and potentially imprecise data into the EHR with at least the potential for negative impact on clinical decisions. While researchers and policy makers need to be attuned to the emergence of unexpected behaviors or outcomes associated with 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 is expected to increase adoption of patient portal services including secure electronic messaging and direct patient access to electronic health records. At the same time, a broad 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, and even among these studies, many 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 the collaborative design, implementation, and evaluation of these tools.

Fig. 19.2 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)

Emerging Trends

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 that are becoming accessible to consumers, although not yet uniformly available to all, nor broadly adopted or institutionalized.

Blue Button®

The Blue Button® concept emerged in 2010, aimed at enabling more direct consumer access to personal health information by adding a "Download My Data" button to patient portal systems [167]. Within the next 6 months, the US Department of Veterans Affairs (VA) added the Blue Button® symbol (**see** Fig. 19.2) to the VA patient portal, My HealtheVet, enabling Veterans to securely download their own health record electronically. 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 visual representation of Blue Button® data, and novel applications emerged to enable consumers to import and aggregate their Blue Button® data from various sources [168, 169]. 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 [170] to help consumers locate and access their personal health information sources.

As discussed in the Major Drivers section, to promote broader availability, Stage 2 of Meaningful Use incentivizes healthcare organizations and professionals to provide patients with the ability to view, download, and transmit their personal health information. While many consumers are beginning to use Blue Button® features, additional work is needed to enhance consumer awareness and provide education and training for effective use [90], and to evaluate the impact of enhanced consumer access to electronic data on both processes of care and outcomes [42]. Blue Button® represents a fundamental shift in health care, promoting unprecedented consumer access to and ability to use personal health data.

OpenNotes

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 [171]. Early evidence demonstrated positive effects with minimal impact on provider's workflow. Patients with access to their doctors' notes felt in more control of their care, and reported better understanding of their health and conditions, improved recall of their care plan, and being more likely to take their medications as prescribed [107]. These findings were replicated on a nation-wide scale 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 [99]. Additional outreach and education is 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 additional therapeutic benefit [172]. The VA study concluded that healthcare professionals who are 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 that healthcare professionals need to effectively capitalize on patient access to notes.

Consumer Mediated Exchange and Health Record Banks

Health information exchange (HIE) is defined as the electronic movement of health-related information among organizations according to nationally recognized standards [173]. As described in Chap. 11, the goal of health information exchange is to facilitate

access to and retrieval of clinical data to provide safer, timelier, efficient, effective, equitable, patient-centered care across care settings. Organizational health information exchange (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, some challenges remain including workflow issues, privacy and security concerns, and the lack of a compelling business case for system sustainability [174]. 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 and systems that enable them to view, download, and securely transmit their personal health information [175]. While significant progress has been made, issues with interoperability and technical maturity will need to progress in order to accomplish the goal of enabling consumers to securely transmit their personal health information across systems and settings. 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.

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 [131, 176]. 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 [177]. 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 [178].

Mobile Health: Devices, Monitors, and Sensors

We include mobile health or "mHealth" as 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" [179]. The term "mHealth" was coined by Robert Istepanian in 2005

to describe the emerging use of mobile communications and network technologies for healthcare [180]. More recently, mHealth has been described simply as "the delivery of healthcare services via mobile communication devices" [181]. These devices include a growing array of mobile phones (including smart phones), tablet computers, personal data assistants (PDAs), and patient monitoring systems and sensors 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 which enable consumers to measure and monitor various types of data: from fitness activity to sleep patterns and other types of measurements.

The convergence of portable computing power and increases in broadband and wireless Internet access have resulted in new opportunities which are shifting consumer access to eHealth tools with some potential to reduce the digital divide [182]. Advocates of mobile health technologies point to many advantages including: anytime/anywhere access, the convenience of portability, cost effectiveness, and increased rates of consumer adoption. Analysts predict that the market for mobile is poised for growth [183]. Advances in technology, however, are outpacing the science of mHealth and more research is needed to understand evolving trends in consumer behavior, and to also assess the impact of mHealth tools with scientific rigor [184]. Clinical informaticists will play a crucial role in the evolution of mHealth, as early pilots move towards fuller implementation.

Complementary 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, use of alternative methods such as online assessment forms and/or secure email messaging offer the advantages of convenience, efficiency, and cost effectiveness [185]. 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. 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 [186]. Early assessments reveal that these forms of virtual care may also attract a younger patient population who place high value in convenience [187].

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" [188]. He also notes, however, that the combination of newly empowered consumers armed with actionable information plus significant advances in information technology have the potential to "radically transform and improve health care delivery." Clinical informaticists will be essential in realizing that potential.

Equipped with 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.

Questions for Discussion

1. Although the hospital network has provided a patient portal for the last 7 years, only 5 % of enrolled patients have signed up to use the portal service. What strategies should the clinical informaticist recommend in order to improve adoption and use?
2. The new strategic plan for a mid-sized integrated healthcare system calls for the purchase and installation of a new patient portal within the next 6 months in order to meet Meaningful Use Stage 2 guidelines. What implementation strategies should be used to develop an effective approach?
3. The Chief of Staff has requested a presentation by the clinical informaticist that includes recommendations on whether to join the OpenNotes movement and enable patient access to clinical notes. What recommendations should the presentation include?
4. The hospital technology department recently launched a new mobile application that allows patients to securely communicate with their healthcare provider; however clinicians were not made aware or provided with education or training in advance of the launch of the new feature. Patient complaints have been coming in to the hospital director's office that messages are not being responded to. What went wrong and what can the clinical informaticist do now to develop an action plan to begin to solve the problem?

5. The clinical informaticist has been asked to consult with the research team to develop an evaluation plan for the healthcare system's patient portal. What methods should be included in order to effectively evaluate the patient portal-?

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Chapter 20
Public Health Informatics

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Learning Objectives

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

- 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 the ways in which clinical and public health informaticians work together to monitor and improve population health

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Core Content

The following core competencies are covered in this chapter:

- Domains/subspecialities in informatics (1.1.1.3.)
- Public health (1.2.2.2.)

Key Terms

Population health, public health, surveillance systems, immunization registries, disease registries

Case Vignette

Community HIE is an organization that started as Regional Health Information Organization (RHIO) that was funded by payers and included health care providers associated with two major hospital associations in the geographic region around the RHIO. As the organization grew, more and more stakeholders became involved in the exchange of 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, as well as local and the state public health agencies.

Providers in the community used the RHIO's infrastructure to submit electronic laboratory results for communicable diseases to public health authorities, and public health agencies used the electronic health records to investigate disease outbreaks. Life was generally good in the community, until epidemiologists at the state health department noticed an increase in the incidence of measles, a vaccine preventable disease. Investigators noticed that a cluster of children began showing up in emergency departments with measles who had not received the vaccine.

Tracking down these children's past medical and vaccines records, unfortunately, required investigators to consult the state's immunization information system (IIS; sometimes referred to as a registry) and the RHIO's electronic health records separately. The IIS was a good source of information for children that had been vaccinated; the RHIO was a good source of information on children that had not been vaccinated. However, it was difficult to query the RHIO for unvaccinated children, because the IIS was not integrated into the RHIO 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. Since the state agency's budget had been mostly flatlined and periodically reduced, it only had enough funding to support minimal services provided by the RHIO. Although the leadership at the RHIO was passionate about public

health, as business owners they had to be good stewards of their limited funding and could not afford to offer very many services free-of-charge to the state health department. Luckily, a local philanthropic foundation was identified and convinced to provide the funding necessary to integrate the IIS with the RHIO.

Once the IIS and RHIO were integrated, state health authorities were able to query the RHIO to identify school-aged children who had not yet been vaccinated for measles. Analysis of the results identified three geographic areas with a high concentration of unvaccinated children. The health department then set-up vaccine clinics 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. From that point forward, epidemiologists were able to more efficiently monitor vaccination rates for the community, and the clinical partners involved in the RHIO could efficiently query the IIS to receive up-to-date vaccine forecasts for their pediatric patients.

Introduction

Informatics is the *science of information*, studying the representation, processing and communication of information by computers, humans, and organizations [1]. Informatics draws upon a broad spectrum of theories from the computer, information, and social sciences, and it seeks to fill the gap between (1) the correctness of the 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 the 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 both clinical and public health informatics as depicted in Fig. 20.1 [5]. Whereas clinical informatics applies health information technologies in the provision of individual clinical care [6], public health informatics seeks to apply health information and technologies to improve population health, including the surveillance and prevention of disease as well as general health promotion [7].

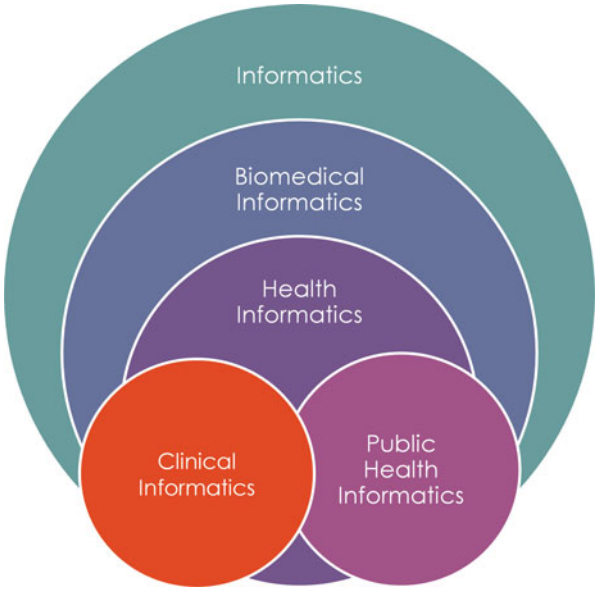

Fig. 20.1 Relationship of Public Health Informatics to other areas in Informatics

The Scope of Public Health Informatics

Although public health professionals have utilized information and communications technologies (including the fax machine) to capture, store, manage, exchange and analyze information about populations, the rise of PHI as a discipline within both 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 U.S. [9] and the Tokyo subway attacks [10], as well as global health threats such as SARS [11] and the H1N1 pandemic [12]. While the threat of a large-scale epidemic has not diminished in recent years, as evidenced in 2014 by MERS [13, 14] and Ebola [15], changes in national policies and funding priorities have steered PHI in new directions [16]. Today PHI not only supports core public health functions [17], but PHI contributes to the following activities in support of population health and strengthening the public health infrastructure [18]:

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 Ministry of Health, in which PHI supports the capture, management, and exchange of data for monitoring 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 [19], 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 are contributing to better measurement of clinical outcomes using e-measures (refer to Chap. 5), PHI focuses on the development of population level indicators of health. Public data sets, including the Behavioral Risk Factor Surveillance System (BRFSS) from the CDC as well as the American Community Survey from the U.S. Census Bureau, are integrated and leveraged to create the County Health Rankings [20], composite scores representing the health of the population living in a geographical county within the United States [21].
3. Implementation of patient-centered care models which 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 take into account patient preferences, self-management, and self-reported outcomes into clinical decision-making (refer to Chap. 19). Contributions from PHI include leveraging social media and short messaging service (SMS) texts to (a) identify disease outbreaks [22] (b) improve material child health outcomes [23, 24]; and (c) inform at-risk populations about methods for lowering their risk of infection [25].

Informatics Capacity in Public Health Agencies

Informatics is challenging in public health given limited resources and a limited workforce. Budget reductions in public health since the 2009 American economic recession limit the ability of public health agencies to develop, purchase and deploy new informatics systems [26, 27]. For example, while the Health Information Technology for Economic and Clinical Health (HITECH) legislation 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 [28]. This is particularly problematic because with increased provider EHR implementation comes more data in different formats for public health agencies to process. Limited financial resources are compounded by a shrinking public health workforce. Some forecasts estimate that an additional 250,000 public health workers will be needed by 2020 to maintain current public health capacity [29].

The size and characteristics of the current informatics workforce within public health agencies are largely unknown. Currently the CDC sponsors an official, registered apprenticeship program in PHI [30, 31] that supports approximately 10 fellows each year who are placed in state and local health departments. Yet while the CDC publicly reports on the activities of its trainees during their fellowship, the agency does not publish data on the jobs held by these individuals after fellowship completion. In a recent analysis of the 2013 profile survey by the National Association of City and County Health Officials (NACCHO), Mac McCullough and Goodin [32] found that health departments deemed to be 'high capacity' with respect to PHI employed "information systems" personnel at a higher rate than departments deemed to be 'low capacity.' However, this most recent study did not

assess the number or characteristics of PHI related roles within local health departments. Anecdotal data suggest there are very few individuals in the public health workforce whose title includes the word informatics. Only a few state health departments have a Chief Public Health Informatics Officer (CPHIO) as opposed to dozens of such positions in hospitals and health systems.

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, the CDC reorganized its division responsible for national public health surveillance coordination. The division hosted strategic planning sessions culminating in the release of several reports detailing the challenges facing national surveillance activities [33]. Second, the Council of State and Territorial Epidemiologists (CSTE) updated its "Blueprint" for public health surveillance, outlining the challenges facing state-level surveillance activities [34]. 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 & Programs in Public Health (ASPPH) convened a panel to review and update the Masters in Public Health (MPH) core to reflect twenty-first century challenges [35].

Although convened independently, these groups managed to reach 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 as well as other public health training programs that will lead to a public health workforce knowledgeable about PHI as well as a larger segment of the workforce that concentrates on PHI.

Major Players in Public Health Informatics

Because the public health system is complex with various organizations at local, state and federal levels, there are numerous entities with an interest in public health informatics. At the Federal level, the CDC remains the leading public health institute in the United States. In 2008, several public health associations came together to form the Joint Public Health Informatics Taskforce (JPHIT). Since that time, 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 performance of the public health system through informatics [36]. The list of members and affiliates of JPHIT provides a "who's who" of PHI and includes (as of 2015):

- American Immunization Registry Association (AIRA), which promotes the development, implementation and interoperability of IIS.
- American Medical Informatics Association (AMIA), which is 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, the Public Health informatics working group focuses on the intersection between technology and public health.
- American Public Health Association (APHA), which is focused on improving public health. The Health Informatics Information Technology member section is specifically focused on public health informatics.
- Association of Public Health Laboratories (APHL), which advocates for public health labs 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 for State and Territorial Epidemiologists (CSTE), which works to advance public health policy and epidemiologic capacity.
- International Society for Disease Surveillance (ISDS), which seeks to improve population health by advancing the science and practice of disease surveillance.
- National Association of City and County Health Officials (NACCHO), which serves local health departments in the United States including the use of informatics in local health agencies.
- National Association of Health Data Organizations (NAHDO), which seeks to improve health care data collection and use.
- NAPHSIS, which represents the state vital records and public health statistics offices in the United States.
- North American Association of Central Cancer Registries (NAACCR), which 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.
- Public Health Data Standards Consortium (PHDSC), which seeks to empower the healthcare and public health communities with health information technology standards to improve individual and community health.

There are a number of groups working on various aspects of public health informatics. No matter what the effort, the success of public health informatics is predicated on a large volume of available individual patient data. As more providers implement Electronic Health Records, this will increase the availability of information which can be used in the aggregate to support public health. Examples of specific systems which are used to support public health will be outlined in the next section.

Examples of Public Health Informatics Systems

Public health practice uses a wide variety of data types, data sources, and data management techniques. While the data necessary for many public health processes can be provided solely by data generated during routine clinical care, supplemental data and improved information extraction techniques that could better inform public health processes are either inconsistently present or are typically absent from clinical systems [37]. For example, while clinical transactions serve immediate patient care needs, they are often incomplete and lack specific patient, provider, or clinical information necessary for informed public health decisions. [38] Further, many public health processes need data not only from clinical systems, but also require nonclinical information to more accurately identify and characterize public health trends as well as the broader set of health determinants [39, 40]. Nonclinical 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 [41–45] Thus, to fully inform public health processes and improve population health outcomes, clinical data must be augmented with additional, nonclinical data sources. 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 needed to identify clinical data needed for public health processes [46]. For example, while EHR systems can route the results of a laboratory culture for MRSA (*Methicillin-resistant Staphylococcus aureus*), clinical systems often lack the capacity to 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 [47, 48]. Finally, because clinical and nonclinical data are often stored in separate databases as separate islands of information, public health often lacks efficient access to integrated population-level health data, which hinders the ability to identify and manage the specific public health needs of a community. Thus, effective integration with EHR systems, HIE networks, and other health data systems are needed to optimize digital support of public health processes [49].

Electronic Lab Reporting

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 timeliness and completeness of disease reporting [50] Most states in the U.S. have the capacity to receive electronic reports from laboratories, [51] and the volume of electronic reporting to state agencies is expected to increase given Stage 2 "meaningful use" program incentives (i.e., increased reimbursement for the adoption and use of EHR systems) from the U.S. Centers for Medicare & Medicaid Services (CMS) that

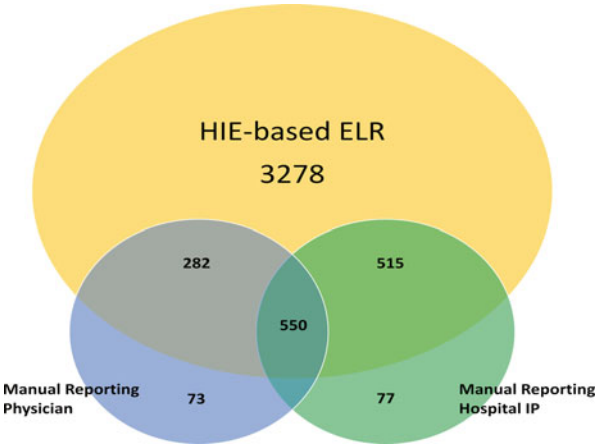

Fig. 20.2 Overhage et al.'s comparison of ELR messages identified by an HIE to manually report cases from physicians and hospital infection control professionals [50]

require eligible hospitals and encourage eligible providers to submit notifiable disease laboratory results to public health agencies using ELR [52] However, limitations of ELR have been reported [53]. Laboratories often lack detailed patient demographic information required by public health departments, and for certain diseases, are unable to determine when a test result reflects a new case or chronic disease. As clinical data is increasingly captured in electronic form, 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 above noted limitations by enhancing population-based reporting with additional data such as recent laboratory results, enhanced patient and provider demographics, as well as medication history [37, 38]. For example, Overhage et al. [39] compared ELR messages identified by an HIE to manually reported cases from physicians and hospital infection control professionals (Fig. 20.2). The analysis revealed that an automated ELR detection system implemented with fairly basic rules can significantly improve the identification of cases that need to be reported to public health authorities.

Syndromic Surveillance

Syndromic surveillance refers to a spectrum of processes that focus on real-time use of early disease indicators derived from pre-diagnostic data to detect and characterize events requiring public health investigation before definitive diagnoses are made [54]. Such systems may leverage patient level data, aggregate data, or a combination of both. Many states leverage surveillance systems for their entire populations [8, 55]. While some early syndromic surveillance systems relied upon manual data

collection, the need for timeliness focused efforts on automation of the full cycle of surveillance [56]. Subsequently, several studies demonstrate that electronic data from emergency department encounters, hospital admissions, and retail pharmaceutical sales can signal the onset and evolution of disease outbreaks earlier than traditional surveillance methods [57]. Although traditional syndromic surveillance began with pre-diagnostic data from acute care settings such as emergency departments [58], the "meaningful use" incentive program from CMS are expected to expand both the volume of syndromic surveillance data transmission, and the diversity of syndromic surveillance data sources.

Population Health Disease Registries

Population-based registries contain records for individuals residing in a defined geographical area who meet criteria for a specific disease. Public health has traditionally maintained disease-specific population registries to support a variety of public health functions including traditional epidemiological analyses and emerging use cases that more closely coordinate population health management with clinical stakeholders [59–61]. 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 counsel for state and territorial epidemiologists (CSTE) identify six categories of information captured by chronic disease registries, including: cancer, cardiovascular disease, tobacco and alcohol use, physical activity and nutrition, other diseases and risk factors, and overarching conditions [62]. Because chronic disease registries span a wide spectrum of conditions, their implementation and supporting systems vary.

Immunization Registries

Immunization registries, often called immunization information systems (IIS), have demonstrated both the ability to increase population coverage rates for vaccines and also mitigate administration of duplicate immunizations [63, 64]. Meaningful use incentives encourage healthcare providers to transmit immunization records to IIS's. Consequently, clinical care systems have deployed automated unidirectional electronic transmission of immunization data to public health. However, while routine bidirectional information exchange between clinical systems and IIS's is not widely deployed, strategies for doing so are emerging [65, 66].

Cancer Registries

To effectively monitor and address cancer burden, cancer registries capture a details for each cancer case in the United States and includes patient history, diagnosis, treatment, and status. Data are first collected by local cancer registries and contribute to population-based registries. The data supports a variety of analyses, including: determining cancer incidence; calculating survival rates; evaluating clinical outcomes, efficacy of treatment modalities, and quality of life; and assessing referral patterns and informing geographic distribution of resource allocations [67, 68]. While cancer case reporting is comprehensive, early case reporting can be delayed and incomplete [69, 70]. Electronic sources may help address these shortcomings [71]. The HITECH Act has incentivized case-based cancer reporting by offering it as an option through the EHR meaningful use program.

Community Health Assessment

Integrating electronic health record (EHR) data with community information systems (CIS) holds great promise for addressing disparities in social determinants of health (SDH) [72]. While EHR's are rich in location-specific clinical data that allow us to uncover geographically dependent inequities in health outcomes, CIS complements that data to support analysis of community-level characteristics relating to health. When meaningfully integrated, these data systems enable clinicians, researchers, and public health professionals to actively address the social etiologies of health disparities [50, 73, 74] (see Fig. 20.3).

Towards Public Health Decision Support

As discussed in Chap. 6, 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 [75]. Among other quality and safety outcomes, CDS has been shown to effectively improve clinician adherence to preventive care guidelines and alerting clinicians to potentially adverse medication outcomes [76–78]. Various forms of CDS have been introduced into current care processes through implementation of electronic health record (EHR) systems [79, 80].

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 such as

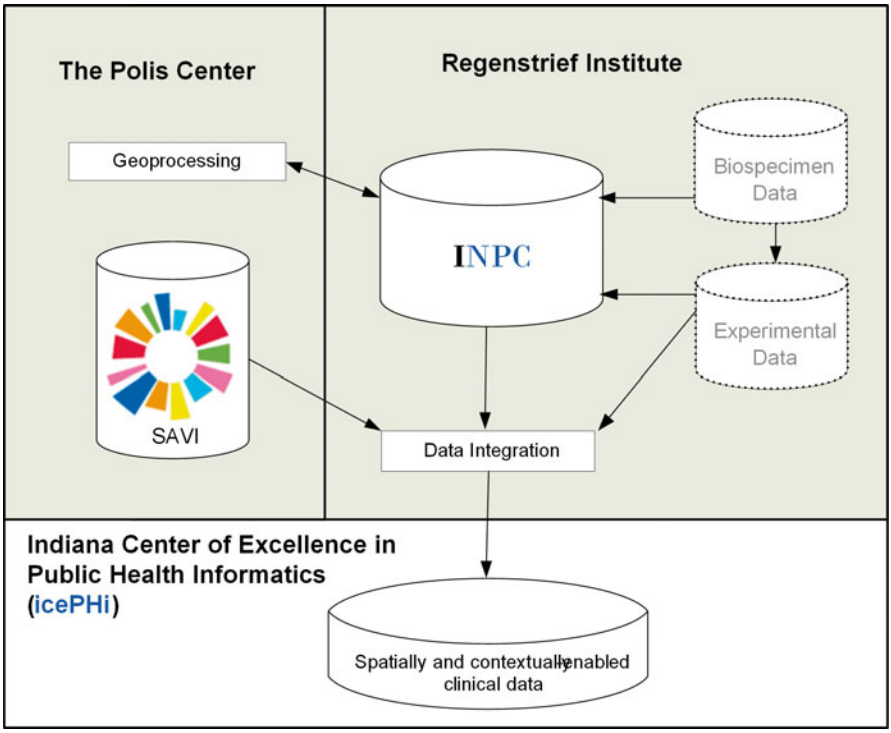

Fig. 20.3 Example of integration of different types of information in Indiana

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 their 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 wellbeing of populations using of electronic information [81].

Public Health EHR Alerting

The New York City Department of Mental Health and Hygiene developed and deployed 40 public health decision support alerts, such as screening measures for influenza and pneumococcal vaccines, to more than 2000 physicians via commercial EHR systems [82]. 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 and reporting delays [83] as well as time-consuming follow-up by public health to get needed information [84]. To address these issues medical informatics scientists at the Regenstrief Institute electronically pre-populate report forms with available clinical, lab and patient data to streamline reporting workflows, increase data completeness and, ultimately, provide access to more timely and accurate surveillance data for public health organizations.

Infrastructure to Support Bidirectional Exchange

While these examples highlight the promise of PHDS, to fully realize the potential of public health decision support, advanced clinical information systems must not only be able to transmit data to public and population health systems but also have the capacity to consume information from public health. Immunization data exchange represents one such use case [63]. Today many clinical systems transmit vaccination data to an IIS. Recently there has been increased interest in leveraging IISs to generate immunization forecasts to inform healthcare providers about past due and upcoming immunizations [60]. Electronically exchanging information both to and from public health, so-called "bidirectional communication", [85] requires a robust HIE infrastructure, which is still in its nascent stages.

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, when informing clinicians about events such as influenza disease burden and localized enteric outbreaks, health departments not uncommonly send letters via US postal mail. 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 threat to public health.

Emerging Trends

As the context in which health care is delivered changes, application of informatics to public and population health will evolve. Integrated EHR systems and increasing interoperability will make it possible for examining the wider set of health

determinants from clinical and nonclinical systems. Health reform will impact the way in which clinical and public health organizations work with each other to assess the health of populations in the community. Furthermore, the emergence of personal health devices will make capturing data on health behaviors (e.g., exercise, nutrition) easier and, in parallel, more challenging to analyze given their volume and veracity.

The HITECH Act and related policy activities (refer to Chap. 3) have enhanced the adoption and use of EHR systems in the clinical settings. The meaningful use (MU) program not only enhances health care delivery but also impacts public health informatics activities within local and state health departments. For example, several MU criteria for public health, including syndromic surveillance and electronic laboratory reporting, are increasing the transmission of data to public health authorities. In many cases, this puts pressure on health authorities to implement and enhance information systems as well as business processes. At the same time, other MU measures such as the requirement to document smoking status in the EHR also support public health authorities' capacity to aggregate data at a community level to monitor disease burden and outbreaks. Such measures are important to stimulate clinical-public health partnerships and interoperability.

MU activities are only the beginning of what's possible with public health informatics. Integration with organizations that do not qualify for MU incentives, such as long term and post-acute care (LTPAC) organizations, are also important for community health efforts. For example, monitoring community levels of MRSA or antibiotic resistance is only possible when 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 poison control centers [86], over-the-counter pharmacy sales [87], and social media [88, 89]. 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, however, and thus more work is necessary 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.

Health care reform is similarly changing the relationship between clinical and public health informatics. The shift towards accountable care organizations (ACOs) has also brought with it the need for community health assessments at the hospital and health system level; work that traditionally has been performed by public health authorities. Change has ushered in new partnerships between health systems and public health, including much needed resources to support health assessment in a community. On the informatics front, it has further brought new ideas around how best to leverage EHR data for measuring health in a community. EHR systems and HIE networks might be a source of more objective data around health status; or at least a complementary source to the traditional population-based surveys conducted by public health authorities [89]. 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 public health informatics and the capture of electronic data for use in population health. The vast array of patient-centered devices and technologies (refer to Chap. 19) entering the market has the potential to open new sources of data to public health authorities on population behaviors and health status. For example, health agencies are increasingly interested in the potential of social media information as well as Internet user search queries [90, 91]. Yet while there was initial promise and excitement with the release of data sources such as Google Flu Trends [92], 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." [22] There is even greater promise with consumer devices such as the new Apple watch and the many varieties of Fitbit devices. These devices and new sources of data will need to be evaluated and refined in the coming years to produce accurate current assessments as well as predictive models of population health.

Summary

Information systems and technologies are revolutionizing the delivery of health care as well as the practice of public health. Just as we've observed a growing demand for informatics capacity in health care organizations, a similar process is 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. Much of the data, like in medicine, is fragmented; and there is a growing number of new data sources both from clinical and non-clinical sources on the horizon. Together there is an opportunity for clinical and public health informaticians to work together to achieve the aims of meaningful use of health information technologies while enhancing the science and practice of public health leading to better population health outcomes for communities.

Questions For Discussion

- How does public health informatics complement clinical informatics? In what ways are they distinct?
- What roles do various stakeholders and information systems play in public health informatics?
- Why is increased EHR adoption important for public health informatics?
- What is the importance of syndromic surveillance?
- Which methods, tools, or systems from public health informatics might be useful for clinical informaticians to use within health systems?

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