Health Informatics

Joan M. Kiel
George R. Kim
Marion J. Ball *Editors*

Healthcare Information Management Systems

Cases, Strategies, and Solutions

Fifth Edition

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Health Informatics

This series is directed to healthcare professionals leading the transformation of healthcare by using information and knowledge. For over 20 years, Health Informatics has offered a broad range of titles: some address specific professions such as nursing, medicine, and health administration; others cover special areas of practice such as trauma and radiology; still other books in the series focus on interdisciplinary issues, such as the computer based patient record, electronic health records, and networked healthcare systems. Editors and authors, eminent experts in their fields, offer their accounts of innovations in health informatics. Increasingly, these accounts go beyond hardware and software to address the role of information in influencing the transformation of healthcare delivery systems around the world. The series also increasingly focuses on the users of the information and systems: the organizational, behavioral, and societal changes that accompany the diffusion of information technology in health services environments.

Developments in healthcare delivery are constant; in recent years, bioinformatics has emerged as a new field in health informatics to support emerging and ongoing developments in molecular biology. At the same time, further evolution of the field of health informatics is reflected in the introduction of concepts at the macro or health systems delivery level with major national initiatives related to electronic health records (EHR), data standards, and public health informatics.

These changes will continue to shape health services in the twenty-first century. By making full and creative use of the technology to tame data and to transform information, Health Informatics will foster the development and use of new knowledge in healthcare.

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Editors
Joan M. Kiel
Duquesne University
Pittsburgh, PA, USA

George R. Kim
The Johns Hopkins University
Baltimore, MD, USA

Marion J. Ball
The University of Texas at Arlington
Arlington, TX, USA

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The editorial work of this volume is dedicated to the memory of:

Thomas D. Kiel, M.D.

by Joan M. Kiel, Ph.D.

Meg Koppel, Ph.D. (in honor of Ross Koppel, Ph.D.)
My parents
Andrew R. Scholnick

by George R. Kim, M.D., F.A.A.P.

My beloved husband John Charles Ball who, throughout my career, had been:

– a guiding light and supporter of my professional activities,
– a dedicated father to our beloved children: Charles Jokl Ball and Elizabeth Ball Concordia, as well as
– a devoted grandfather to our five grandchildren: Alexis Marion Concordia, Alexander John Ball, Michael John Concordia, Ryan Jokl Ball, and Erica Adelaide Concordia.

I was blessed to have John at my side for fifty-eight years. Without him, I would not be where I am today.

In loving memory,
Marion Jokl Ball, Ed.D.

We join our co-editor, Marion Jokl Ball, in honoring and remembering Dr. John Charles Ball, a scholar and a friend.

Joan and George

Foreword

Information is life. Or not. Quite literally in healthcare, the correct (or incorrect) information at the right time in the right context creates a bright line that separates life from death for many patients. The technological systems which accept, store, retrieve, and present this critical information continue to evolve—but the history of their development is littered with more failures than successes. While we should learn from our failures, too often we simply press forward and communally repeat the same failures devolving into a vicious cycle of innovation for innovation's sake. Technology can help us solve problems in healthcare; however, it is when we start by clearly understanding those problems that the most fertile environment for virtuous cycles of information, process, and technology innovation occurs. When we apply the creative capability of our collective efforts toward understanding the jobs to be done, the problems to be solved—that is when we shine the brightest in our success.

I write this foreword as we begin to emerge from the global pandemic wrought by COVID-19. In the last year, we have seen telemedicine and remote care advance by leaps and bounds. Concurrently, we are seeing more successful cyber-attacks shut down healthcare around the world. The pandemic has created not just an environment for change, but an imperative to change. Barriers—political, economic, logistical, even technological—have given way to the irresistible force of immediacy of need, a metaphorical "burning platform" (à la Clayton Christensen).

In this past year we have lost far too many souls to the tragedy of this global pandemic. My reasons for serving in healthcare have always been rooted in the losses of family and friends to death and disease as well as the injury and illness suffered daily by those I love. When we choose to serve in healthcare, we choose to be healers. Whether our path is through research, technology, clinical care, or any of the other innumerable branches of health and care—we make a difference, we contribute, we matter.

Throughout the pandemic, healthcare researchers and practitioners have rallied in an incredible effort to provide care and compassion to the billions impacted. We have heard stories of unrelenting resolve alongside stories of tragedy and loss. As I experience connections with students in my classes, we consider the future of healthcare through a "visioning" experiment. In this experiment, each student closes their eyes and is led to consider what healthcare at their organization will look like in another 10 years. Across all the students I serve—including nurses, doctors, technologists, informaticists, and

many more—a recurring theme of optimism can be heard. When they consider the potential futures within their own organizational healthcare context, all see a more convenient, efficient, and personal healthcare system. While it may seem obvious, that system will not come about on its own—it depends on the efforts and faith of those who serve in it. May each of us, whether serving on the front lines of care, the backstage of support, or the academic community of preparation, find our personal vision of a bright future which makes that future inevitable.

This book describes numerous successes as well as some useful failures in our work toward more virtuous healthcare information technology. Through the narration of the community of contributors in this edition, we experience the breadth of actualities and possibilities in our world of healthcare IT.

There are many books about healthcare, technology, and even healthcare information technology. However, none of those other books rival the one you hold in your hands (literally or figuratively) at better representing the current collective knowledge and experience of healthcare information systems experts. Within the chapters of this text, you will encounter nurses, physicians, informaticists, technologists, researchers, analysts, educators, scientists, and many others with titles and positions that represent the broad world of healthcare information professionals. The scope of their experience spans the globe and represents the best and brightest our professions have to offer. Many I am privileged to know as friends, others I know by reputation, and I welcome you to partake in their collective wisdom through this text.

This volume offers the opportunity for students, professionals, and leaders who are responding to a calling to care to walk through a door of understanding into a room of knowledge. This knowledge represents the exponential impact that healthcare information systems bring when designed, implemented, and used well for the power of healing. Information is the lifeblood of healthcare and technology is the catalyst for information efficacy.

Transformation, leadership, informatics, ethics, technology, analytics, vision, architectures, innovations, modeling, interoperability, remote care, regulations, economics, safety, patient empowerment, public health, disaster management, and virtual care are some of the essential topics addressed by the experts assembled within this volume. While the topics venture far and wide, the consistent theme across every chapter is the inevitability and the imperative for advances in healthcare information technology.

We have entered the fourth revolution. Boundaries are shifting, blurring, and disappearing between the organic and inorganic, the digital and the physical. The possibilities for good have never been greater, but like prior industrial revolutions the potential for great harm also exists. Our choices in how we apply advanced digital capabilities to health and care will be a signal to the rest of society about the likelihood of our collective direction: good or harm, healing or hurt, division or unification.

We are always faced with the options of entrenchment in our own current environment as well as the risk-laden option to venture out into the newness of innovation and change. While our minds tell us change is required, our hearts sometimes fear and seek solace in the familiar. As leaders in health and care, our obligation is to press our hearts and minds into an integrated whole

and face the needs of our patients, communities, organizations, and even ourselves as we step out of the familiar into the bright future set before us.

Timothy Stettheimer

The College of Healthcare Information Management Executives (CHIME)
Ann Arbor, MI, USA

Woods College of Advancing Studies
Boston College
Birmingham, AL, USA

Acknowledgments

With the rapid growth of information technology, a global pandemic, and discoveries in healthcare, it was clearly time for the fifth edition of *Healthcare Information Management Systems: Cases, Strategies, and Solutions*. This book showcases the theory to practice approach of information technology transforming healthcare delivery and the people driving those transformations. In a time of so much change and challenge, this fifth edition could not have been created without a myriad of people whom we acknowledge.

We thank the Springer staff, Grant Weston, Raagai Priya Chandrasekaran, and Rakesh Kumar Jotheeswaran, who were invaluable in the organization and production of the final product. We also thank the industry and domain leaders who contributed their expertise and experience in the foreword and chapters of this book. Their perspectives and personal stories bring to light the incredible excitement of information technology in healthcare. The result is a compendium of ideas and realities that are enhancing healthcare and its delivery.

Joan M. Kiel
George R. Kim
Marion J. Ball

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Contributors

Shabbir Syed Abdul Artificial Intelligence and Digital Health, Taipei Medical University, Taipei, Taiwan

Abdu Adamu, MD, MSc, PhD Cochrane South Africa, South African Medical Research Council, Cape Town, South Africa

Frances Ayalasomayajula, MPH, PMP Reach Thought Leadership, San Diego, CA, USA

HP Inc., San Diego, CA, USA

Sugato Bagchi, PhD IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Richard S. Bakalar, MD, FATA ViTel Net, McLean, VA, USA

Sasha E. Ballen, MS R-Health Inc, Elkins Park, PA, USA

Marion J. Ball, EdD Multi-Interprofessional Center for Health Informatics (MICHI), The University of Texas at Arlington, Arlington, TX, USA

IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Johns Hopkins School of Medicine, Baltimore, MD, USA

University of Texas, Arlington, TX, USA

Stephen Bandeian, MD, JD Elevance Health, Bethesda, MD, USA

Bonnie Blueford, MA The Blueford Gorup, LLC, Coaching/Leadership Development/Communications, Annapolis, MD, USA

Tiffani J. Bright, PhD, FACMI IBM Watson Health, Sandy Springs, GA, USA

Hans J. Buitendijk, MSc, FHL7 Chester Springs, PA, USA

Bridget C. Calhoun, DrPH, PA-C John G. Rangos Sr. School of Health Sciences, Duquesne University, Pittsburgh, PA, USA

Prithwish Chakraborty IBM Research, International Business Machines Corporation, Yorktown Heights, NY, USA

Allen Chen, MD, PhD, MHS The Johns Hopkins University School of Medicine, Baltimore, MD, USA

Ching-Hua Chen, RN, PhD IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Mohamed-Amine Choukou Department of Occupational Therapy, College of Rehabilitation Sciences, University of Manitoba, Winnipeg, MB, Canada

Irene Dankwa-Mullan, MD, MPH Merative (formerly IBM Watson Health), Bethesda, MD, USA

Ashwini Davison Johns Hopkins University, Baltimore, MD, USA

Eshita Dhar Graduate Institute of Biomedical Informatics, Taipei Medical University, Taipei, Taiwan

Peter H. Dziedzic, MS Division of Neurosciences Critical Care, Precision Medicine Center of Excellence for Neurocritical Care, Center of mHealth and Innovations, Department of Neurology, The Johns Hopkins University School of Medicine, Baltimore, MD, USA

Winnie Felix, MS, MPH Merative (formerly IBM Watson Health), Bethesda, MD, USA

Lindsey Ferris, DrPH, MPH Chesapeake Region Information System for Our Patients (CRISP), Columbia, MD, USA

Morgan A. Foreman, BS IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Thomas A. Gagliardi, BS IBM Watson Health, Cambridge, MA, USA

Judy George, PhD IBM Watson Health, Cambridge, MA, USA

Mohamed Ghalwash IBM Research, International Business Machines Corporation, Yorktown Heights, NY, USA

M. Chris Gibbons, MD, MPH The Johns Hopkins School of Medicine, Baltimore, MD, USA

The Greystone Group, Inc., Greenbelt, MD, USA

Reach Thought Leadership, San Diego, CA, USA

Clifford Goldsmith Microsoft Corporation, Health and Life Sciences, Redmond, WA, USA

Mark Hagland Healthcare Innovation, Chicago, IL, USA

William Hersh Oregon Health & Science University, Portland, OR, USA

Anne M. Hewitt, PhD, MA Seton Hall University, Nutley, NJ, USA

David Horrocks, MBA, MPH New York eHealth Collaborative, New York, NY, USA

Musa A. Kana, MD, MPH, PhD National Institute of Environmental Health Sciences, Epidemiology Branch, Durham, NC, USA

Hema Karunakaram, MPH IBM Watson Health, Chicago, IL, USA

Ahmad Khanijahani, PhD, CPH, CHDA John G. Rangos, Sr. School of Health Sciences, Duquesne University, Pittsburgh, PA, USA

Hadi Kharrazi, MD, PhD, FAMIA Johns Hopkins School of Public Health, Baltimore, MD, USA

Joan M. Kiel, PhD, CHPS Duquesne University, Pittsburgh, PA, USA

George R. Kim, MD, FAAP Johns Hopkins School of Medicine, Baltimore, MD, USA

Ross Koppel, PhD, FACMI Department of Sociology, School of Arts and Sciences, University of Pennsylvania, Philadelphia, PA, USA

Department of Biomedical Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

Department of Biomedical Informatics, Jacobs School of Medicine, University at Buffalo, Buffalo, NY, USA

Akira Koseki IBM Research, International Business Machines Corporation, Tokyo, Japan

Eileen Koski, MPhil, FAMIA IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Michiharu Kudo IBM Research, International Business Machines Corporation, Tokyo, Japan

Darren Lacey, JD Johns Hopkins University and Johns Hopkins Medicine, Baltimore, MD, USA

Man Qing Liang, PharmD, MSc Student TIGER Initiative, HIMSS, Montreal, Canada

Faina Linkov, MPH, PhD John G. Rangos, Sr. School of Health Sciences, Duquesne University, Pittsburgh, PA, USA

Bhagyashree (Disha) Maity, MS, BSN, RN Clinical Informatics Lead, San Francisco, CA, USA

Shwetambara Malwade Taipei Medical University, ICHIT, Taipei, Taiwan

Steven F. Mandell Division of General Internal Medicine, Biomedical Informatics and Data Science, The Johns Hopkins University, Baltimore, MD, USA

Healthcare Information Systems, Johns Hopkins Hospital, Baltimore, MD, USA

Molly McCarthy, MBA, RN-BC Microsoft Corporation, US Health and Life Sciences, Redmond, WA, USA

Ruth E. Metzger, PhD, MBA, BA, BSN Indiana State Department of Health, Division of Long-Term Care, Evansville, IN, USA

David L. Meyers, MD, MBE, FACEP Adjunct Faculty, Johns Hopkins University, Baltimore, MD, USA

Emergency Medicine, Sinai Hospital of Baltimore, Baltimore, MD, USA

Nicole Mollenkopf, PharmD, MBA The Johns Hopkins University School of Medicine, Baltimore, MD, USA

Toria Shaw Morawski, MSW Professional Development, HIMSS, Schaumburg, IL, USA

Kenney Ng IBM Research, International Business Machines Corporation, Cambridge, MA, USA

Yoonyoung Park, ScD IBM T. J. Watson Research Center, Cambridge, MA, USA

Malinda Peeples, MS, RN, CDCES, FADCES Clinical Services and Research, Welldoc, Inc, Columbia, MD, USA

Department of Medicine, Division of General Internal Medicine, Johns Hopkins Medicine, Baltimore, MD, USA

Samantha Pitts, MD, MPH The Johns Hopkins University School of Medicine, Baltimore, MD, USA

Mark Polyak Ipsos, Washington, DC, USA

Trisha Pongco, CAHIMS Clinical Informatics, HIMSS, Brooklyn, NY, USA

Ismail A. Raji, MD, MSc, MPH Department of Community Medicine, Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria

Stephanie L. Reel Johns Hopkins Medicine, Johns Hopkins Health System, Johns Hopkins University, Baltimore, MD, USA

Division of General Internal Medicine, Biomedical Informatics and Data Science, The Johns Hopkins University, Baltimore, MD, USA

Christopher Regan Microsoft Corporation, Office of the CTO, Health and Life Sciences, Redmond, WA, USA

Fernando Suarez Saiz, MD IBM Watson Health, Toronto, ON, Canada

Elisabeth Lee Scheufele, MD, MS IBM Watson Health, Boston, MA, USA

Yahya Shaihk, MD, MPH The MITRE Corporation, McLean, VA, USA

John S. Silva, MD, FACMI Silva Consulting Services, Phoenix, MD, USA

Moninder Singh, PhD IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Paul Slater BillionMinds, Woodinville, WA, USA

Jane L. Snowdon, PhD IBM Watson Health, Cambridge, MA, USA

Brett R. South, MS, PhD, FAMIA IBM Watson Health, Salt Lake City, UT, USA

Daby M. Sow IBM Research, International Business Machines Corporation, Yorktown Heights, NY, USA

IBM T. J. Watson Research Center, Yorktown Heights, NY, USA

Timothy Stettheimer, PhD, CHCIO, FACHE The College of Healthcare Information Management Executives (CHIME), Ann Arbor, MI, USA

Woods College of Advancing Studies, Boston College, Birmingham, AL, USA

Jose I. Suarez, MD, FNCS, FANA Division of Neurosciences Critical Care, Precision Medicine Center of Excellence for Neurocritical Care, Departments of Anesthesiology and Critical Care Medicine, Neurology, and Neurosurgery, The Johns Hopkins University School of Medicine, Baltimore, MD, USA

Bridgette Thomas, PharmD Johns Hopkins Home Care Group, Baltimore, MD, USA

Christopher P. Tompkins, PhD Brandeis University, Waltham, MA, USA

Tianna M. Umann Microsoft Corporation, Office of the CTO, Technology Strategy, New York, NY, USA

Stephen L. Wagner, PhD, FACHE, LFACMPE Seton Hall University-Interprofessional Health Sciences Campus, Nutley, NJ, USA

John M. Walker, MA, IT Professional, Canton, GA, USA

Patricia Hinton Walker, PhD, RN, FAAN, MCC CoachingSteppingStones.com, Canton, GA, USA

Canton, GA, USA

Gabriela Mustata Wilson, PhD, MSc, FHIMSS, SNAI Multi-Interprofessional Center for Health Informatics (MICHI), The University of Texas at Arlington, Arlington, TX, USA

Taylor Woodroof, PharmD, MHIIM Johns Hopkins Home Care Group, Baltimore, MD, USA

Hiroki Yanagisawa IBM Research, International Business Machines Corporation, Tokyo, Japan

Yushi Yang, PhD Armstrong Institute for Patient Safety and Quality, The Johns Hopkins Health System, Baltimore, MD, USA

XinXin (Katie) Zhu Center for Biomedical Data Science, School of Medicine, Yale University, New Haven, CT, USA

Part I

The Current State

Two decades of federal incentives have moved certified electronic health record technology (CEHRT) into all sectors of US health care and have established the centrality of electronic data in the daily work of clinical medicine. The mutual assimilation of information technology (HIT) and US healthcare infrastructures has led to significant changes to how healthcare gets done:

- The availability of up-to-date electronic clinical and administrative data for individuals and populations is providing data infrastructures for maintaining institutional awareness of health and healthcare metrics for timely response, improvement, and prevention.
- The ability to measure outcomes from aggregate data is providing new opportunities to link health quality and remuneration, moving from fee-for-service to value-based payment models based on provider and institutional performance.
- With these affordances have arisen new needs and responsibilities to assure the confidentiality, integrity and availability of healthcare data, infrastructures, and functionalities. This in turn has led to the need for new expertise, resources, and expenditures to protect the content, privacy, and security.

Topics covered in this Section include:

- A consideration and estimation of ongoing annual costs of electronic health record (EHR) and other healthcare information technologies (HIT) in the United States by Ross Koppel
- An overview of the evolution of models for healthcare payment/remuneration with respect to value and quality by Chris Tompkins and Steve Bandeian
- A discussion on the ongoing and changing needs of healthcare leadership in the era of electronic health records by Patricia Hinton Walker and colleagues
- Considerations for developing the healthcare informatics workforce on a global scale by Man Qing Liang and colleagues

- An exploration of the new needs of clinicians and patients in the era of virtual and remote healthcare by Bridget Calhoun
- Expositions on developments in

  – Healthcare privacy and security by Darren Lacey
  – Interoperability by Hans Buitendijk
  – Healthcare Information Exchange by David Horrocks, Lindsey Ferris and Hadi Kharrazi

1 Estimating the United States' Cost of Healthcare Information Technology

Ross Koppel

Abstract

Current US healthcare involves extensive use of shared electronic health records (EHRs) and other data from health information technologies for clinical care, data collection, billing and regulatory reporting. Business and regulatory processes also are dependent on EHRs and a cornucopia of other medical services, devices and platforms (wearables, home health monitors, medical imaging software, etc.). The healthcare world has created an enormous medical information infrastructure that itself has ongoing operating, maintenance and updating costs. This chapter is a first attempt to estimate the scope and magnitude of those software costs, and an invitation for others to join in the discussion.

Keywords

Electronic Health Records: classification
Economics · Statistics and numerical data
Trends · Clinical pharmacy information systems · Classification · Economics
Statistics and numerical data · Telemedicine
Economics · Organization and administration
Nurses · Physicians · Community health
Economics · Medical care

Learning Objectives

On completing this chapter, the reader shall be able to:

- Describe/Discuss the impact and *annual* costs of electronic health records and other clinical software in US healthcare
- Enumerate and describe considerations involved in estimating HIT costs for different clinical functions and specialties
- Appreciate/articulate the magnitude of ongoing costs to US healthcare

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R. Koppel (✉)
Department of Sociology, School of Arts and Sciences, University of Pennsylvania, Philadelphia, PA, USA

Department of Biomedical Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

Department of Biomedical Informatics, Jacobs School of Medicine, University at Buffalo, Buffalo, NY, USA
e-mail: rkoppel@sas.upenn.edu

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1.1 Introduction

In recent years, researchers, clinicians, journalists and even supporters of healthcare technology have renewed questions about the effectiveness and burdens of electronic health records (EHRs) and other healthcare information applications. Although EHRs have been cited as a major reason for clinician rage, burnout and early retirement, ***we do not address these collateral costs/damages of healthcare IT (HIT) herein, but the topic is well documented*** [1–11].

1.1.1 The Myriad Benefits of HIT

A full analysis of the cost of HIT must reflect the many dramatic efficiencies and advantages HIT affords. These benefits go far beyond clinical services, business operations and scheduling—from speeding information to any and all clinicians, to supporting clinical decisions, improving legibility, error-checking and tracking. In addition, HIT has become an essential and regulatory requirement for billing and reimbursement by government (e.g., Medicare, Medicaid and CMS) and insurance companies.

Our aim here, however, is more modest than enumerating HIT's many benefits. Our focus here is on the direct financial costs of US healthcare's software; specifically, on the ongoing costs of buying, implementing and maintaining the software on which US clinical care has become dependent: e.g., EHRs, dental IT, pharmacy IT, visiting nurses IT, laboratory IT, telemedicine, and so on. In examining the published literature, we find that few have examined the aggregate cost of *healthcare software* for the range of medical services described herein.

1.1.2 A Frequent Misunderstanding

Many articles on the cost of healthcare IT (HIT) [4] focus on the $36 billion in incentives, part of the American Recovery and Reinvestment Act (ARRA) and of the HITECH (Health Information Technology for Economic and Clinical Health of 2009) Act to spur EHR adoption and use. However, these funds were only *seed money* to incentivize hospitals and physicians to purchase, implement and use EHRs. This effort was stunningly successful, resulting in extraordinary increases in HIT sales and implementation, with hospital EHR adoption growing from about 9% in 2009 to 97% in 2021, and with an equally remarkable uptake of EHRs and related technologies by doctors' offices.[1]

1.1.3 "Carrot and Stick"

The "carrot" of federal incentives and subsidies for EHR adoption was reinforced by a "stick" of regulations for non-participation in the form of Medicare and Medicaid reimbursement deductions for non-adopters. As Medicare and Medicaid cover about 42% and 16% of all US patients respectively, such deductions would be *de facto* bankruptcy for most medical providers and hospitals. And in fact, inability to face EHR implementation and use (in other words, to accept financially infeasible Medicare/Medicaid reductions), caused many medical practices, usually older and smaller ones, to close.

1.1.4 The "Real" Costs

Software, and its implementation, while very expensive, is a small part of total US healthcare costs. As we document below, it represents about 7–8% of the $4 trillion the US spends on healthcare.

Significant parts of healthcare system IT costs are supported by taxpayers through Medicare and Medicaid, the National Library of Medicine (NLM), the Office of the National

[1] If instead of asking about the ROI to the government's $36 billion in seed money, one might ask about vendors' return on convincing the government to enact the HITECH legislation. That ROI is almost beyond calculation. Certainly, the billions of dollars returned for every dollar spent convincing the government to require hospitals and clinicians to purchase the technology was the best investment ever made.

Coordinator of Health Care IT (ONC), in addition to other HHS and NSF programs. We estimate the actual amount for HIT software and implementation to be almost just over 300 billion dollars (almost 9 times the original $36 billion in seed money). These estimates reflect costs of maintenance, customization, modifications and connection of EHRs to existing/legacy healthcare technology (e.g., patient monitoring devices and displays). They also reflect a very small proportion of the costs of training, consultants, additional IT staff and associated access utilities and devices.

1.1.5 Our Scope and Plan

In this work, we first enumerate the costs of healthcare IT (HIT) that we include in this examination and estimation. We focus only on the cost of the software and its implementation. We exclude all hardware costs. We also list the users of these software products. We lay out the general method by which we obtained estimates and calculated costs. This is followed by a domain-by-domain accounting of our findings (with source citations and rationales) with notations on the special considerations for each domain in annual cost estimations. What follows is a tally of these costs as a "first" estimate of annual US health IT costs. Our brief conclusion is an invitation for ongoing dialogue and discourse on the impact and ongoing costs of healthcare information technology in US healthcare.

1.2 Our Task

In this examination of HIT costs, we endeavor to:

1. Enumerate and document the clinical services that purchase and employ HIT software.
2. Outline and estimate costs of the healthcare software and its implementation in US medical facilities and offices, including setup and maintenance.
   (a) System pricing varies, with some vendors charging periodic (yearly, monthly) fees, and others charging by person (users, patients) and tiers (e.g., stepwise increases for numbers of users: 1–10, 11–100, etc.).
   (b) Add-on services are additional costs for specific functionalities, e.g., scheduling and patient reminders, SMS texting to patients, plus set up and training fees--some at no extra cost, others at thousands or tens of thousands of dollars.
3. However, we do not include in these cost estimates the frequently discussed negative costs of EHRs, which reflect time-intensive data entry tasks [12] often associated with lost productivity, inefficiencies, burnout and additional training [12].

Nor do we include:

(a) Losses associated with legal efforts related to HIT-linked problems, a focus of work by the Health Law Group of the American Bar Association [13].
(b) Losses due to ransomware and data breaches (fines, recovery, reputational loss, and remediation).

1.3 Who Buys and Uses HIT?

1.3.1 Inclusions

Government Systems

Ambulance services/EMS (if not part of a fire department system)
Dept of Defense health care software
Indian Health system
Prison health system software
State and County Health Systems IT
Dept of Veterans Affairs health system (VHA)

Home Care, Long Term Care, and Elderly Care

Adult Day Care
Home Health Care
Hospices
Remote Patient Monitoring Systems—if separate software and costs from hospital or medical practice systems
Skilled Nursing Facilities
Visiting Nurses

Clinical and Other Services (Usually Not in Hospitals)
Acupuncture
Chiropractic
Clinical trial software
Dental Care
Dialysis centers (free standing)
Medical Offices/PCPs
Occupational Therapy (if not included in general hospital software)
Optometry
Pharmacies (chain and independent)
Pharmacy Benefits Mangers' software
Physical Therapy
Podiatry
Telehealth Systems/Virtual Medical Visits--Outpatient

Hospitals and Usually Linked Services
Hospitals
ICU telemetry and monitoring within the hospital system.
Medical Imaging (X-rays, MRIs, etc.)
Medical Laboratory Information Systems
PACS (Picture Archiving and Communications Systems) software if not included
in the total facility costs
Medical social services

Also included is cybersecurity software insurance premiums (excluding hardware)

Our list of users, although extensive and probably unique, obscures the complexity of deriving cost estimates. For example, EHR costs may be shared across hospital chains, groups and facilities. Each implementation, even in the same medical system, however, may demand separate efforts because of different legacy devices and software, staff experience with previous software, patient populations, state regulations, and availability of ancillary services (e.g., nearby labs or pharmacies), etc.

As facilities (such as private medical practices) merge with larger or more prosperous entities (such as hospital groups) [14] , there may be shifting and/or modification of existing EHR systems. One example of this is the need of national pharmacy information systems to accommodate varying state regulations on medication labeling (font size, formats, additional information). Another is the need to accommodate systems for unusual local conditions (such as climate). An example of the latter is a southern US hospital system with one mountain-based facility with a need for not previously loaded protocols for frostbite. Such variances create additional costs for healthcare systems.

1.3.2 Exclusions

We exclude many types of HIT, some because of uncertainty in the accuracy of estimating software or implementation costs, and some because of concerns about double counting. Undoubtedly, their absence will result in noteworthy undercounting, but we would rather err on the side of under- rather than over-estimation. These exclusions are:

- Medical billing software, including revenue cycle software
- Data warehouse software
- Blood bank IT software
- Psychologists' software and all behavioral health software, including all mental health facilities (hospitals and clinics)
- Software for most social workers
- Pharmaceutical manufacturers' or distributors' software
- Artificial Intelligence (AI) clinical software, e.g., used to predict sepsis, treatment protocols, discharge, bed use, etc. These exclusions included the vast new AI firms and programs linked to medical facilities and services
- AI for robotic devices, such as robotic surgery or brain-to-speech functions, etc.
- Data sharing, e.g., Health Information Exchanges (HIEs), direct exchange, query-based exchange, etc.
- Connectivity costs for telehealth IT
- Extra time (pajama time) of clinicians entering data after workhours
- Implementation costs for software that is shared with other systems
- Pharmaco-surveillance software
- Software for the increasingly popular mail order pharmacies

- Public or other health clinics—including AIDs centers, etc.
- All rehabilitation facilities (separate EHRs, not part of regular hospital systems)
- Urgent care centers' software
- Nurse Practitioners (NPs) using telemedicine software who work in hospitals and NPs who work in medical offices but are not in primary care.
- Costs to the VHA for annual software licensing and maintenance. (Excluded because of the long implementation time)
- The value of thousands of VHA clinician hours assisting the VHA implementation effort at the VHA facilities. Neither do we include the $4.9 billion the VHA is spending to maintain VistA during the Cerner roll-out
- Physicians who left the profession because of the requirements to use and bill via EHRs
- The lost productivity and the implementation costs for many of the services enumerated below. (We only include such costs when we have hard numbers for those functions for each specific type of software implementation
- User fees for physicians at SNFs

Adding these to our totals might well double our total estimated costs. But we do not do that for the reasons articulated above.

1.4 Cost Estimates: Method

1.4.1 Information Sources

We have enumerated many clinical services that use healthcare software ("Who Buys and Uses HIT? Inclusions") and sought to contact all known vendors in all relevant service fields (e.g., software for dental practices, visiting nurse associations, hospices, chiropractors, EHRs for medical enterprises, medical imaging centers, ambulatory clinics, nursing homes, etc.). We collected information via direct phone calls, website request forms, contract forms, and email requests to vendors and others. We often were obliged to view demonstration videos and talks before we could seek price information. We also signed up for 302 price quotes from HIT vendors. We established a separate website, email, and phone number to avoid overwhelming our personal and university email and other systems.

In addition to "direct" efforts, we reviewed:

- The peer-reviewed literature that addresses software costs and EHRs, with articles addressing implementation costs (e.g., training, consultants, retrofitting devices, IT costs). These included JAMIA, ACI, JAMA, NEJM, etc.
- The literature on healthcare finance, cybersecurity costs, and information systems
- Regulatory agency websites and publications for software and implementation costs, including DHHS' Office of the National Coordinator for Health Information Technology (ONC) and DHHS Information Technology Agency Summary for software expenses [15]
- Relevant professional and trade publications, e.g., American Medical Association, American Dental Association, Visiting Nurse Associations of America, HIMSS, CHIME and AMDIS
- Budgets in city, county, state, and federal reports on healthcare software costs. For example, the Indian Health Service and the Veterans Administration are obliged to publish budgets for congress. Many publicly funded hospitals and services are also obliged to submit budget documents. Also, most public agencies must disclose their budgets in state and county databases and reports [16, 17]
- Scholarly literature and reports on these issues, e.g., from AMIA, IMIA, European and other Informatics Associations
- Budget analyses for software costs by industry, from data marketing firms [18], published comparisons of software spending by industry. We note also that healthcare software costs are expected to increase significantly as "software as a service" (SaaS) becomes more popular vs on-premises software
- Associations of medical CFOs, CTOs, CIOs and others
- Professional organizations focused on healthcare institutions' HIT, e.g., CHIME and

AMDIS—often via personal contacts and reports or documents
- Hospitals and other reports on costs of software--both reports to CMS and other agencies
- Webinars from healthcare staff and vendors--often sharing their improvements to efficiencies, cost-effectiveness, staff satisfaction, etc. [19]
- Additional clarifications in response to our questions, e.g., in one case the software contract disclosures (revealed via FOIA from known disputes involving publicly funded hospitals and from publicly available pre-trial disclosures)
- Many requests to listservs of many of the above associations and organizations.

1.4.2 Responses from Vendors and Limitations

Many vendors responded to direct and indirect requests for information. Almost one-third (32%) of vendors for many service areas were forthcoming about prices, especially after we probed repeatedly for additional costs, such as fees for set-ups, data migration, patient reminder functions, user training (in-person and remote, the latter because of COVID-19), additional billing functions (if not included), revenue and personnel management, linkages to CMS or insurance companies (if not included), etc. Often, we re-contacted them for clarification on price charts or fee schedules.

These estimates represent the most encompassing effort of which we are aware. We realize, of course, that they are undoubtedly subject to error. Many estimates are based on available data, augmented by interviews with providers, administrators, vendors, government reports (state and federal), industry research, scholarly reports, and financial documents (e.g., reports from hospitals and government agencies, etc.). While we always sought to triangulate data, estimates and sources, these are subject to limitations: censored data (e.g., truncated on one side or the other), under- and over-statements of costs or efficiencies, lack of forthrightness/knowledge of interviewees, bias (intentional or unintentional) in presenting costs or functionality, etc. In addition, there may be errors in assumptions or calculations. In all cases, however, we have sought to make those calculations and assumptions transparent. We invite those with more recent or detailed data to access the following website: universityhitsoftware@socialresearchcorp.com and share additional sources or more precise data. We also urge others to continue this initial effort and to advance the understanding of HIT's costs.

1.5 Software Cost Estimates: Findings

1.5.1 Introductory Notes

These findings exclude all hardware costs. In all cases, we distinguish estimates for one-time costs (implementation/customizations) from yearly costs (e.g. monthly or annual licenses). For the one-time costs we amortize the expense over at least 5 years to provide an annual cost estimate for each of the thirty-two categories listed below.

1.5.2 Government Systems

1.5.2.1 Emergency Medical Services (not part of Fire Departments)

There are 21,283 separate EMS units in the US. However, 40% are linked to fire departments as part of many communities' protective services. We therefore remove them from inclusion in calculating HIT software costs, with the resulting number equaling 12,770. These remaining EMS departments are funded by over 34 different agencies and sources—including state funds, medical systems, local agencies, and a very wide range of federal funds, including federal emergency preparedness funds and the US Department of Homeland Security [20].

Based on review of EMS EHR vendor data and interviews with both vendors and local officials [21–23], the implementation costs for these EMS units (i.e., the 60% of EMS units not linked

to fire departments) is approximately $5,342 per system, which for 12,770 systems equals $68.216 million as a one-time cost. Amortized over 5 years, this equals **$13.653 million.**

EMS HIT software license fees are based on the number of ambulances in each unit. There are 52,000 ambulances in the US (not counting the military, tribal systems and scores of other agencies). With a mean license fee of $57/month/per ambulance = $654/yr per ambulance. This totals to $34,008,000 million for the US. Combining the amortized implementation costs and the license fees equals **$47,661,000.**

1.5.2.2 Department of Defense: Cerner-Leidos-Accenture EHR Implementation

Originally, the cost of the US Department of Defense project to replace its existing EHR and medical information system (the Composite Health Care System/Armed Forces Health Longitudinal Technology Application (CHCS/AHLTA) [24]) with a commercial solution, was $4 billion, which subsequently increased to $5.2 billion by 2018 with the proviso then that the cost would increase [25]. This cost was recently increased to account for issues with interoperability with the VHA system and with the expansion and implementation of the scheduled 23 "waves," each targeting specific regions over the next few years [26, 27].

We estimate the cost at $5.6 billion, and we do not add costs for the thousands of military and civilian personnel assisting in this effort. Amortized over 7 years because of delays caused by COVID and other factors, the estimated cost is $5.6 billion/7 or $800,000,000.

The annual maintenance contract is estimated at $850 million. Thus, the combined implementation and maintenance costs are estimated at: **$1,650,000,000**

1.5.2.3 US Indian Health Service (IHS)

In a detailed public report to Congress, the 2021 enacted budget for the Indian Health Service's (IHS) Electronic Health Record System, its Electronic Dental Health Record and its TeleBehavioral Health Center are $34,500,000, $2,500,000 and $831,000 respectively [28]. We do not include costs of implementation, licensing, maintenance, patches, or repairs.

The total of these is $37,831,000.

Based on budget reports, we add four percent for management, operations and quality and oversight budgets (4% of $9,898,000) [28] = $395,920.

Estimated combined Indian Health Service EHR/HIT costs**: $38,226,920**

1.5.2.4 Prison and Jail EHR Software

Persons in prisons (state and federal institutions) are medically vulnerable populations, with rates of HIV, drug dependence, hepatitis, and mental illness far exceeding those of the general population. Sixty-three percent receive medical care and 53% are taking prescription medications. For persons in jails (local short-term holding facilities), 45% receive medical care and 39% take prescription medications [29–31]. In addition, there are required intake, yearly, and exit medical inspections.

Federal law dictates that all care provided in prisons and jails must be medico-legally documented and (sometimes billed) via software that is similar to a regular EHR (some with less functionality than those of hospitals). Licensing costs are usually by prisoner (or bed), with fees ranging from $15 per prisoner per month to $90 per prisoner per month [32]. It should be remembered that the number of comorbidities and the severity of their illnesses often involved hospitalization (within the prison). We use a mean of $30/mo per prisoner (Annual = $360). Moreover, because of the transient population in jails (vs. prisons) we reduce the population by 40%, from 2.3 million to 1.38 million. We do not include any cost for implementation, training, lost productivity or set up fees, although these are considerable. Multiplying only the reduced population numbers by the annual software license fee = $**496,800,000**

1.5.2.5 State and County Health Departments

Collectively, state healthcare agencies spend over $1.5 trillion on direct expenses. Separately, county healthcare agencies spend over $1.7 trillion on direct expenses. Federal budget reports and the

healthcare literature reveals that healthcare (**not** *healthcare IT*) represents 9.4% of those totals [33]. Estimated IT expenses for state and county health departments is 2.9%, of those costs [34].

Thus, the collective **state health departments**' software costs [35] are estimated at **$98,500,000.**

The collective healthcare software costs [36] for 3006 counties in the US, based on data from the National Association of Counties, totals **$1,856,000,000.**

Together, these equal **$2,398,500,000.**

1.5.2.6 The Veterans Health Administration (VHA) Cerner EHR Implementation

Originally, the Veterans Health Administration (VHA) project to convert the VHA hospitals' EHR from the Veterans Health Information Systems and Technology Architecture (VistA) to a Cerner implementation was listed as a $16 billion effort [37], but quickly increased to $20 billion [38]. Recent reports, and the several Inspector General and congressional reports now put the figure at $26.5 billion [39–44].

Many interviews with VHA clinicians cite this $26.5 billion as a significant underestimate because many thousands of clinician person-hours are being assigned to work with the implementation effort at the many target facilities, diverting direct patient care to rates lower than before the implementation process began. However, we do not have an accurate metric for this loss of service and extra expense, hence we do not include it in our estimate. Neither do we include the $4.9 billion the VHA is spending to maintain VistA during the Cerner roll-out [45].

Licensing/maintenance/repair costs, ordinarily assessed on the software portion of the effort, would be only a tiny fraction of the implementation cost, and because of the long implementation time, we assess no cost to those usual fees.

Because the Cerner implementation is occurring in many VHA hospitals and clinics, and because of the repeated delays and ordered "stand-downs," we have not amortized the cost over 5 years, but rather over 7 years. Thus, our estimate for the cost of the VHA Cerner implementation and software cost at $26.5 billion/7 = **$3,785,700,000** [46–48].

1.5.3 Home Care, Long Term Care, and Elderly Care

1.5.3.1 Adult Day Care

According to the US Centers for Disease Control and Prevention (CDC) [49] there are 4,600 adult daycare centers that each serve between 2–530 adults (a mean of 66 adult patients per center). The total number of FTE staff for the centers (users) is 19,900 [50].

Interviews with vendors and their literature reveal that the mean cost for software licenses in adult day care (ADC) is $1,596.00 per staff user per year. For 19,900 FTE US staff users, this is a total cost of **$31.76 million** per year [51].

Most vendors in this sector appear to include set up and implementation costs as part of the package (i.e., no additional cost for this function). Estimates for lost productivity (mean = 3 weeks) and implementation (mean = 1 week) add $3,500.00 per center (not per user), which, for 4,600 centers, yields a one-time total of **$16.1 million,** which amortized over 5 years is **$3.222 million**.

The estimated US cost for ADC software is $31.76 million plus $3.22 million, which totals to **$34,980,000**.

1.5.3.2 Home Health Care (HHC)

According to the US Bureau of Labor Statistics (BLS), there are 3.5 million US home healthcare workers (HHW) whose work is organized, scheduled, billed and paid for via 12,200 agencies and services [52, 53].

Costs per HHW: Based on CDC data, interviews with providers and vendors, and on industry reports, we estimate software costs to average ~$40 per month per HHW [54]. Thus, an initial estimate of home health care software costs in the US is: $40 per month per HHW × 12 months per year = 480 per HHW.

Therefore, the initial estimate of $480 per HHW per year × 3.5 million HHW in the US = $1.680 billion before adjustments (below)

To put this into perspective, total US annual spending for home health care, in 2021 dollars, is $17.985 billion [55]

However, we then reduce the cost to reflect the reality that the number of users should be reduced by 25% [56] (estimated) due to the high turnover rates of HHWs--with the expectation that software services do not need to be paid for those not working for a month. Thus the $1.680 billion × 0.75 (reduction) = **$1.260 billion**

- Addition of one-time costs (per agency) for set up (average $1,117.5), training (average $140.00 which is included in some packages), implementation (average $310) and lost productivity during implementation and learning (based on a mean of 3 weeks, we estimate at a lower end of range of costs: $12,000 per agency).

  For 12,200 US home health agencies, this one-time cost:
  ($1,117.50 + $140.00 + $310.00 + $12,000.00) per agency = $13,567.50, amortized over 5 years is $2,713.50 per agency, which for 12,200 agencies yields **$33.105 million** estimated US home health care initial costs [57].
- Adding these adjustments ($33.105 million + $1.260 billion) yields an adjusted annual cost of for home healthcare software of **$1,293,105,000**.

1.5.3.3 Hospices

There are between 4,515 and 6,800 hospices in the USA. The numbers differ by sources and by definitions of in-home vs institutional [58, 59] with CDS data indicating the workforce is 48% RNs, 8% LPNs, 31.8% nursing aids, and 11.4% social workers.

Hospices are generally much smaller than hospitals (the mean average daily census is 63, but the median is 31, and most (62%) have fewer than 50 patients. Nevertheless, they serve 1,162,500 patients each year [59]. Unlike hospitals, but similar to SNFs, hospices are generally (65.2%) for-profit institutions [58, 60].

For Medicare and Medicaid funding and to bill insurance carriers, hospices need digital systems similar to EHRs, often, however, with fewer features. The large vendors are Epic (the largest), Homecare, Homebase, Brightree, Wellsky, and Netsmart. As the US population ages, the "silver tsunami" is causing a growth in the number of hospice patients and in the number of hospice beds, with increases in the cost of hospitalizations and acceptance of end-of-life care.

Hospice HIT Cost: Using similar metrics for other long-term care facilities (see SNFs, below), albeit with significantly reduced fees and denominators, we reduce implementation costs, productivity loss, et cetera by 20% of the SNF's costs discussed below ($24,000, compared to the SNFs at $30,000); and we use a per bed cost of $10 per bed per month ($120 per bed per year) with no additions for laboratory linkages, pharmacy connections, etc.

To determine the number of facilities, we use the mean of the two hospice estimates (4,515 and 6,800/2 = 5,672) and we take only 70% of that number (= 3,970) because we wish to avoid the possibility of double counting any home care services.

For implementation costs (training, set up and lost productivity), we use both a reduced number of facilities (70% = 3970) and a reduced cost of $24,000 per facility. This equals a total of $95,280,000, which amortized over 5 years is $19,560,000 per year**.** The bed fee is $120 per bed per year times 1,162,500 = $139,500,000. The combined total is **$159,060,000** [61]

1.5.3.4 Remote Patient Monitoring (RPM)

Remote Patient Monitoring (RPM) is experiencing exponential growth. Increasing availability and reliability of sensors and devices, real-time physiologic and biochemical monitors, tracking tools (for weight, vital signs, glucose levels, activity), wireless and cloud technologies etc. are improving the scope and quality of care. The convergence of technology with drivers such as an increasing older population that is better served

at home than in hospitals [62], the desire to reduce healthcare costs and improve outcomes through awareness of preventable morbidity (in chronic disease) and reduction of hospitalizations (admissions and lengths of stay), the need to extend clinical person-power (to care for more patients with fewer physicians and nurses), and more recently, the COVID-19 pandemic [63], have allowed insurance reimbursement for the use of RPM—a point made repeatedly in the software vendors' advertisements. Over 88% of hospitals are investing in RPM and the ability to implement and document remote care.

RPM software packages vary depending on the technology (sensors, recording, storage and retrieval of clinical data), and with linkage to EHR software for documentation and billing. Pricing packages are based per patient and range from $30 to $98 per patient per month, depending on the amount and level of communication with the patient, the functionality for analysis, interpretations, and servicing for devices [64–68].

Based on review of the literature [69, 70] and interviews with providers, we use a mean toward the low end of the range: $45 per patient per month ($540 per patient per year). The literature from the Society of Critical Care Medicine reveal [71] that there are 25.8 million US patients who are monitored remotely. We do not include implementation, set up, or delivery costs and focus on the software licensing costs. When the 25.8 million is multiplied by $45 per patient per month ($540 per patient per year) it yields an estimated RPM software cost of $13.932 billion per year. This number, however, would overestimate the cost because not all patients are remotely monitored for a full year. We therefore reduce the number of patients by 25% [72] to equal a cost of **$10,449,000,000.**

1.5.3.5 Skilled Nursing Facilities (SNFs)

There are 15,600 skilled nursing facilities in the US, with a total of 1.7 million licensed beds, housing over 1.35 million people. More than 70% of facilities are for-profit institutions; with 4% run by hospitals. Skilled nursing facilities (SNFs) and continuing care facilities reflect about 5% of all US healthcare expenses [73]. SNFs employ 1,534,120 workers of whom 43,420 are in management and 6,410 are top executives. The vast majority (630,550) are nursing assistants or in related fields, and only about 153,000 are RNs [74].

EHR software for SNFs incorporate many hospital EHRs functions as well as administrative and scheduling tasks such as patient scheduling and tracking, nursing care and patient flow and regulatory reporting [75, 76] SNFs are served by many software vendors.

As with most products of this type, ongoing costs are based on either the number of users or number of beds, with a few combining charges for both. Several vendors' charges are based on the number of beds and have caps on the number of users.

- Estimated SNF HIT Costs per Bed For vendors that charge by the bed, the costs for basic services average $10/bed/month ($120 per bed per year) [77, 78].
- Estimated SNF HIT Costs per User For vendors that charge by the user, the costs range from $280 per user per month to $1,000 per user per month, with a mean of $430 per user per month. This figure may be high because some vendors offer discounts based on the number of users above some minimum. Thus, we use a far lower number: $80 per "basic" user per month ($960 per user per year). Some plans charge physician users more than three times that cost (i.e. $3,000 per physician per year). We do not include that in our calculations [79].

Not all SNF have full-functionality EHRs. Based on CMS and industry reports, we estimate that only 80% of licensed patient beds are linked to full EHRs. Therefore, we reduce the number of beds from 1.7 million to 1.36 million.

The following calculations are based on the remaining 80% of the facilities. Based on interviews with vendors, SNF industry representatives and publications, we estimate that that 60% of the SNFs are charged for their software by bed, and 40% are charged by user.

Base Assumptions and Estimates

- Number of Beds: As from the previous section, the total number of licensed US SNF beds is estimated to be 1.36 million, adjusted from 1.7 million. From that, 60% (816,000 beds) are charged software costs based on a per bed per year charge. Thus, 60% of the estimate annual US SNF HIT Costs (by bed) is 816,000 beds × $120 per bed per year which yields $97,920,000 per year.
- Number of Users (non-physician): According to the BLS, there are 630,550 nursing assistants or related professionals and 153,000 RNs. (Total = 783,550). Using a similar estimate of 80% of those users yields an estimate of 628,840 non-physician users for all facilities. To estimate costs by HIT that charge by users, we take 40% (from the above section's description), which yields 425,736 users. However, because of the high employee turnover rate at SNFs and because some assistants may not use the HIT, we estimate a reduction of that number by another third to yield 283,824. Thus, 40% of the estimated annual US SNF HIT Costs (by Users) is 283,824 users × $960 per user per year to equal $272,471,040 per year.

As noted, we do not include any fees for the physicians, who pay about 3 times the usual user fees.

- Analytics software package: Another ongoing cost for those SNFs that use it, is the analytics package sold as an "add on" to the EHRs. The cost, according to interviews with vendors, is $21,600 per year. Based on interviews with vendors and SNF leaders, we estimate that only 20% of SNFs pay for that service (Note this is 20% of the 80% of SNFs with EHRs). Thus, the estimated cost of analytics software (as used) is the number of SNFs that purchase it (20% of 12,480 or 2,396 SNFs) which is multiplied by the cost of $21,600 per SNF per year to equal $51.753 million per year.
- One-Time Costs: Independent of the per bed or per user fee structure, implementation costs range from less than $4,000 to over $48,000. This is charged for each facility; not directly based on per bed or user numbers. Similarly, training and lost productivity can "cost" three weeks' worth of activity.

In addition, integration with laboratories can be an additional $300 per facility per month ($3,600 per facility per year) for each facility with that functionality. However, we do *not* include these costs.

- *Summary of One-Time Costs:* Based on interviews with vendors, vendor contracts and interviews with hospice leaders, we use a mean implementation cost of $30,000 per facility, which includes lost productivity, set up fees, and training time. For these one-time implementation cost calculations (training, lost productivity, set up, etc.) we use the number of facilities, not the beds or the users.

  Because we assume only 80% of facilities have EHRs, we apply this only to 80% of facilities we conservatively estimate who use EHRs (80% × 15,600 facilities = 12,480 facilities). Thus 12,480 facilities × $30,000 mean implementation cost per facility = $374.4 million, which amortized over 5 years is $74.88 million**.**
- Additional software for direct links to laboratories: Based on vendor and SNF interviews and using vendor contract data, we estimate that only 40% of the reduced number of SNFs pay for the links to laboratories. Thus, the cost of direct links to laboratories from SNFs is: 40% of the remaining SNFS (40% of 2480 = 4992 SNFs) X the cost of $10,000 = $49.920 million, which amortized over 5 years = **$9,984,000.**

The table below summarizes the findings (Table 1.1):

Summary

The total cost of software for SNFs is estimated to be **$497,024,640.**

For comparison, the US spends about 5% of its health care budget (5% of $4 trillion = $200 billion) on nursing homes and continuing care

Table 1.1 Cost of SNF Software (minus 20% of SNFs b/c they may not have EHRs)

Beds = 1.7 million reduced to 1.36 million	
Users: 783,550 reduced to 628,840	
We know 60% of vendors charge by beds, and 40% charge by users.	
40% of users = 628,840 × .40 = 251,536 × $960,471,040	$272,471,040
60% of beds = 1.36 × .6 = 816,000 × $120/bed = 97,920,000	$97,920,000
Analytics package: after removing 80% of facilities = 2,396 × cost of $21,600	$51,753,600
One-time: implementation for 80% of SNFs (*N* = 12,480) × $30,000 = $374,400,000. This is amortized over 5 years to equal	$74,880,000
Total	$497,024,640

facilities. Thus, as a percentage of SNF's budgets, HIT costs are remarkably modest.

1.5.3.6 Visiting Nurses

In the US, over 500 visiting nurse *associations*, representing over 12,000 *agencies*, employ approximately *95,000* nurses, and many multiples of that number for other healthcare workers, usually with more restricted licenses, e.g., nursing assistants, LPNs) [80].

Many software providers offer programs to these agencies. Their charges incorporate both the number of users (nurses, aides, back-office personnel) and the number of patients. The latter numbers are substantial, with visiting nurses serving over 4 million people annually [81]. Interviews with vendors and visiting nurse agency officials plus review of vendor contract details reveal that the mean EHR/HIT licensure costs per user (both clinicians and administrators) averages to $40 per user per month ($480 per user per year), with a cap on the number of patients [82].

Implementation costs average about $5,080 per agency with fewer than 40 nurses/nurse assistants/back-office personnel. Larger agencies' software installations cost more.

To avoid double-counting other home health services, we cut the number of visiting nurse agencies from 12,000 to 6,000, using the mean cost of $5,080 per agency/implementation. This yields an estimated total implementation cost of $30,480,000, which amortized over 5 years to be: $6,096,000 per year.

We estimated the total number of users as 95,000 nurses, 200,000 aides, and 12,000 administrators, billing and insurance personnel which yields 307,000 "users." Licensing costs/fees ($480 per user per year) yields an estimated $147,360,000 per year, which added to amortized implementation costs of $6,096,000 per year yields a total of: **$153,456,000** per year.

1.5.4 Clinical and Other Services (Usually Not in Hospitals)

1.5.4.1 Acupuncturists

Acupuncture is covered by Medicare/Medicaid and private insurance and is approved by the VHA for pain management. There are 24,954 practitioners working in the US, providing more than 10 million treatments yearly [83], creating a revenue stream of $650 million per year. As with all medical services, software is required for billing, record keeping and insurance.

From vendor literature and interviews [84–86], the mean cost of software is $122.00 per month ($1,464 per year) per user, which for 24,954 US practitioners is **$36,532,636**.

Not included in this calculation because of partial or incomplete data coverage, are fees of $20-$45 month per practice for data migration, custom medical forms, training, etc.)

1.5.4.2 Chiropractic

There are 70,000 independent US chiropractors and 40,000 chiropractic assistants (CAs) [87], who pay user fees averaging $1,747.00 per user per year (but which can be as high as $3,380 plus additional fees other services (e.g., training, set up). Using the lowest estimates, this results in a US cost of **$192.17 million** for yearly chiropractic software fees.

Vendor estimates of implementation and lost productivity costs are estimated at $7,600.00 per practice, which amortized over 5 years is

$1,520.00 per practice [87]. We apply this only to fully licensed chiropractors (not CAs), yielding a total of $106.40 million per year. Added to the yearly software fees yields and annual software cost of **$298,570,000**

1.5.4.3 Clinical Trials Software

At the time of writing this, there were 387,063 registered clinical trials (CT) known to the US government, of which 144,853 were operated by US researchers/firms (of which 125,323 were entirely in the US) [88]. Software for these entities and research groups (such as independent contract research organizations (CROs) must support institutional board review, recruitment/enrollment of human subjects, informed consent, payment tracking (to subjects and all involved entities), coordination of teams and research sites and their documentation. The software must assure collection and secure storage of all of the participant information, compliance, outcomes, adverse events, et cetera according to regulatory requirements for protecting human subjects. Increasingly, CT software must be remotely and securely accessible by a number of devices: smartphones, tablets, notepads, laptops. It must also manage compliance needs, protocol changes, reminders, and updates.

Information assurance (confidentiality, integrity, availability) of data and subject privacy must be managed and updated constantly. There are at least 60 firms that provide software to this industry. Pricing is based on the number (of trials) and trial size (number of human subjects) or the number of users (research staff). Costs for pharmacovigilance software is usually based on the number of cases (human subjects) rather than the number of staff (users) [89–91].

The collective CRO workforce is estimated at 450,000 persons. This large labor force is, in part, due to the very high employee turnover rate (ranging from 22% to 27%), to the vast number of trials conducted at any one time and the wide range of skills required for the tasks [92]. Job titles include: case managers/coordinators, biostatisticians, payment specialists, physicians, medical device technicians, and pharmacists, among others. We focus only on those using paid software for trial and pharmacovigilance work, which is estimated at 360,000 users [93, 94].

Licensing Costs: These are quoted at a mean of $2300 per user/per year. Larger firms (with bigger trials and more employees) may pay less per user than smaller firms with fewer employees. Using these averages, total licensing costs are estimated to be $828 million per year [95].

Implementation Costs (and lost productivity during training): These are estimated as a cost per site (location where patients are recruited for data collection, which is neither the number of companies performing a research project nor the number of subjects). In the US, the number of research sites is estimated to be 2300 at any given time. Implementation Costs are estimated at $40,000 per site, which amortized over 5 years yields $5,000 per site per year. Thus, Implementation Costs are conservatively estimated to be $11.5 million per year.

Combining Licensing and amortized Implementation Costs yields an estimate of **$839,500,000** per year.

1.5.4.4 Dental Care

There are 201,117 licensed dentists in the USA. Most are working at about 193,000 dental office establishments [96]. Almost all employ some form of software for medical records, billing, scheduling, insurance claims management, etc.

Based on the software license agreements and interviews with vendors and providers, we include dental hygienists ($N = 150{,}000$) and dental assistants ($N = 354{,}600$), who must pay monthly user fees [97, 98]. Thus, the total number of "users" is 555,867.

From that number we subtract 10% of dentists (not assistants or hygienists) who are involved in research, administration or who work in other settings. Thus, the final N of users is 536,567. From the same ADA sources we determine the annual license fee averages to $4,464. When we multiply that fee times the number of users, the total is $2.396 billion

Implementation, lost productivity etc.**:** Based on the vendor data and market research reports,

we calculate set up fees, lost productivity, training and implementation costs plus commonly assessed additional fees for connections to patients' insurance companies, labs, dental device manufacturers, connections to patient's EHRs and patient reminders, etc. This brings the total to $37,640, which we amortize over 5 years to equal $7528 per office/practice (n = 193,000). This cost is not per user, but per office.

Summary: 193,000 Times $7528 = $1.453 billion. When added to the license fees ($2.396 billion) the total = **$3,849,000,000**

Note that $3.849 billion is only 2.85% of dental expenses in the USA in 2021. The 2.85% is considerably lower than the expected ratio spent on software in most healthcare settings [99].

1.5.4.5 Dialysis

In the US, 554,038 patients received dialysis. Cost estimates for the basic software fee is $2.30 per treatment. However, dialysis software must be connected to EHRs (for the dialysis unit as well as for clinics and primary physicians), clinical services (pharmacy and laboratory information systems), scheduling and reminder systems, billing (Medicare/Medicaid, private insurance) and revenue management. This total cost for (routine) dialysis software operation alone is estimated at $3.85 per treatment/patient (excluding costs of set up/training or of other aspects of dialysis care) [100–102]. Thus, an estimate for US dialysis software cost for one year (for a standard 3 times a week schedule) is: $ 3.85 per treatment per week per patient × 3 treatments per week × 52 weeks per year =11.5.

For the US patient population requiring dialysis: $6,006 per patient per year x 554,038 US patients provides an estimate of **$3,327,552,228**

1.5.4.6 Medical Practices' EHRs (MD, DO, some NPs)

Calculating the cost of general medical practice EHRs requires estimation of:

- The number of clinicians (MDs/DOs/NPs) with independent offices that are not entirely part of a larger hospital system
- Disaggregating clinicians who work within hospitals or other large organizations with EHRs, but who also have independent practices (to avoid double counting) while also counting clinicians with both hospital and "private" practices who pay for their EHRs
- The cost of implementation, set up, et cetera of such systems.

Considerations: In 2020, almost 40% of physicians worked directly or partially for a hospital or for a practice owned by a hospital or health system (increased from 29% in 2012 to 34.7% in 2018). Those working solely for a hospital increased from 5.6% in 2012 to 9.3% in 2021.

An increasing number of clinicians who work within (hospital) systems and within other healthcare contexts (e.g., pharmaceutical firms, public health organizations, research institutions, etc.) that do not require individual EHR licensure. The number of physicians with separate practices varies widely by specialty and by business considerations [103, 104]. "Surgical specialties had the highest share of owners (64.5%) followed by obstetrics/gynecology (53.8%) and internal medicine subspecialties (51.7%)" [105].

Physicians: Based on the several studies of physicians with EHRs (both independent of larger organizations or with additional EHRs for private practice), we estimate that 38% of MDs/ODs pay for separate EHRs [105]. In terms of the numbers of relevant clinicians, this means that rather than 525,000 active physicians with their own EHRS, we estimate that the number is 199,500 physicians.

Nurse Practitioners: We further estimate that of the 190,000 NPs, only 18%, or 34,200, should be included as incurring expenses for EHR licenses. Moreover, we do not include any implementation costs for the NPs because we assume those expenses are absorbed by the separate offices in which they work.

The AMA survey data show 49.1% of patient care physicians worked in physician-owned prac-

tices, down from 54% of physicians in the 2018 AMA survey [106]. The cost of implementation of physician practice EHRs is in part determined by the number of services covered. These include: billing and links to insurers, scheduling, patient reminders, patient portals, links to laboratories, referral services, revenue management, administrative oversight, and analytic functions. Based on industry data, interviews with vendors, and interviews with clinicians, we determine that implementation costs are very conservatively estimated at $215,000 per physician, which we amortize over 5 years to equal $43,000.

EHR license fees vary considerably by amount of functions, and if there is "free" access by nurses and other team members, etc. We calculate that a cost of $5,200 per month per clinician, or $62,400 per year is a median price.

To summarize: Implementation costs for the 199,500 physicians are calculated at the amortized cost of $43,000 each. License fees are calculated at $62,400 for the 199,500 physicians and 34,200 NPs (total = 233,700). Thus: Implementation costs of $43,000amortized for 199,500 physicians = $8,578,500,000; and license fees for 233,700 clinicians, totals to $14,528,880,000. The combined total is $23,107,380,00.

1.5.4.7 Occupational Therapy

In the US, of 126,610 occupational therapists (OTs), approximately 69% work in hospitals, academia, mental health facilities, and long-term health facilities whom we assume do not pay licensing fees for separate software. The 31% who work in other settings are obliged to use EHR/HIT for OT (with licensing fees) that provides additional clinical/administrative functions: e.g. telehealth, mobile access, scheduling, and appointment reminders [107–109].

On average, OTs see 5–8 patients per day. Software pricing is predominantly based on the number of practitioners/users, although a few companies charge by number of patients. We found there are few if any charge for implementation, setup or training. There is lost productivity when learning the system, but we do not include that cost.

Licensing and total Costs: This ranges from $99 per practitioner/user per month to over $600 per practitioner/user per month. Based on review of the contracts, interviews with the vendors and OT leaders, we use a mean of $245 per practitioner/user per month ($2,940 per practitioner/user per year) for the 31% of OT practitioners). With no implementation costs, the total estimated OT EHR/HIT licensing cost is (31% of 126,610 × $2,940 or **$115,392,060 per year.**

1.5.4.8 Optometry

There are 41,000 optometrists in the US [110]. Software vendors charge by user, and there are, on average, usually two or more users per facility, or a total of 82,000 users (assuming only two per practice). Mean software cost is $2,988 per year per user, which yields **$245 million** per year in optometry software license costs.

One-time costs for set up and implementation costs average $500 and $400 per practice respectively. Lost productivity and implementation times are said by the vendors to be three weeks, but we do not count the entire time because optometrists continue to operate during the implementation, but at a lower rate. We thus use a very low cost for total estimated onetime costs of only $3,700 per user, counting only the optometrist (i.e., not staff). Thus, $3,700 X 41,000 = $151.7 million, which amortized over 5 years = **$30.34 million.**

This yields $245.016 million for the license plus $30.34 million of amortized one-time costs. Thus, total US optometry software costs per year is **$275,360,000**

1.5.4.9 Pharmacies--Chain and Independent

There are 88,000 pharmacies in the US. Of these, approximately a quarter, 23,000, are "independent" (of chains). There is a critical distinction in the pricing of pharmacy software for chain vs. independent pharmacies.

Chain Pharmacies: Chain pharmacies use one of several "back-office" software products (e.g., SAP, Salesforce) that coordinate individual Point-of-Sale (PoS) software at the physical loca-

tions in the chain. PoS software, in combination with the back office software, connect chain locations to other systems, including pharmacy benefits managers, insurance companies, state agencies and local healthcare providers. Note that both the back-office software and the PoS software must be customized to meet local regulatory requirements for labeling of prescriptions and pharmacy data management program (PDMP) reporting for controlled substances.

Chain pharmacy software requirements:

- Yearly maintenance fees for corporate license (usually about 20% of the cost)
- Customization, adjustments and repairs (includes repairs after installation by consultants, e.g., Deloitte, Accenture). This includes updating the formulary, regulatory changes and price adjustments (both price and copays).
- Key here are the links to the pharmacy benefit managers (PBMs) that both serve as middlemen for payers--insurance companies, employers—and for the retail sales/copays for individuals.
- Additional builds (added or modified software)
- Local point-of-sale software; not part of the back-office software noted above
- Local state by state for PoS software, e.g., state labeling rules, PDMP links.
- Connections to local and regional hospitals and clinicians
- Connections to local/regional insurance companies, etc.

The "back-office" software for the largest chains costs as much as 10 million dollars, and far less for smaller chains (costs outlined below).

Chain store data: The largest 24 big pharmacy chains have a collective 39,914 stores, with a range from 9,900 stores to 88 stores); another large group are supermarket pharmacies and "big box" pharmacies, e.g., Costco, Giant, Publix, Sam's Club, Kroger. Many of these are large enterprises, selling millions of prescriptions via thousands of outlets. There are also medium size chains that have a total of 7,086 stores; and the remaining (smaller) chains have a total of 18,000 stores (Total = 65,000)

As noted above, the mean cost of "back-office" software licenses differs by chain size. Based on the large software sellers, the largest groups pay about $10 million for their software—both the pharmacy chains and the large supermarket and big box stores. (Note this is not the cost per pharmacy, but rather the cost for the corporate headquarters IT group that covers all of the outlets. Note also this is not, for example, for a CVS located in a Target store, which shares real estate.) Medium size chains pay a mean of $5.4 million for their enterprise software. The smaller chains have lower costs, at $1.7 million.

Each chain site requires a separate PoS license that is integrated with the corporate "back-office" software, customized to local needs (links to local providers, hospitals, regional health systems, nursing homes, billing, inventory, in addition to maintenance, repairs, integration with new systems, etc.). Excluded from this are: individual site licenses ($47,000 per site), additional builds and web-based enterprises (i.e. Amazon).

The table below summarizes the types of chains, costs and market sizes Table 1.2 [111].

Independent Pharmacies The 23,000 independent pharmacies must have software that performs PoS functions, just as for the chain operations—and links to: PBMs, PDMPs, billing; claims processing, inventory, ordering, customization for state labeling rules; connections to local and regional hospitals, clinicians, formularies, and to local/regional insurance companies. Software services to independent pharmacies must also address repairs and modifications, as required [112]. There is a very large market of software vendors to serve independent pharmacies, and many offer combined services. Thus, independent pharmacies can purchase combined packages for as little as $44,600 that accomplish what they need [113].

For independent pharmacies, we multiply $44,600 times the 23,000 sites = **$1.026 billion.**

Independent pharmacies do not obtain the cost savings of the larger chains, which benefit significantly by using one contract for "back-office" services.

Table 1.2 For chain pharmacies

Chain size	N sites	Backend SW fee for each chain (not store)	Total
Major chain $N = 24$	39,914	$10 million	$240 million
Major sellers that are part of supermarket or big box store, e.g., Kroger, Giant) $N = 133$	4,453	$10 million	1.330 billion
Subtotal big stores	*44,367*		
Medium $N = 92$	2,643	$5.4 million	$496.8 million
Small $N = 943$	18,000	$1.7 million	$1.603 billion
Total for chain stores	*65,000*		$3.67 billion
Individual PoS licenses for each location is $47,000. For the 65,000 chain sites			$3.055 billion
Total for back end and PoS for chain pharmacies =			**$6.725 billion**

Total Software Cost for Independent and Chain Pharmacies: Thus, the combined pharmacy software costs for independent pharmacies ($1.026 billion) and chain pharmacies, from above, ($6.725 billion) in the US is **$7,863,000,000**

We do not include implementation or hardware costs, or even the mail-order software license costs (for the increasingly popular mail order pharmacies).

1.5.4.10 Pharmacy Benefit Manager (PBM) Software

In the past few years, pharmacy benefit manager firms (PBMs) have consolidated and become vertically integrated into insurance companies; often also vertically integrating with healthcare providers. Although there are 66 listed PBMs [114], most of the market is concentrated in 11 firms, with much of the work controlled by 6 firms that are vertically integrated with insurance carriers and providers. Of these, CVS, Express Scripts and Optum control 32%, 24% and 21% of the market respectively. The market size is listed as $458 billion [115–117].

PBMs manage insurance coverage of prescribed medications by: "advising" (limiting) patients and prescribers of "approved" medications and indications through formularies, assuring prior approvals for coverage of prescribed drug regimens, and ensuring availability of approved/covered drugs. They are paid by insurance companies and similar entities, e.g., CMS.

As might be expected, the industry is both capital intensive (with ratios of 1:1 for labor and capital expenses) and software intensive. Based on review of the PBM software vendors, interviews with vendors and PBM providers, plus US BLS data, we estimate the number of employees in PBMs totals 114,800. However, the proportion of that work with paid software is only about 50% of those employees, which equals 57,400. Multiplying the 57,400 by the mean software licensing cost of $3,400 per employee/user per year, produces a total of **$195,160,000**.

We do not include any costs for implementation, training, lost productivity, etc.

1.5.4.11 Physical Therapy (PT)

There are an estimated 258,200 physical therapists (PTs) working in the US, aided by an additional 149,300 assistants and aids (Total 407,500) [118, 119], with many working at hospitals, home health agencies, and residential care facilities. After interviewing PTs and vendors of services, we estimate half of PTs at such facilities use clinical and other software provided by those institutions as part of the general EHR or separate PT-specific modules. For our calculations, we do not include these PTs in our cost equations.

Thus, we focus on the PTs [120–123] who require software to document, bill (submit insurance claims), provide exercise libraries, patient portals and other functions:

- Users in PT offices/clinics (33% of 407,500 = 134,475);
- Self-employed PTs (8% of 407,500 = 32,600); and
- PTs who work in facilities but must have separate clinical software licenses (50% of the remaining 240,425 = 165,034). The total is 332,068 users.

Software License Costs: Software license costs are based on the number of users (clinicians). Based on a review of the vendors' marketing literature, advertisements, and interview responses, we find the mean fees are $85 per user per month. Annualized, this equals $1,020 per user per year. For the 332,068 PTs, assistants and aides who pay separate licensing fees (at $1,020 per user per year), the total is $338,709,360.

Implementation Costs: We calculate PT-specific EHR/HIT (i.e., for PT centers and not for other facilities that employ PTs (e.g., hospitals, nursing homes etc.) at an average of $600 per facility per year. We conservatively estimate lost productivity (a mean of 3 weeks) on the assumption that clinicians can trade off time/patients during the installation and deployment. The US Dept of Labor's Occupational Outlook Handbook reports that PTs earn an average of $91,010/year; and PT assistants earn $49,970 per year [124]. For each PT center, we estimate the loss of one week for only one PT to calculate a loss of $3,640, not including costs for training. Each PT center is assumed to spend $2,100 on Implementation and $3,640 on lost productivity. For the 38,000 facilities the total is $5,749 X 38,000 = $218,120,000, which we amortize over 5 years to equal $43,624,000

In summary: For PTs, the estimate of EHR-type licensing costs is $338,709,360; and amortized implementation costs ($43,624,000) is **$382,333,360**

1.5.4.12 Podiatry

The number of practicing podiatrists in the US is listed as between 15,000 [125] and 18,000 [126] We use the lower number for estimates—15,000. The average cost for podiatric software is $268.00 [127] per user per month. This results in:

- $268.00 per user per month x 12 months × 15,000 users = $48.24 million per year
- One-time costs (lost productivity, implementation/setup) are estimated to be $4,850 per user, which amortized over 5 years is $970.00 per user per year for 15,000 users = $14.55 million per year

These sum to an estimated annual US podiatric software cost of **$62,790,000**

We do not include non-podiatric staff, which are usually counted as "users," and would significantly increase the estimates. Nor do we include $0.10 cost for each SMS appointment reminder that the HIT vendors charge their podiatrist users.

1.5.4.13 Telehealth

Telehealth expanded exponentially during the COVID 19 pandemic. A recent AMA study found it was used by over two-thirds of physicians, with some areas—psychiatrists—employing it almost universally [128].

A Web search discovered over 170 vendors, with names running from *Zipnosis* to *Anytime Pediatrics* to *DoctorConnect*, to well-known vendors such as *Nextgen, Athenahealth, or EpicCare EMR* [129]

In addition, we benefited from extensive PubMed searches. Many research reports, plus government and consultant services, provided useful breakdowns of costs for licenses, implementation, per user costs, integration with EHRs, HIPAA compliance, etc.[130, 131]

Excluded: We do not include costs of hardware, used in telemedicine, e.g., devices that are sent to patients to enhance cell phones data for clinicians, including: digital telescopes, examination cameras, or ENT scopes; or the myriad devices for what is called "telehome" such as home-installed digital blood pressure cuffs, scales, etc.

Connectivity: Estimates of costs to set up "connectivity to portable devices or integrating additional APIs" were between $5000 and $10,000," but we excluded them with the assumption that such costs will be shared with a practice offices' other IT costs.

Consultants: Training is estimated at two-to-three weeks (of lost productivity) with training program costs ranging from $200 to $2,000 per location, depending on the number of users, additional installations, and technical training for IT staff. We use the lowest estimates at $200 for the training, and lost productivity at $5,000—assuming learning times will be distributed in cost efficient ways. The amortized cost of $5,200 is incorporated below, in the implementation cost analysis.

Implementation: Implementation (one-time cost) can be surprisingly expensive. The higher complexity or functionality of a telehealth app, the higher the cost. Telemedicine software cost can exceed $370,000 if *one chooses* a highly complex and feature-rich solution. On the other hand, solutions are available from $50,000 [132]. We use a lower range estimate of total cost for software for telehealth at **$62,600** (before amortizing). Thus the implementation total for telehealth totals: training ($200), lost productivity ($5,000), software set up and integration into the EHR ($62,600), which totals to $63,700. Then we also amortize all costs over 5 years, which reduces the onetime cost to $12,740.

Relevant population: We limit the costs to only the MDs/DOs and NPs who use telehealth and who are not part of a larger system's setups (e.g., not part of a hospital or larger system's telehealth system). To determine the applicable users, we calculate that only one-third of the MDs/DOs in active private practice use telehealth. Thus, while there are 900,000 physicians with licenses, only 525,000 are actively practicing physicians. Moreover, a portion of these 525,000 are with larger systems, or working in the insurance or pharmaceutical industry, public health, etc. We therefore use only one-third of the active physicians to determine a population of 174,825 MDs/DOs [132].

To this we add the nurse practitioners adjusted as follows: Total N = 325,000, of which 290,000 have active licenses [133]. We then subtract all those in hospital settings and all those not in primary care, which reduces the number to only one-quarter of their number—to only 72,500 NPs—undoubtedly a low estimate.

Cost and numbers: The two, reduced numbers, (174,825 MDs and DOs) and NPs (72,500) totals to 247,325 clinicians, which we multiply by the amortized implementation costs of $12,740 (from above) to = $3,150,920,500

Yearly software licenses: The reports reveal that the software license fees range from $420 a month to "several thousand dollars" a month. We use the near-lowest end of the range ($550/month). Thus, our estimate for a one year the license is $6,600. Allocating this to the numbers of clinicians from the above paragraph = ($6,600 X 247,325) determined above equals: $1,632,345,000

We add legal fees from estimates of the *American Telemedicine Association's website* for state-by-state estimates. Originally, we were not going to include legal fees because pandemic related legislation allowed telemedicine clinicians to practice without additional restrictions. However, after June of 2021, many states are again imposing restrictions that are being challenged in court. Because, however, these issues are not universal across the US, we use only 30% of the legal fee reported rates of $75,000 ($75,000 X 30% = $22,000). Thus, we only add on $22,500 per state, and only multiply that times 25 states, which equals **$ 1.875 million** to reflect the entire nation's telehealth legal costs.

Summary: Total of all amortized implementation fees = $3,150,920,500; total of all license fees = $1,632,345,000; total legal fees for states = $1,875,000. Thus, the total for telehealth and related services not part of hospitals or other entities is **$4,785,140,500**

Note that the 4.785 billion is less than 1/4th of the $20 billion estimates of other studies.

1.5.5 Hospitals and Usually Linked Services

1.5.5.1 Hospital EHR Costs

Calculating the cost of EHRs for hospitals is challenging. The systematic cost underestimate biases noted earlier [134] apply here with great force; and we outline them below. On the other hand, there are literally hundreds of cost estimates, many from reliable sources.

Data Sources for Hospital Software Costs

Biases and challenges in obtaining estimates include:

- Underreporting of software costs in trade journals, dependent on EHR vendors and consultants for advertising and other expenses, with the added observation that journals may be published by trade associations
- Attractively low cost and staffing estimates quoted by vendors, including their suggested EHR implementation time requirements [14]
- Vendor statements about the need for fewer IT personnel post-implementation—statements that emerge as marketing efforts, and that are documented as unrealistic [14].
- Not including and not counting the use of existing staff in the implementation process, e.g., not including the cost of staff to design order sets, CDS alerts, review problems, address issues, staff help desks, train, help optimize the system (an ongoing expense) and the training and use of "superusers"
- Self-interest of CMIOs and CIOs to not reflect the full costs of implementing their recommended EHR choice
- Federal regulators who saw their mission as encouraging the sale and use of EHRs. Note we do not suggest these motivations were ill-intended [1, 3, 135, 136]
- Increasing purchase and incorporation of physicians' practices by hospitals and often by larger entrepreneurial enterprises—with significant effects on how EHRs will be merged, serviced, licensed, and invoiced. Hospitals, especially, are predicted to become even more of the "hub" for medical care in an area. Hospitals now own more than one-quarter of physician practices; and corporate entities now own more than one-fifth (22.1% ref) of physician practices [137, 138] This last datum is especially important in estimating the number and percent of physicians who do not pay for separate practice EHRs because either they are employees of hospitals, or because their practices use hospital software.

In contrast, there are many sources of reliable, vetted data-supported information on estimates and ratios with which triangulation is possible. A few simple examples include:

- Gartner and other reports on the mean cost of HIT per healthcare employee [139], in which hardware costs can be disaggregated from software costs [140].
- Detailed data on IT operating expenses in relation to hospital operating expenses.
- Data on implementation costs, including the software, implementation, training, retrofits, builds, extra IT staff, etc. (Note that implementation is generally 3–5 times the cost of the software) (see Box 1.1).
- Vendor industry sales and investment figures
- Software sales figures and predictions from vendors, market researchers, and others [141–144]

BOX 1.1 Examples of Data Sources on Cost of Software, Implementation, Training, Retrofits, Builds, Extra IT Staff, etc.

- The percent of hospitals' budgets devoted to software, including percent of operating budgets, percent of personnel working on clinical software
- Percent of hospital IT budgets devoted to capital (25%) vs operating expenses (75%)
- Spending by I.T. functional areas, i.e., data centers 20%; end user computing 10%

- Cost percentages: service desk 5%; network 13%; application development 9%; application support 32%; IT. management, finance, and administration 11%
- Estimates of all hospital spending on software and other studies by Gartner and others [145]
- Operating IT budgets for The Cleveland Clinic's main campus; NYU Langone Tisch Hospital, Vanderbilt Univ Medical Center, MGH and 21 more institutions [146]
- Budget details for all hospitals in various states [147]
- Several guides to IT budget processes, e.g., IT costs from "Gartner IT Key Metrics Data" [148]
- Publications from the ONC and AHRQ on cost of software, e.g., "How much is this going to cost me?" [149]
- *Budget reports on hospitals, e.g., reports on the cost of hospital IT service desks [150]
- *Other government estimates, e.g., "Medical Practice Efficiencies & Cost Savings" [151]
- Electronic Health Records – "*Health IT Playbook*," which defines line-item costs for EHR software, implementation, training, and support — for both on-site licensing models and cloud-based platforms [152]

Cost Estimates

Cost estimates for hospital EHRs can be divided into three groups:

1. HIT Operating Costs
2. HIT Implementation Costs for hospitals with new or recently replaced EHRs
3. Licensing Costs (including maintenance, updates and service)

HIT Operating Costs

We used four methods to estimate hospital IT operating costs:

First Method: HIT Operating Cost per hospital employee according to PWC reports is $6,850 per employee [153]. For 7.6 million US hospital employees [154] at a mean HIT cost per hospital employee ($6,850) the total in 2021 dollars is **$52.060 billion.**

This is a conservative estimate as the industry is estimated to have spent $120 billion on HIT in 2021 [155]

Second Method: The American Hospital Association provides an annual US hospital HIT cost of per bed of $56,614.28, which for 919,599 US hospital beds yields a figure within .01 percent of the cost based on per hospital employee or **$52.0624 billion** [156]

Third Method: HIT Operating Cost based on total healthcare organizations/hospital spending. Hospitals represent about a third of all healthcare spending, that is, 1/3 of $4 trillion or $1.320 trillion [157]. If the estimate of 4% of total budget is spent on US hospital HIT Operating Cost, the estimate is **$52.8 billion.**

Fourth Method: HIT Operating Cost based on recently published and available data for 15 hospitals' HIT Operating Budgets, number of beds, and total patient revenue (see Box 1.S1 in supplemental notes), the mean IT operating cost is $132,030.80 per bed. For the total number of US hospital beds (AHA: 919,599), the estimated cost is **$121.416 billion.** (This is considerably more than twice the other three estimates, but we average the four. However, as a reality check of this method, we note that IT operations form 3.85% (range 2.79% - 4.77%) of total patient revenue = 3.85%, which are consistent across many industry measures.

Averaging these 4 estimates of hospital HIT Operating Costs listed above, we find the mean costs of US HIT Operating Costs to be **$56.085 billion.**

As a second "reality check", we multiply our mean US HIT hospital operating costs from above ($56.085 billion) as a percent of all hospital costs of $1,475.5 billion that the US spends on hospital care [158]. The percent is 3.8%, which is very close to the national average for most industries.

HIT Purchase and Implementation Costs (One Time Costs Amortized Over 5 Years)

To calculate US hospital HIT implementation costs for software, we first use data from four medical centers with listed and recent purchase costs (including per bed costs) for their EHRs. Again, this reflects software and implementation costs only, not total system costs. The 4 systems are:

- University of Pennsylvania (Epic): $62,906 per bed.
- University of Arizona (Epic): $41,641 per bed
- Cape Cod Health Center (CCHC) (Epic): $66,001 per bed
- Lehigh-Valley-Health system (Epic): $45,122 per bed

The data for each system are presented in Supplemental Box 1.S1.

We take the average per bed of purchased HIT software cost at the four institutions. The mean cost after amortization (i.e., divided by 5) is **$53,917.5 per bed.** This cost reflects some of the costs of training, retrofitting to legacy software and customizations (order sets, etc.). but does not reflect the years typically required for full implementation.

To estimate the implementation cost we multiply the purchase price by the usual ratio of implementation cost to purchase price, which varies from three-fold to five-fold. We use a four-fold ratio. However, we do not use the actual purchase price because implementation takes several years. It also does not reflect the cost of additional IT personnel required with each EHR implementation, which can be considerable [14]. Thus, we base our multiple on the amortized costs, i.e., 1/5th of the purchase price. Thus, for the four systems, the amortized implementation costs are:

- University of Pennsylvania (Epic): $62,906 per bed X 4 = $251,624
- University of Arizona (Epic): $41,641 per bed X 4 $166,564
- Cape Cod Health Center (CCHC) (Epic): $66,001 per bed X 4 = $264,004
- Lehigh-Valley-Health system (Epic): $45,122 per bed X 4 = $180,448

Based on the calculations presented above in Box 1.1, we calculate that the mean for hospital EHR implementations is $170,548 per bed. Which, when added to the mean amortized purchase cost of $53,917.5 totals to $244,465.5 per bed. We do not, however, multiply that number times the 919,519 beds because that would generate an exaggerated figure that fails to reflect the reality that only a portion of hospitals are recent buyers and installers of EHRs. Instead, we take only the 27.6% of all hospital beds that reflect more recent EHR purchases [159]. The 27.6% of 919,599 beds equals 253,809 beds. Multiplying that bed number by the $244,465.5 of cost equals: **$62,047,544,090.** We thus exclude almost three-quarters of hospitals' costs in this part of the calculation.

Licensing Costs (Including Maintenance, Updates and Service)

Annual maintenance, service and licensing fees for hospitals with EHRs range from 18-23% of the purchase price of the software. However, we must account for the fact that many US hospitals have older systems with lower annual HIT licensing costs. Using full recent costs would exaggerate the licensing fees. Thus, we segment hospitals by dates of EHR purchase [159] and apply adjusted licensing costs as follows:

- "New" EHRs – 27.6% of all hospital beds (919,599) x full licensing cost of $53,917.5 (from above) X 253,809 beds = $13,684,746,758.
- "Older" EHRs 72.4% of all hospital beds x 65% of full licensing cost = ($35,046 per bed) for 665,790 beds = $23,333,276,340

Adding the $13,684,746,75 and the $23,333,276,340 totals to $37,018,023,098

In summary, US Annual Hospital HIT Costs:

• HIT Operating Costs	$56,085,000,000
• HIT Purchase and Implementation Costs:	$62,047,544,090
• Licensing Costs (including maintenance, updates)	$37,018,023,098
• Total:	**$155,150,567,188**

Again, this does not reflect the many years required to implement an EHR (noted as typically four years), three quarters of all hospitals' older purchases of EHRs, and all of the inhouse work by clinicians and others.

1.5.5.2 ICU Monitoring: Tele-Monitoring for ICU Beds

Of the 68% of US hospitals with ICU units, 36% of those have telemonitoring systems. Data on ICU beds indicate 68,558 adult ICU beds (medical-surgical 46,795, cardiac 14,445, and other ICU 7,318), 5137 pediatric ICU beds, and 22,901 neonatal ICU beds. Additionally, there are 25,157 step-down beds, and 1,183 burn-care beds: for a total of 237,684 ICU-type beds [160]

More recent studies [161] indicate a significant increase in ICU beds (in part due to COVID 19) to conservatively increase the number by an additional 15%, which equals another 35,653 beds, or a total of **273,337** beds, of which we assume only 36% have telemonitoring (same percent as the estimate above, which is almost certainly an underestimate). Thus, we take 36% of those beds to equal the resulting figure is 98,401 ICU-T tele-monitored (remotely monitored) beds.

One-Time Costs: Based on several industry and critical care medicine reports [162, 163], initial software costs for these beds range from $2.5 million to $1 million each. We use $1.3 million per bed. Multiplied by the number of ICU-T beds (98,401) = $127,921,300,000, which amortized over 5 years yields **$25,584,260,000** per year

Central monitoring units cost $3 million each, and we calculate that one monitoring unit is needed for every 25 beds. Therefore, with 1 station for every 25 beds, or 1/25th of 98,401, is 3,936.02 X $3 million = $11,808,120,000, which amortized over 5 years is **$2,361,624,000**

The total for the initial software and monitoring stations, amortized, is **$27,945,884,000** per year.

Licensing Fees: The annual cost per bed (license, support, repairs, patches etc.) is between $50,000 and $100,000/year. We use the estimate of $75,000. Thus, for 98,401 beds, licensure costs are $7,380,075,000 per year.

Combining the amortized costs and the annual fees = **$35,325,959,000** [164] per year.

1.5.5.3 Medical Imaging

US expenditure on medical imaging is estimated to be 10% of all healthcare expenses, equal to $400 billion [165]. Imaging has expanded to include not only radiology, tomography, sonography, nuclear medicine, et cetera; and medical imaging is now incorporated into many "new areas of image-based work in: ophthalmology, surgical specialties (inclusive of laparoscopic surgery), invasive cardiology, pulmonology, neurosurgery, urology, speech pathology, dermatology and burn/wound medicine, etc. Imaging is a ubiquitous service and is also offered and performed now in 10.7% of urgent care visits [166].

We focus only on the cost of the software portion of imaging, its implementation, and user licensing costs. We used cost information based on industry data [167], federal agencies (CMS) [168], disaggregated hospital reports to federal agencies [169], interviews with hospital leaders (CFOs, CIOs), medical imaging vendors and healthcare providers, plus review of medical imaging contracts (via FOIA from others' legal cases).

Implementation Costs: Implementation cost is based on the facility and the types of equipment used. In the US, there are approximately 19,985 facilities: ~5,200 hospitals, 7,000 free standing medical clinics and 7,885 urgent care centers that provide imaging services. To focus on software implementation costs, we must first disaggregate the cost of software from that of hardware and the intrinsic structural costs of certain types of imaging modalities, such as facilities for magnetic resonance imaging (MRIs) centers.

Based on the sources previously described, we also used: data on industry growth rates [170], reports to CMS from providers, and industry reports to estimate medical imaging software implementation costs at $60 billion, which, amortized over 5 years, is $12 billion [171]

Licensing Costs: The US Bureau of Labor Statistics indicates there are currently 36,134 practicing US radiologists and 250,700 radiology and MRI technologists, for a total of 286,834 "users" [172].

Unlike implementation costs, which are based on the physical location and the equipment, fees are often associated with the number of "users." Note that "fees" here is an expansive term that often includes maintenance, upgrades, many repairs, and patches. These combined fees and services average $100,000 per "user," with variations by type of equipment, e.g., a sonogram license fee and an MRI license fee differ widely. When multiplied by the number of "users" in those many settings, the total US medical imaging licensing costs is 286,834 X $100,000 **= $28.683 billion**.

Adding Implementation and licensing costs, the total estimate for ongoing US medical imaging HIT software costs is $12 billion + $28.683 billion = **$40,683,000,000**

While seemingly large, software costs for imaging are only 1.0% of the US healthcare bill in contrast to the 10% of all healthcare costs that is the estimate of medical imaging ($400 billion out of total US healthcare bill of $4 trillion.

1.5.5.4 Medical Image Management--Picture Archiving & Communications Systems (PACS)

PACS are high-capacity, high-speed hardware systems for handling medical imaging, and over 96% of hospitals have them either in house or as cloud services used [173] for multiple purposes, and no longer limited to imaging/radiology. Our focus is only on the software costs, not the hardware. With the advent of high-capacity, low-cost, cloud-based storage and high-bandwidth connections, most software and licensing costs are borne by institutions for integrating PACS with EHRs and other data capture/rendering devices throughout facilities (and to individual offices) and managing user access.

Software costs include IT support, and ongoing services (e.g., patches and updates) [174].

Software licenses vary by size and function but the mean is $60,000 per hospital per year, which we multiply by the number of US hospitals (6,090, less 208 federal hospitals = 5,882). This equals an annual US PACS software cost of **$352,920,000**

1.5.5.5 Medical Laboratory Management Systems (LIMS)

Medical laboratories, either tethered to other medical institutions or separate enterprises, require software to operate and bill. Required functionality includes: sample management, connection to instruments and EHRs, results reporting and tracking, quality assurance/control and quality control, workflow automation, regulatory management/compliance, and invoicing, among others. In 2021, the US listed 29,227 "Diagnostic & Medical Laboratories Businesses" [175]. In addition, laboratories must share and report results to local and state governments (health information exchange) [176].

Laboratory information management software (LIMS) configure and store data in 4 methods:

- Client servers (in house)
- Web-based
- Standalone
- Thin-client servers (information is housed elsewhere).

Two major vendors of LIMS that serve 30% of the industry are: Abbott Laboratories and Thermo Fisher Scientific. The rest (70%) are served by over 400 other software providers.

Reports on revenue and cost data are available from industry publications and software companies [177–183]. Based on these reports, and on interviews with medical providers who use their

services, we find that US LIMS Costs for the 29,227 services are a mean of $15,742.29 each, which yields an annual total of **$460,100,000** per year.

1.5.5.6 Medical Social Workers

In the US, there are 176,110 healthcare/medical social workers, most of whom work in hospitals, family service clinics, home healthcare, skilled nursing facilities, etc. It is estimated that only 13,700 (or 7.7%) work in outpatient care centers [184], on which we base estimates for professional software costs.

Licensing Costs: Based on quotes, literature and digital displays from vendors [185, 186], we estimate the mean fees to be $68 per user per month ($816 per user per year). Thus, for 13,700 medical social workers the total licensing costs are estimated to be: **$11,179,200 per year**.

Implementation Costs: These are minimal and we estimate them as only $400 per user, which amortized over 5 years is $80 per user per year. For 13,700 users, this yields annual estimated total Implementation Costs to be: **$1,096,000 per year**.

Literature and vendor quotes indicate that a few weeks is allocated for training and lost productivity, but we do not include any cost for this.

Summing the annual licensing costs ($11,179,200) and amortized Implementation Costs ($1,096,000) for Medical Social Worker/EHRs yields an estimate of **$12,275,200.**

1.5.6 Cybersecurity Risk Insurance Premiums

The rise in ongoing ransomware attacks, data breaches, and hacking has accelerated cybersecurity (cybersec) to be a prime concern for CIMOs, CIOs, and CISOs [187]. In this estimate, we include only the HIT cybersecurity software premiums. We do not include increases in cybersecurity staff, processes or equipment--limiting our scope to only the software insurance premium costs [188–191]. We do not, for example, include the "cost" of reputational damages, rebuilding databases, etc. However, such collateral damage to the reputation of healthcare institutions due to data breaches is often considerable.

We also note that:

- Healthcare software and data are especially vulnerable because of the many stakeholders and users that are involved, i.e., clinicians, clinical services laboratories, pharmacies, administrators, business associates for billing, insurance, etc. [192, 193]
- EHR and medical insurance claims data are especially valuable to cyberthieves because they contain protected health information (PHI), patient financial data (credit cards, SSNs, insurance accounts), and personal and private health data, and information that can be used to fraudulently bill insurance companies and CMS.

As a result, cybersecurity insurance premiums have increased significantly—both in actual premium amounts and areas covered (e.g., more software under the insurance umbrella and more expansive coverage (data recovery, data breach, business interruption, cyber extortion and 3rd party liability), resulting in general increases in cybersecurity budgets by about 53% [194].

Premium Increases: Interviews with medical facility CIOs and review of insurance carriers' data [195] reveal cybersecurity premiums, that have traditionally been about 4% of the total institutional software costs, have dramatically increased, with premiums in Q1-4 2020 and Q1-2 in 2021 now estimated at 6.5 to 7.5%. We use 7% in our estimate [196]. Thus, we take the total software and implementation costs of HIT (= $298,126,041,732 (see Table 1.2, directly below) and add 7%, which is $20,868,822,921.

1.6 The Final Tally and Estimate

Combining the total costs for the software and implementations for each of the services outlined above provides a grand total. We show this for the

Table 1.3 Cost Estimate for HIT Software and Implementation

All data for 1 year. Percent of total with and without cybersecurity Insurance premiums			
	Cost	Percent w/o ins	Percent w/ ins
Hospitals	$155,150,567,188	48.64%	52.04%
Medical Imaging software	$40,683,000,000	12.75%	13.65%
Hospital ICU telemonitoring	$35,325,959,000	11.07%	11.85%
Medical practices' EHRs (PCPs MDs ODs)	$23,107,380,000	7.24%	7.75%
Remote Pt Monitoring SW only	$10,449,000,000	3.28%	3.50%
Pharmacies	$7,863,000,000	2.46%	2.64%
Telehealth	$4,785,140,500	1.50%	1.61%
Dental care	$3,849,000,000	1.21%	1.29%
VHA/Cerner	$3,785,700,000	1.19%	1.27%
Dialysis SW (separate facilities)	$3,327,552,228	1.04%	1.12%
County and State Health Dept	$2,398,500,000	0.75%	0.80%
DoD Cerner, Leidos EHR	$1,650,000,000	0.52%	0.55%
Home Healthcare	$1,293,105,000	0.41%	0.43%
Clinical Trial software	$839,500,000	0.26%	0.28%
SNFs	$497,024,640	0.16%	0.17%
Prison Health Services	$496,800,000	0.16%	0.17%
Medical Laboratory Information Systems SW	$460,100,000	0.14%	0.15%
Physical Therapy	$382,333,360	0.12%	0.13%
PACs (med images) SW	$352,920,000	0.11%	0.12%
Chiropractic	$298,570,000	0.09%	0.10%
Optometrists	$275,356,000	0.09%	0.09%
Pharmacy Benefits Managers	$195,160,000	0.06%	0.07%
Hospice	$159,060,000	0.05%	0.05%
Visiting nurses	$153,456,000	0.05%	0.05%
Occupational Therapy	$115,392,060	0.04%	0.04%
Podiatry SW	$62,790,000	0.02%	0.02%
Emergency Medical Services (not part of fire depts)	$47,661,000.00	0.01%	0.02%
Indian Health Service	$38,226,920	0.01%	0.01%
Acupuncturists	$36,532,636	0.01%	0.0%
Adult Day Care	$34,980,000	0.01%	0.01%
Med Social Workers	$12,275,200	0.00%	0.00%
Total Excluding Cybersecurity Premiums	**$298,126,041,732**	93.46%	100%
Cybersecurity Premiums	$20,868,822,921	6.54%	
Grand total	**$318,994,864,653**		

sum of all HIT costs before the cybersecurity insurance premiums (**$298,126,041,732**), and then with cybersecurity insurance premiums added. Table 1.3 illustrates the cost in descending cost order; first column without cybersec premiums and the second column with the premiums added. (Supplemental Table 1.S1 shows the estimates in alphabetic order.)

As can be seen, after inclusion of cybersecurity premiums, the combined cost of software and the cybersecurity premiums is **$318,994,864,653** per year.

As a percent of total US healthcare spending of $4 trillion, the cost (**$298,126,041,732**) before adding the insurance premiums) reveal that software and the many implementation costs reflect 7.45% of the nation's healthcare costs. When we add cybersecurity premiums, the combined totals are 7.97% of total US healthcare costs.

The above table presents the data *arrayed in descending cost order* and with percentages of total for both with and without cybersecurity premium costs.

1.7 Conclusion

A common refrain in the medical and informatics literature is that healthcare is more about information than anything else. As such, it is not surprising that US healthcare has become so dependent on software to collect, share, access, process, and analyze that information. It is therefore understandable that software has a significant and ongoing (annual) cost. Herein, we have attempted to estimate the cost of this critical element. This cost has increased over time and is under 7.5% of the total cost of US healthcare—both a staggering figure and yet quite modest compared to its vital and encompassing role.

We have based these estimates on available data, augmented by interviews with providers, administrators, vendors and reports from state and federal, industry and scholarly sources. These numbers are undoubtedly subject to error and should be augmented by more complete information from vendors, providers, consultants, IT staff, and others. Also, we have consistently underestimated the costs—usually because we decided not to include costs without hard numbers. We also recognize this is a first effort at a comprehensive estimate, and we await others to add to or to amend these figures. Be that as it may, the numbers are clearly consequential, and further study is needed as the role of US HIT continues to evolve and expand.

We encourage others to build on and refine this work.

Question and Answer

1. What are primary drivers for the increased adoption and widespread use of certified electronic health record technologies (CEHRTs) in US healthcare?
   (a) One driver is the call to improve the quality of healthcare (safety, effectiveness, patient-centeredness, equity, timeliness, efficiency) through continuous performance measurement through HIT, innovation in care, such as patient-centered medical homes (PCMH). Another driver has been regulatory: federal incentives for CEHRT adoption and meaningful use linked to essential Medicare/Medicaid payments and penalties for non-adoption. A third driver is the current focus on value-based payments and pay-for-performance, linked to aggregate electronic clinical quality metrics (eCQM). Note, however, that many dispute the utility of, and metrics used to account for, "value-based care." Currently, also, the use of medical practice EHRs that are linked to other health care entities (hospitals, health information exchange, public health agencies) is viewed by some of the public as a sign of quality and as a marketing driver.

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My colleague and friend, Dr. Stephen Soumerai of Harvard, was always urging me to include additional and important costs. Because this document is focused only on the software and implementation costs—and does not engage in the debates about HIT's negative aspects--Steve's advice was confined to the list of items that I excluded from the calculations. But they are serious issues that should be examined in later analyses.

I'm not going to name the many HIT vendor salespeople who spent hours with me providing numbers and

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Innovating Payment Models for High-Value Healthcare

2

Christopher P. Tompkins and Stephen Bandeian

Abstract

Unsustainable spending on healthcare in the US has led to many attempts to modify payment systems. In recent years, alternative payment models (APMs) have sought to reward higher value and to define remuneration for services, contingent on performance, in turn, based on clinical and financial data from multiple electronic sources. Key generic objectives and components of a model are described to illustrate how innovation might optimize payment for high-value healthcare. A multistakeholder framework for payment models currently in use is described.

Keywords

Healthcare · Payment models · Financial risk Episodes of care · Bundled payment· Capitation · Quality · Cost · Value Accountability

C. P. Tompkins (✉)
Brandeis University, Waltham, MA, USA
e-mail: tompkins@brandeis.edu

S. Bandeian
Elevance Health, Bethesda, MD, USA

Learning Objectives

After reading this chapter, the student should be able to:

- Describe and locate information on a variety of alternative payment models for healthcare
- Define value-based purchasing as it applies to healthcare and to articulate data and information requirements to support it
- Describe current gaps and future opportunities for additional HIMS support of payment and high-value care

2.1 Introduction

The relentless rise of healthcare expenditures for more than half a century and the lack of politically acceptable and sustainable solutions have created interest in alternative payment systems [1, 2]. Despite this rise, US spending on healthcare remains twice as much as for other nations [3].

Value-based purchasing and payment (VBP) systems attempt to quantify and improve the quality and value of healthcare while reducing spending and costs. Two ways to increase the *value* of healthcare are: (a) maintain the quality and benefits of current services while reducing spending or (b) maintain spending while improving the quality and benefits of care.

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Two challenges in the implementation of VBP are:

- Creation of incentives for high value across providers and settings of care, and
- Alignment and reinforcement of those incentives by all payers.

Key to meeting these challenges is the management and processing of electronic data needed for analytics and payments.

2.2 Toward an Aligned and Comprehensive Healthcare Payment System

2.2.1 History

Private health insurance was created in the US to ensure and stabilize revenues for hospitals and providers [4]. Premiums collected in advance from employees were paid to hospitals for services, thus spreading costs across covered populations. The introduction of third-party payers, including Blue Cross and Blue Shield and commercial indemnity insurance products, was the mechanism for increasing access to services, with the market for products growing rapidly among employed populations. In the 1960s, public programs were implemented to bring similar access to populations not in the workforce. Medicare provided coverage to retirees, permanently disabled, and patients with End-Stage Renal Disease. Medicaid provided coverage to the temporarily unemployed, to families and to the disabled, blind, and medically impoverished. Medicare and Medicaid adopted prevailing fee-for-service (FFS) payment systems used by Blue Cross and Blue Shield to reimbursement providers for covered services.

Funds collected in advance and low out-of-pocket payments allowed consumers to seek providers and services with little concern or even awareness about the true costs of those services. Spending increases were passed along to workers and society as higher taxes, lower wages, and higher consumer prices. And so began more than 50 years ago the US domestic policy "crisis" of rising healthcare spending [5]. Currently, national health expenditures are projected to grow at an average annual rate of 5.5% for 2018–27 and represent 19.4% of the US gross domestic product in 2027 [6].

2.2.2 Innovation and Payment

Research has shown repeatedly that the inordinate cost of healthcare in the US compared to other countries is primarily due to higher prices paid for services [7, 8]. Moreover, the unsustainable growth rates in spending per capita are largely due to the adoption of new technology, which can introduce treatments and tests that were previously unavailable or replace existing technology often at higher cost per treated patient [9]. Open-ended payment systems encouraged development and adoption of the new treatments, and led to "medical arms races" among hospitals and practices competing for patients [10]. Failure to reimburse for new services is often inferred as impeding medical progress.

Current efforts in redesigning payment for healthcare focus on paying for performance and avoiding services of low value. While some believe that cost controls reduce access and quality [11], others believe that alternative payment systems and accountability methods have the power to inform, motivate, and optimize spending and the quality of care.

Modified payment and incentives can effect changes in provider and system behaviors. For example, fixed payment for inpatient stays (as opposed to payment per day) leads to shorter lengths of stay. Consistent change requires consistent and inclusive payment systems across patients, conditions, providers, and insurers. Suppose a payer accounts for 10% of the patient volume for a hospital. If that payer offers an incentive program that is dissimilar to or even contradicts those of other payers, it might not get much attention or response. Generally, service utilization patterns tend to reflect incentives that are typical for most patients; change requires overcoming inertia and reaching a sufficient

tipping point to justify the re-engineering of patient flow and care redesign.

Calls for payment alignment are intended to steer healthcare organizations to provide greater and more consistent value. Each practice and facility would be responding in its own way to the direct incentives, while supporting and participating in what amounts to overall systemic improvement. However, the adoption of new technologies and their contribution to healthcare price inflation is not fundamentally an issue that is under the control of local markets. The development, adoption, and pricing of new technologies are determined by national and even global markets. Local initiatives cannot individually alter global trends or even diverge significantly from regional or national trends without facing a backlash for depriving local citizens of medical abilities that others can access in other markets. Thus, in addition to alignment at the local level, alignment would need to occur more comprehensively across regions and address the adoption of medical technologies with respect to their contribution to value.

2.3 Units of Care, Payment, and Accountability

2.3.1 Total Cost, Price and Quantity

A traditional "unit" of care is a procedure code (e.g., a routine office visit or a blood draw). Under FFS, procedure codes are the basis for payment for professional and ancillary services. Frequently, codes are grouped or bundled to lump sum payments for specific care such a hospital inpatient stay or outpatient procedure. For contracts and budgets, aggregate payments may be expressed as covered lives per annum or per-member-per-month (PMPM). That is the case under capitation whereby an insurer reimburses a healthcare organization to manage all services and costs for enrolled populations.

The total cost (TC) of healthcare is the sum of the price per unit (P) times the quantity of units (Q). That is, one could arrive at the total cost of healthcare by selecting any one of the units and doing the math for all instances of such units.

$$TC = P \times Q$$

Hypothetically, TC will go down if P is reduced while Q is constant, or if the Q is reduced while P remains constant. In healthcare, when the unit is the procedure code, high TC may result from high service volumes (Q), including duplication and clinically low-value services. When the billing unit is the individual patient (when payment is fixed), then providers have incentives to control and limit costs per person (reduce either P or Q or both). Providing all covered services needed by patients involves a wide range of discretion affecting cost as well as access, equity, and quality.

There has been increasing awareness and interest in units of accountability to fill the space between procedure codes and all covered benefits. Several units of care and payment fall within the range between the two extremes. One example is the prospective payment for the set of services provided by a hospital for an inpatient stay. Medicare's Inpatient Prospective Payment System (IPPS) uses Medicare Severity-Diagnosis Related Groups (MS-DRG) to define and determine the price of the hospital stay.[1] Generally, professional bills are submitted and paid separately outside of the Diagnostic Related Grouping (DRG) system. Medicare subsequently implemented a system for outpatient facilities, the Outpatient Prospective Payment System (OPPS), which is a partial and somewhat looser attempt to bundle ambulatory services into standard units of payment.[2]

The hospital inpatient stay and the outpatient visit are examples of "events" that including a number of individual procedures but are limited to single settings of care and relatively short time intervals. A core challenge in patient care is to coordinate care over time and across care settings. The objectives include to prevent potentially avoidable events and, when such events do

[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

[2] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS.

occur, to transition to aftercare and secondary prevention.

2.3.2 Episode-Based Accountability

A useful general concept is the episode of care. Episodes can be defined in terms of the reason the patient is seeking care such as a clinical condition or the particular service, such as surgery, provided to diagnose or treat a condition (Table 2.1).

A unit of accountability can be the episode in its entirety including all relevant services and their costs.[3,4] Known as bundled payment programs, these go beyond IPPS and OPPS by including professional services along with facility and ancillary services from the defining or "triggering" event to a predetermined end point (e.g., 60 or 90 days afterwards). A related concept is that of a "warranty period" in which providers take responsibility for adverse events occurring during an episode [12, 13].

In some payment models, provider organizations are paid a specified price for producing the bundled service. However, in most implementations, providers continue to bill for services using conventional FFS payment systems; final payment reconciliation occurs by comparing the actual total spend to expected amounts that are calculated using historical or cross-sectional data comparators known as benchmarks. With either a prospective flat amount, or a reconciliation of actual versus expected amounts, the final unit of payment, accountability, and their inference is the episode or bundle in its entirety.

Generally, episodes for acute or chronic conditions consist of hundreds of individual units of care (procedure codes) that are delivered during relevant time periods from the onset to resolution or continuing condition management. This combination of clinically relevant services within specific time periods offers a flexible framework for operationally defining healthcare for the purposes of payment and accountability (Table 2.2).

Table 2.1 DRGs and hospital revenues

• Medicare determines the applicable DRG for a patient's stay using information on the reimbursement claim submitted by the hospital.
• Key data elements include principal diagnosis, and any other conditions that were "present on admission," which can qualify as comorbidities.
• Other important diagnoses can reveal complications or major complications.
• Key procedures or utilization events such as the use of a mechanical ventilator can alter or modify the eventual DRG.
• Hospital HIS includes software that anticipates criteria that might "upgrade" a case to a higher paying DRG and makes sure the bills submitted include all the relevant information in the right order to maximize DRG revenue. This is commonly referred to as "DRG creep."[a]

[a] https://oig.hhs.gov/oei/reports/OEI-02-18-00380.asp

Table 2.2 The construction of episodes

• Some payers build episodes manually one type at a time. For example, Medicare might start with a DRG or a type of treatment (e.g., chemotherapy); build time windows and specify which services to include or exclude from the bundle.
• Software vendors sometimes build custom solutions for individual clients, and in some cases, offer general software solutions that construct episodes from claims data that conform to common formats.
• Often called "episode groupers," the software generally uses available claims data including mental health and retail pharmacy to identify (trigger) episodes and to assign services and costs.
• Clinical metadata are used by the software in conjunction with the administrative claims. These provide the clinical logic that understands the information on the claims to trigger and populate the episodes for each patient.
• Some episodes require additional information about a patient beyond what is available in claims. For example, claims do not include specific information about the stage or severity of cancer. HIS must retrieve such detail from other sources such as electronic medical records or special data repositories like disease or surgical registries.

[3] https://innovation.cms.gov/medicare-demonstrations/medicare-participating-heart-bypass-center--demonstration#:~:text=The%20Medicare%20Participating%20Heart%20Bypass%20Center%20Demonstration%20was,HCFA%20originally%20negotiated%20contracts%20with%20four%20applicants%20(1991).

[4] https://innovation.cms.gov/innovation-models/bundled-payments.

Optimal clinical management of certain chronic conditions might reduce the incidence and quantity of certain types of complications or procedural episodes as a natural consequence. For example, management of ischemic heart disease could reduce the number of acute exacerbations such as acute myocardial infarction (AMI, or heart attacks), or surgeries to restore blood flow such as Percutaneous Coronary Intervention (PCI, or "stents") or Coronary Artery Bypass Graft (CABG). Similar reductions may occur in the incidence or quantity of episodes through management of other conditions such as diabetes, osteoarthritis, hypertension, and substance abuse. Additionally, optimal management of acute episodes also can help to reduce the incidence of other acute episodes or even the onset of chronic conditions. For example, avoidance of AMI during major surgery could avert a chain of events such as acute kidney injury or acute and chronic heart failure.

A price or predicted cost (target) could be calculated for patients and cohorts experiencing each type of episode of care. Generally, pricing models use one of two approaches. One approach calculates the historical average cost for an episode using the accumulated amounts paid for patients attributed to a particular provider organization that has entered a contract to manage such episodes. In other words, a provider's historical cost information is trended forward to the anticipated contract performance period to produce spending targets or prices going forward. Success for the provider comes with holding actual spending to amounts below the targets based on its own past experience.

The second approach calculates cross-sectional mean spending amounts for the episode of interest across attributable providers. Success in this context comes with holding actual spending to below the targets reflecting the average of all other providers. This approach is sometimes referred to as a "tournament" because providers are competing against each other in real time and thus reference standards or targets are not knowable in advance.

In either case, the intent is to lower prices per unit (episode) over time without spawning or inducing new episodes as an unintended consequence or gaming opportunity. As providers beat their own historical performance, they are lowering their own cost profile and future expected spending amounts (future prices). As providers compete against each other to perform below the collective mean spending amount, there is downward pressure on the actual overall mean dollar amount, which lowers future spending expectations and commensurate prices. An important aspect of a payment system is the schedule used to reset or rebase prices. As long as benchmarks remain constant, based on past experience, then providers who continue to beat those benchmarks can reap rewards. When benchmarks are rebased to reflect more current performance, then providers need to modify their practice patterns again to beat the lower benchmarks.

Performance contracts with provider organizations can increase the scope of these dynamics by including broader episodes of care, such as underlying chronic conditions and their nested acute events, and by increasing the number and types of episodes. With the episode framework, contracts can specify which episodes are covered and thus operationally define the clinical scope of accountability for single-specialty practices, primary groups or multispecialty practices and potentially including acute, post-acute, or long-term care facilities. Payment and incentive structures can be customized and built to suit the entities responsible for the care.

2.4 Measuring the Value of Care

To pay for healthcare to optimize value for a covered population, we need to define a relative value, and establish incentives that reward higher value and penalize suboptimal performance (lower value). A related concept is efficiency: the resources consumed to produce a specific product or service. An efficient provider or system produces the same output or result with fewer resources compared to an inefficient provider or system. Value builds on that concept by specifying the output or result of interest.

According to the National Quality Forum (NQF), value of care measures a specified stakeholder's (individual patient, consumer organization, payor, provider government, or society) preference-weighted assessment of a particular combination of quality and cost of care performance [14]. Decision-makers at their discretion can give more or less weight to various measures of quality or outcomes, and to cost, in the measure of total performance.

Achieving longer life or lower disease burden for a given expenditure, for example, represents higher value. For society, total benefit and value increase with higher spending as the greatest needs are met first until diminishing returns eventually lead to minimal benefits from services that do not justify their cost. Further spending leads to the so-called "flat of the curve" when total benefits are unchanged despite more services, and subsequently decrease in the aggregate as harmful consequences occur from ill-advised treatments and unjustified risk exposure.[5] To maximize value would be to fund and provide all the services that are net beneficial in relation to cost, and to avoid all services beyond that point.

For individual patients and their families, preferences can be highly subjective and contextual. In contrast, third-party payers are concerned with whole populations or patient cohorts, and determine value from statistical inferences and the distributions of benefit-cost ratios. The challenge for payers is to define the level of "success" or benefits observable for a population of patients, and to compare those levels to predetermined, expected, or normative standards.

[5]The curve in mind plots spending levels on the horizontal axis from lower to higher. Conceptually at the societal level, zero spending would lead to zero benefit. As spending increased for a population systemwide, dollars would be well spent at first as highly treatable conditions and injuries would yield high net benefits. But with higher spending and more services, the payoff inevitably decreases because patients' needs are less acute and less responsive to treatment. Still higher spending would include dubious or duplicative services that have predictably low benefit or value. Even further spending includes contraindicated services such as polypharmacy causing more harm than good. Thus, the curve showing this relationship first rises, flattens, and eventually declines.

2.4.1 Healthy Life Expectancy (HALE) Score

An intriguing goal would be to define a health summary score for each person in the population or patient in the cohort of interest. A good conceptual example is the Healthy life expectancy (HALE) measure used by the World Health Organization (WHO) and defined as the average number of years that a person can expect to live in "full health" by taking into account years lived in less than full health due to disease and/or injury [15]. To serve as a measure, the denominator is the full life expectancy of a cohort, and the numerator is the full life expectancy minus years lost or health deficits resulting from observed health markers. This emphasizes the importance of non-fatal health outcomes in the overall health summary measure.

The Blue Cross Blue Shield Association has adapted this approach to implement a person-level score of the number of expected healthy years as a proportion of the full life expectancy for persons of the same age and gender.[6] It uses claims data for the calculations. For each patient, the measure aggregates information for each clinical condition or context. It can be updated with each significant change, such as the occurrence of an acute exacerbation or a surgical operation. The result is an index with a maximum value of 1.0 (no reductions in life expectancy or excessive disease burden), and lower values resulting from probability of premature death or health markers indicating important clinical states (Table 2.3).

Table 2.3 Calculating the health summary [16]

• Using claims information for each patient, conditions, symptoms, and severity levels are identified with start and end dates.
• Complications and symptoms are linked to causative conditions.
• Disability weights and mortality risks are attached to each condition and time period in longitudinal sequence.
• Years of lower life expectancy and Years with unhealthy burden are calculated for each condition sequence over the member's entire future life (up to age 100).

[6] https://www.bcbs.com/the-health-of-america/health-index.

Because the calculations are at the patient level, cohorts can be formed using similar contexts, such as a clinical condition, acute phase of illness, or definitive surgery or other treatment. HALE measures for patients in the cohort can be analyzed and evaluated for trends, using specific comparisons such as geography or attributed providers. Used prospectively, cohorts identified during a baseline period could be compared over time for the maintenance of health, deleterious effects of acute exacerbations, complications, or the rates of illness progression.

2.4.2 Quality Measures

More typically, various quality measures stand in for this comprehensive health summary score. A substantial amount of funding over the past dozen years has gone into producing thousands of measures for federal programs [17]. To date, most quality measures have reflected the process of care, which are expressed as the proportion of eligible patients who receive an indicated service. Other measures include intermediate outcomes, patient-reported outcomes, and patient experience.

Currently, Medicare follows the Meaningful Measures Initiative, which aims to reduce data collection and reporting burden while producing quality measurement, focusing on outcomes that are meaningful to patients,[7] including Patient Reported Outcomes and Digital Quality Measures (dQM). As part of the Measures Application Partnership, NQF conducted an environmental scan of best practices using EHRs, determinants of EHR data quality and best practices for addressing these issues for scientific acceptability (i.e., reliability, validity), use and usability, and feasibility of electronic clinical quality measures (eCQMs).[8]

Emphasis on dQMs includes electronic prescribing (e-prescribing), and bi-directional health information exchange (HIE), which supports electronic referral loops by sending, receiving, and reconciling health information. Similarly, enhancing consumerism, patient education, and self-care includes providing patients with electronic access to their health information. To that end, the Office of the National Coordinator for Health Information Technology (ONC) has released Version 1 of its US Core Data for Interoperability (USCDI) (Table 2.4).[9] These initiatives could increase the data sources and elements available to measure quality and value and could be leveraged in value-based payment programs.

Medicare payment programs have included measures submitted by Qualified Clinical Data Registries (QCDR),[10] permitting secondary use of data previously gathered and analyzed by providers to monitor and improve patient care. Increased reliance on digital measures has dovetailed with efforts to promote health information technology and interoperability.

Table 2.4 US Core Data for Interoperability (USCDI)

Examples of the topics and fields included:
• Laboratory tests
• Values/results
• Vital signs
• Diastolic blood pressure
• Systolic blood pressure
• Body height
• Body weight
• Heart rate
• Body temperature
• Pulse oximetry
• Inhaled oxygen concentration
• BMI percentile per age and sex for youth 2–20
• Care Team Members

[7] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.

[8] EHR Data Quality Best Practices for Increased Scientific Acceptability: An Environmental Scan FINAL REPORT, National Quality Forum, May 19, 2020.

[9] U.S. Core Data for Interoperability Version 1, Office of the National Coordinator for Health Information Technology, 2019.

[10] 2021 Qualified Clinical Data Registry (QCDR) Fact Sheet, Quality Payment Program, Centers for Medicare & Medicaid Services. https://scorh.net/wp-content/uploads/2020/07/CMS-2021-MIPS-QCDR-Self--Nomination-Fact-Sheet.pdf.

Programs produce a quality composite score that aggregates results for each item chosen to represent a facet of quality or other dimension of performance. The summary score of health or quality is paired with a cost dimension to define value. The linkage between the dimensions might be "unconditional," meaning that a summary cost measure is combined linearly with the other composite score(s) to produce a total performance score. More sophisticated approaches combine cost and quality dimensions conditionally, meaning that the total performance score is conditional on the relative scores in each dimension [18].

2.4.3 Relative Health and Cost

Figure 2.1 depicts a simple version of a conditional value score in which the two dimensions are divided into High and Low regions. Relative value is highest when the health or quality summary score is high, and the relative cost or resource requirements are low. That is illustrated in the quadrant with the highest value score of 2. Achieving a high health summary score but at relatively high cost is the next category down in value and is shown with a score of 1. Still lower in this example of a value score would be low cost paired with low health summary scores, shown here with a score of 0. The inferior quadrant consists of low health summary scores together with high cost achieving a negative score of −1.

Each dimension of health or cost could be divided into more than two categories or measured continuously. The range of value scores could be expanded to increase the contrast between high and low performance and their implications for performance assessment. Raising the relative scores in the superior quadrant (>2), for example, would emphasize rewards and carrots perhaps more than sticks. Lowering the relative scores in the inferior quadrant (<−1) might emphasize penalties and sticks more than carrots. Moreover, some stakeholders might reverse the relative positions of the intermediate quadrants, rewarding efficiency more than relative quality scores. The opportunity is to gauge the consequences of relative performance in one dimension conditional on performance in other dimensions [19].

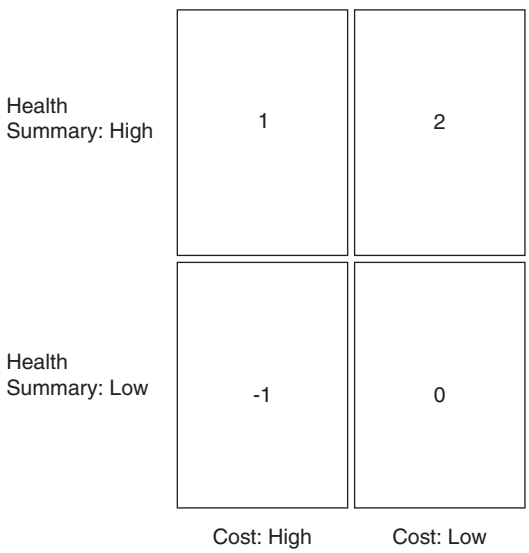

Fig. 2.1 Illustrative value scores in 2 × 2 space defined by relative health and cost

2.5 Attributing Performance Outcomes to Clinicians, Teams, and Risk-Bearing Entities

Value scores (described in the prior section) summarize quality: health and/or spending for geographic or market areas (such as Health Referral Regions),[11] or for time periods. For value-based purchasing, it is necessary and conventional to attribute patient care, its associated quality and cost results to specific providers and organizations that are *responsible* and *accountable* for their care.

2.5.1 Responsibility and Accountability

Who is *responsible* for healthcare quality and cost results?

[11] https://www.dartmouthatlas.org/faq/#research-methods-faq.

First, for preventive care, *primary care clinicians are considered responsible* for promoting wellness and identifying opportunities for early intervention, although specialists can be involved depending on the patient's needs and circumstances (such as patients with chronic diseases that are managed by specialists).

Second, for diagnosis and treatment of medical conditions, *responsible providers for clinical and cost outcomes depends on the condition/problem and role*. Table 2.5 presents a framework that indicates the various roles taken by respective clinicians in care of a patient and in the context of an identified episode.

Example:

A patient with several chronic conditions receives primary care by an internist with some problems managed by a specialist (e.g., a cardiologist for ischemic heart disease (IHD), or psychiatrist for depression).

The patient experiences an acute event/condition (e.g., a myocardial infarction (MI) requiring a revascularization (by a cardiologist) or coronary artery bypass grafting (CABG) procedure (by a cardiac surgeon plus other specialists).

Other clinicians provide supporting and ancillary roles such as anesthesiology, consultations, and tests.

Who is *accountable* for healthcare quality and cost results (in VBP)?

While responsibility is integral to the clinical work, accountability in value-based payment arrangements is contractual. The majority of models are voluntary, and clinicians agree to *accountability*. The payer might wish to utilize simple rules of attribution and avoid the complexity of tracking who is doing what.

Example:

For a patient in a VBP arrangement, all quality and cost indicators for a year would be attributed to the PCP. For a surgical procedure, all quality and cost indicators would be attributed to the surgeon, on behalf of all clinicians on the surgical team.

Table 2.5 Clinical roles defined for each episode of care

Relationship to patient/ episode	Description	Examples
Primary provider	Primary care role; manages patient over time	• Internist • Pediatrician • Family practitioner
Principal provider	Specialist; manages specific condition(s) over time;	• Psychiatrist • Nephrologist • Cardiologist
Episodic provider	Manages an acute condition episode or a procedural episode	• Surgeon • Hospital medicine • Specialist
Supporting provider	Supporting role during an episode	• Anesthesiologist • Radiation oncologist • Consulting specialist
Ancillary provider	Focused role during a single service	• Diagnostic radiologist • Pathologist • Cardiologist (reading ECG)

In Accountable Care Organizations (ACOs) or medical homes, quality results for a patient cohort are attributed to the primary care group that provides most evaluation and management (E&M) services [20].[12] Primary care providers are like general contractors who subcontract to specialists, who in general are not incentivized to optimize care. ACOs and medical homes have referral networks but do not necessarily measure specialist performance.

In bundled payment contracts, performance is evaluated by the total cost of care and predetermined quality measures. Accountability is attributed to the clinician considered "responsible" for patient outcomes. In some cases, the accountable entity is a hospital, without regard to specific clinicians.

[12]In Health Maintenance Organizations (HMOs) and sometimes in other health plans requiring preauthorization for specialty services, a member (patient) must select or be assigned to a specific clinician, who is expected to manage specialty referrals. In such cases, attribution for accountability usually corresponds to such assignment.

Generally, care redesign and improvement are the work of clinicians, administrators, and delivery systems. Attribution rules by payers may incentivize performance improvement by encouraging care teams to reduce fragmentation and increase collaboration and coordination. This inclusive approach is shared accountability.

2.5.2 Identifying Roles for Attribution

In performance evaluation, the unit of analysis is an episode of a patient's care. Key steps in attributing accountability are:

- Identify the clinicians or teams participating in a patient's care. Identifying the clinical team and emphasizing shared accountability is intended to raise awareness and collaboration. See Table 2.6.
- Track the roles and performance of each clinician and team across any number of care episodes. Tracking is intended to be respectful and accurate regarding individual contributions to care and improvement.
- Attribute performance summaries to a risk-bearing entity that can enter contracts with payers for value-based payment. Attribution is intended to spread financial risk over many patients and individual clinicians, allowing statistical inference about overall performance with an eye to outcomes and value in relation to healthcare expenditures.

Table 2.6 Identifying clinicians' roles

• Using claims information for each patient, episodes are identified (triggered) and remain open for a specified period.
• Services are assigned to each episode according to clinical relevance.
• Each clinician (National Provider Identifier, or NPI) who submitted a relevant service for an episode is counted as a clinical team member.
• Algorithms can be used to identify all clinicians who participate in the care for each patient for each type of episode and to infer the role of each.
• Service patterns over the past year can be used to identify primary providers who have been managing the patient's care, overall or for specific (chronic) conditions.

2.6 Paying for Higher Value of Care

Medicare and other payers have implemented value-based payment models. The Center for Medicare & Medicaid Innovation (CMMI) has tested 54 models to date, and a Health Care Payment Learning & Action Network (HCP LAN) has promoted value-based purchasing,[13] producing a taxonomy of payment models (Fig. 2.2). The taxonomy consists of four general categories based on scope of payment and the amount of risk taken by providers participating in the model.

Category 1 is the traditional FFS payment system.

Category 2 models retain FFS but link quality metrics to performance evaluation.

Category 2A involves infrastructure support and Category 2B involves payment for data reporting, both of which are essential to value-based payment models. These include educational programs (Examples: the Million Hearts™ Initiative,[14] the Medicare Diabetes Prevention Program[15]) in which providers help patients with self-care, to improve utilization metrics (Examples: fewer or less severe exacerbations or complications).

Category 2C corresponds to "pay-for-performance," giving bonus payments to providers who meet targets set for quality metrics. (Example: The Premier Hospital Quality Incentive Demonstration gave bonus payments to hospitals for high quality in several clinical areas.)[16]

Category 3 reflects the essence of value-based payment systems, in which participating entities face financial adjustments or consequences based on their performance against benchmarks, with tracks differing in terms of

[13] Alternative Payment Model (APM) Framework Final White Paper, January 12,2016. https://hcp-lan.org/.

[14] https://innovation.cms.gov/innovation-models/million-hearts.

[15] https://innovation.cms.gov/innovation-models/medicare-diabetes-prevention-program.

[16] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalPremier.

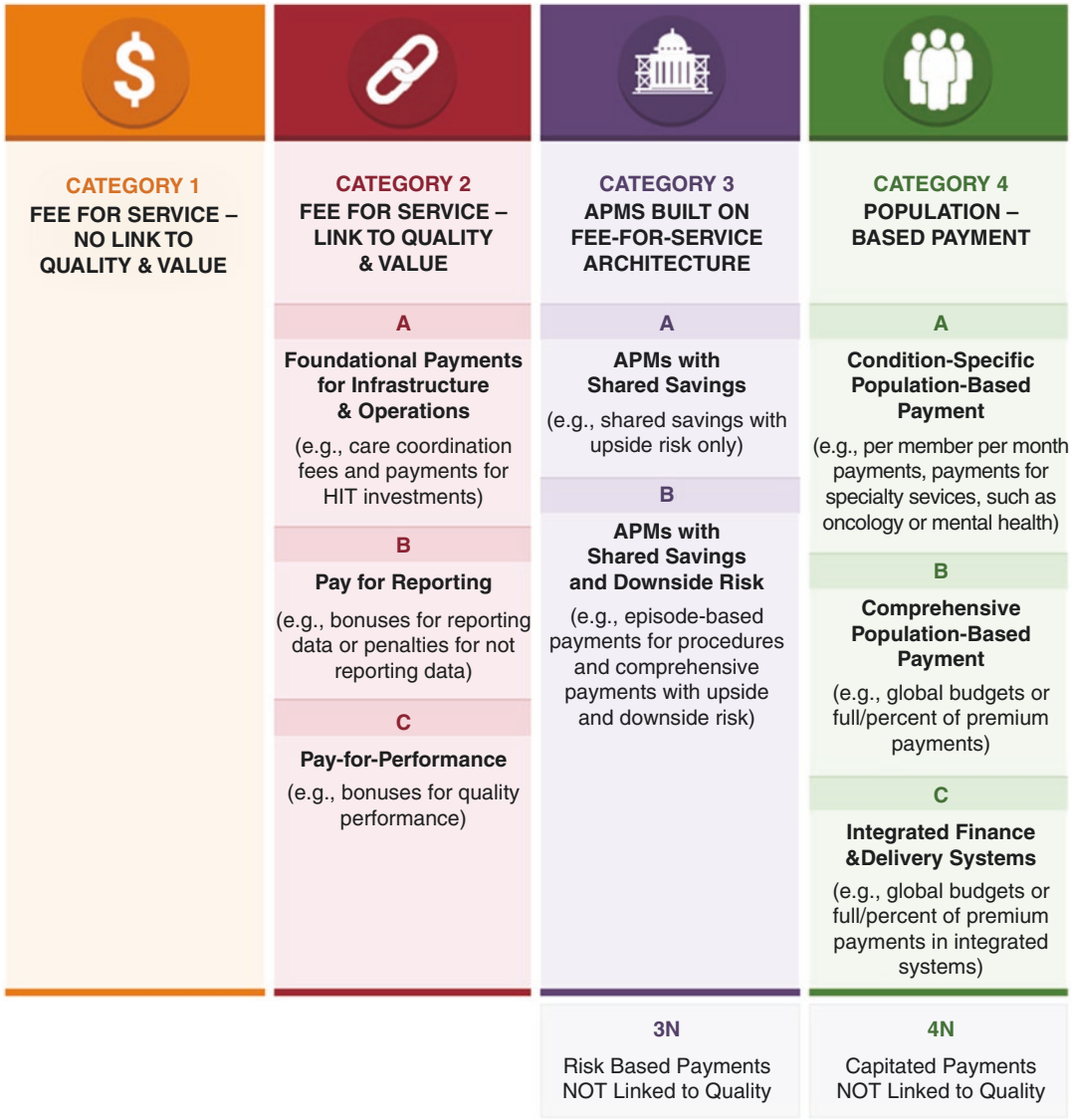

Fig. 2.2 Alternative payment models: THE APM FRAMEWORK Source: THE APM FRAMEWORK, Refreshed 2017, Health Care Payment Learning & Action Network. Reproduced with permission from The MITRE Corporation

how much financial risk is shifted to the participating entity.

Category 3A makes only positive adjustments (allows entities to retain or share savings). This is one-sided or upside-only risk. Category 3B also penalizes (shifts higher than expected costs to) low performing organizations. This is two-sided or upside and downside risk. (Example: The Medicare Hospital Value-Based Purchasing (HVBP) program predated CMMI and became the flagship and blueprint for value-based payment in other categories of

service.[17,18]) Administrative claims are usually the source of detail or services and clinical information but can lack important details describing stage or severity of illness or other important indicators for specific treatment options. These are instances in which claims data must be supplemented with clinical data to capture the important markers. (Examples: The Oncology Care Model and Kidney Choices Model.) [21] [19,20]

Category 4 replaces FFS with prospective (per member per month) payments for certain populations, patient cohorts, or types of services. Category 4A for example, may apply to hospice and Medicare-Medicaid "dual-eligible" beneficiaries faced with decisions about active treatment versus palliative care.[21]

Category 4B and Category 4C Direct Contracting offers global payments (based on total expected cost for a population) to integrated delivery systems or their relevant components. Under Direct Contracting is a suite of options aimed at special needs populations, limited capacity entities and Medicaid Managed Care Organizations (MCOs) for dual-eligible beneficiaries.[22] The Geographic Direct Contracting Model attempts to extend value-based payment to beneficiary populations based on residence.[23]

Experience with ACOs [22] [24] have resulted in (upside-risk only) Medicare Shared Savings Program (MSSP)[25] becoming a programmatic option under Medicare. Other groups have followed the CMS and Medicare lead:

- Vermont obtained a waiver to include Medicare beneficiaries in a State Innovation Model (SIM) initiative[26] and implemented a statewide, all-payer ACO.
- Ohio implemented versions of the original Comprehensive Primary Care model.[27]
- Ohio, Tennessee, and other States have implemented episode-based payment models although not emulating the BPCI model and its use of MS-DRGs to trigger and categorize the qualifying bundles.[28]
- Many private insurers have implemented ACOs in large numbers, and some have implemented episode-based models including UnitedHealthcare, some individual Blue Cross and Blue Shield plans (e.g., Tennessee and North Carolina), Anthem and Cigna. In many cases,

[17] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.

Report to Congress (2007): https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf.

[18] HVBP established the basic components of payment that were later applied to home health and physician reimbursement under Medicare. The summary cost measure used in HVBP was adapted later into the CMMI bundled payment program for hospitals, as well as the Medicare physician value-based payment program discussed later.

[19] https://www.kidney.org/atoz/content/understanding-your-lab-values.

[20] https://innovation.cms.gov/innovation-models/oncology-care.

[21] https://innovation.cms.gov/innovation-models/medicare-care-choices.

[22] https://innovation.cms.gov/innovation-models/direct-contracting-model-options.

[23] https://innovation.cms.gov/innovation-models/geographic-direct-contracting-model.

[24] https://innovation.cms.gov/medicare-demonstrations/medicare-physician-group-practice-demonstration.

[25] https://www.naacos.com/mssp.

[26] https://innovation.cms.gov/innovation-models/state-innovations.

[27] https://innovation.cms.gov/innovation-models/comprehensive-primary-care-plus.

[28] Partly out of convenience given the existence of the DRG payment system, CMMI defined hospital bundles by DRG. Not all payers used DRGs to pay hospitals, which is one limiting factor for uptake. Additionally, determination of DRG is an intermediate outcome that reflects choice of treatment and patient status. For example, consider three patients admitted for treatment of pneumonia. The first patient is discharged with a DRG for pneumonia and is included as a BPCI case. The second patient goes to the Intensive Care Unit (ICU) and onto a ventilator, and is discharged with a DRG for ventilator treatment, and is disqualified from BPCI. The third patient dies and also is removed from BPCI calculations. Thus, BPCI holds the hospital accountable for the cost and value of the first patient but not the other two.

the private insurers have implemented value-based models inside their Medicare Advantage products. This reflects the fact that FFS typically underlies the economic transactions with providers even in managed care plans.

All told, the public Medicare and Medicaid programs, plus many private payers have implemented value-based payment models with models underway spanning the entire LAN framework. Continued work may discover the determinants of success, the limits of the concept, and how to optimize systems and payments.

2.7 Conclusions and Outlook

Sufficient experimentation and experience have provided abundant results from formal evaluations. Unfortunately, evaluations to date have shown tepid or mixed results across the portfolio of CMMI payment models, with more success in a few narrow or small models and some significant losses in some broader, more widely tested models. The outgoing Director of CMMI concluded recently after 10 years and $20 billion that CMMI has fallen short of its goal of transitioning the U.S. health system's volume-to-value transition, and "value-based care will achieve its promise only if the federal government and stakeholders take more aggressive action to prioritize models that can truly achieve savings and improve quality" [23].

A central question is whether we can define value and optimal spending and distinguish instances of low-value and suboptimal spending. If data and analytics can be organized in ways to make such distinctions, then perhaps adverse consequences of inevitable cost-cutting can be mitigated. An accompanying question is whether society can steer the system voluntarily or via regulation to identify and rectify suboptimal spending. That has been and continues to be the quest in value-based payment.

Questions and Answers

1. How can advances in HIT help facilitate or propel further advances in payment models?
   (a) Greater use of clinical and socioeconomic data may help providers to better adjust cost expectations and avoid uncontrollable financial risks.
   (b) Machine learning techniques may help boost predictive analytics to support care decisions in real time, enabling providers to improve value and avoid unnecessary cost.
2. How can digital exchange protocols help payers and providers align efforts by sharing information in real time?
   (a) FHIR and other mechanisms may support and prioritize use cases like price transparency requirements.
   (b) Payers may provide consumers and providers with real-time information about out-of-pocket costs related to possible treatment decisions especially in an episode framework that groups all relevant services.
3. What are two challenges in implementing value-based payments?
   (a) Creating incentives to align stakeholders who are in competition
   (b) Aligning payment systems/rules for all payers and providers competing in the same market areas.

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Leadership and Change

3

Patricia Hinton Walker, Bonnie Blueford, and John M. Walker

Abstract

This chapter discusses changes that leaders must address currently and into the longer-term future. Beginning with the COVID-19 Pandemic, much has changed in organizations, however this is not the only challenge facing healthcare leaders currently and into the future. Technological advances, increasingly relying on teleconferencing, and telehealth is rapidly creating a need for significant change. This chapter highlights the fact that senior leaders MUST build and maintain trust in their teams that support these rapidly changing systems and that this trust must translate to the customer (consumers of health care services). As all members and customers of organizations struggle with issues like the pandemic, an increase in remote (telehealth services), environmental crises (recent Texas weather and Detroit contaminated water), leaders must be empathetic and compassionate to all who are impacted. Focusing on the elements of Post-Traumatic Growth (PTG) allows leaders to address the impact of the recent pandemic and potential future challenges including technology and health IT-related crises as well. A coaching mindset and use of group and team coaching is rapidly becoming another 'must' in organizations. This 'coaching approach' not only enhances growth and builds trust, the organization benefits from valuable, creative contributions from members of the organization. When leaders change from a 'control to coaching' mindset, everyone in the organization is allowed to grow and help design new ways to meet emerging challenges/crises. Leaders also must anticipate and be prepared for Cyber Attacks and increasing unplanned Health IT-related challenges due to climate change (such as the recent Texas weather crisis). This chapter addresses important changes that leaders must choose to better function today and be prepared for rapidly changing new challenges. By embracing the importance of true empathy and compassion, adopting a coaching mindset, focusing on growth, shifting toward more heterarchical versus hierarchical structures/communication, and embracing synchronicity across the organization, leaders will better navigate changing needs and unanticipated crises.

P. H. Walker (✉)
CoachingSteppingStones.com, Canton, GA, USA

B. Blueford
The Blueford Gorup, LLC, Coaching/Leadership Development/Communications, Annapolis, MD, USA

J. M. Walker
IT Professional, Canton, GA, USA

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Keywords

Leadership · Leadership changes · Building trust · Coaching mindset · Psychological safety · Post-traumatic growth · Team coaching · Organizational resilience Hierarchy and heterarchy · Telehealth and other disruptive technologies · Health IT challenges · Leadership and health IT

Learning Objectives

- Identify Leadership Characteristics needed in the current rapidly changing environment.
- Discuss the importance of building TRUST for individual and team leaders.
- Explore the ongoing value of the 'coaching mindset' needed for current and future leaders.
- Identify the five disciplines that team leaders need to address for successful team functioning.
- Describe the challenging mindsets that individual leaders and teams need to address for improved functioning.
- Discuss the need for organizational resilience in uncertain times.
- Describe the difference between hierarchy and heterarchy and the importance of this newer model of organizational structure for leadership effectiveness.
- Explore leadership related to emerging health IT and technology challenges that must be addressed currently and into a very changing and sometimes challenging future.

3.1 Introduction

According to a 1964 song by Bob Dylan that is STILL relevant (perhaps even more so), 'The Times They are a Changing". Another important, still relevant quote by William Gibson in *The Economist,* December 4, 2003: "The Future is Here—it's just not very evenly distributed" Good examples are addressed in 'Predicting the Future of Telemedicine" Modern Health Care, 2020. "Since February 2020, telemedicine grew from less than 1% of primary care visits to nearly 43.5% in April 2020. With telemedicine's current trajectory and rapid adoption rate, it has the potential to disrupt and redefine the way health systems operate, deliver care and manage costs, setting the stage for a vastly different healthcare experience in the future. In the same journal article, Forrester's customer-centric research and analytics indicating that 'it is estimated that we'll see over 1 billion telemedicine visits by the end of 2020". Another author, in the same journal edition, Jack Williams, President of VirtualMed Staff, indicates that patients will become accustomed to virtual care and easier access to health care will decrease patient volumes in systems that do not embrace 'disruptive technology'.

> Also, in a 2019 Deloitte Blog which addresses Health in 2040. "We don't expect to have eliminated disease by 2040, but by using actionable health insights driven by interoperable data and smart AI, we should be able to identify illness early and intervene much more quickly. This can pave the way for a future-focused more on well-being rather than treatment." (Health in 2040: 10 archetypes that could define the future of health, 2019 Deloitte Blog: Health Forward).

For example, it is anticipated that health care consumers will not only demand more personalization, but also greater accessibility with much of health care delivered to consumers where they are (through telehealth and other smart technological advances). Telemedicine has steadily grown over the past decade, but the pandemic skyrocketed its adoption. Also, in this blog, writers indicated that it will be important for current and future leaders to recognize that the health care system of today will be very, very different. Also, increasing transparency will be expected with the increase in automated personal health monitors and sophisticated AI support will be expected by informed, technology-informed consumers.

Other new perspectives/research indicates that the need for empathetic and compassionate leaders will be required for the future. Based on the research reported in the book *Compassionomics: The Revolutionary Scientific Evidence that Caring Makes a Difference* by physician scien-

tists Stephen Trzeciak and Anthony Mazzarelli, healthcare consumers will also demand a more compassionate system of healthcare delivery. The research conducted by these physicians indicates that 'compassion could be a wonder drug for the future' resulting in reversal of much of the cost crisis in health care today while also serving as an antidote healthcare provider burnout [1]. Leaders also need to be agile and anticipate that traumatic situations may again, negatively impact interpersonal relationships among team members and with customers require new strategies to attain/maintain trust and provide caring environments.

3.2 Leadership and Change

In the context of these previously described and already emerging use of disruptive technologies and at the same a call for more compassionate, empathetic care, it is clear there is a need for new and different leaders today and into the future. Signs of these changes are already on the horizon and clearly require new approaches to leadership today and going forward. Instead of using command and control centralized approaches, clearly a much more compassionate, caring, and increasingly competent telehealth and health IT-driven system will require changes for current and future leaders. The future portends to be moving towards consumers of health care receiving much of their care where they are through some form of interprofessional telehealth augmented with actionable insights using AI (artificial intelligence).

In order to address these significant transformation(s) in the future, healthcare leaders must recognize how critical it is to begin making changes now! Changes in behaviors and mindsets will enable greater success as AI continues to change the platform and telemedicine takes hold. Also, in order to expand and meet the needs during the next 20 years, healthcare leaders will need to constantly evolve their job descriptions. The new job description of the future for healthcare leaders includes letting go of control and breaking down silos. Embracing a coaching mindset that enables innovation and brings collaboration to new levels will ensure changing customer requirements and expectations are met. Leaders of the future understand the need and how to create heterarchical, not hierarchal cultures; create agile employee mindsets and assist the development of new emerging team leaders how to nurture to drive performance; adopt a growth mindset that understands the role of post-traumatic growth following the pandemic. It is critical that leaders always have an eye to the future by studying trends in healthcare and embracing synchronicity and getting comfortable with the uncomfortable. Being a healthcare leader is a tall order. The leaders who can make the shifts will enable our communities and citizens to shift toward proactive wellness versus relying on traditional medicine platforms (see Appendix 1).

3.3 Building Trust

Healthcare leaders have an urgent and formidable task—building trust. In the midst of the pandemic, social challenges, and increasing cybersecurity threats there are just a few elemental forces that can help hold a fragmented world together. The one that is the "glue" of society is called trust [2]. Understanding how to build trust is the first step in identifying some of the changes needed for caring and healthcare professions [3]. Trust allows patients, organizations and communities to flourish, while the absence of trust can cause fragmentation, conflict and even war. Trust is hard to define, but many people do know when it is lost (Forbes, Jaffee 2018, Our journal article).

The pandemic has overwhelmed many hospitals and health systems and exposed limitations in delivering care and reducing costs. Virtual health is now on the rise, and the pandemic opened the aperture for AI and digital technologies to solve problems. But if leaders aren't skilled at building trust and ensuring their AI platforms are secure, catastrophic hacks can occur and damage any trust they have built. The recent malware attack at Boston Children's Hospital gave us a glimpse of the vulnerabilities we face as a nation ([4], Nov. 2020).

"Ransomware attacks on a hospital cross the line from an economic crime to a threat-to-life crime because they directly threaten a hospital's ability to provide patient care, which puts safety at risk. Even before COVID-19, the frequency, sophistication, and severity of ransomware attacks on health care providers are increasing. And, the primary perpetrators have shifted from rogue individual hackers to criminal gangs and military units." (AHA Center for Health Innovation, Ransomware Attacks on Hospitals Have Changed, 2020).

In building trust, David Burkas, a leading business thinker and author, shares that the skills used to work—hierarchy, silos, and turf wars, don't work anymore. "In today's VUCA (Volatile, Uncertainty, Complexity, and Ambiguity, hierarchy organizations aren't attractive to employees. Trust now needs to foster unity, partnerships, and collaboration. This requires a shift from hierarchical to heterarchical, where power and decision-making are shared. Communication becomes the "glue" of the organization, and conflicts and crises aren't a threat but serve as catalysts for growth." (Wagner 2018, December 5). Is Heterarchy the Answer to the Crisis of Hierarchy?

Leaders who understand the need for a change in leadership behaviors and mindsets will be able to ensure the future of healthcare. Those who own the critical work of building trust in healthcare will need to focus on safety and wellbeing. Cybersecurity and psychological safety; wellbeing by understanding how trauma informs cultures and the role of resiliency, empathy, and driving post-traumatic growth in accelerating innovation, creativity, and performance.

3.3.1 Psychological Safety: A Coaching Mindset

There's no team without trust," says Paul Santagata, Head of Industry at Google. He knows the results of the tech giant's massive two-year study on team performance, which revealed that the highest-performing teams have one thing in common: psychological safety, the belief that individuals won't be punished when they make a mistake. Studies show that psychological safety allows for moderate risk-taking, speaking your mind, creativity, and sticking your neck out without fear of having it cut off—just the types of behavior that lead to market breakthroughs. (Harvard Business Review, High Performing Teams Need Psychological Safety. Here's How to Create It, 2017). Leaders of the future will have a coaching mindset that allows for dialogue, curiosity, and authentic discussions.

3.3.2 Post-Traumatic Growth Can Lead to Innovation and Empathy (Be Yoda)

The outcome of building a resilient culture is leaders can capitalize on what is known as "post-traumatic growth." The ability to take challenging experiences that spur a greater appreciation for life, a recognition of personal strength, and spiritual growth. In organizations, this leads to more creativity, innovation, and higher individual and collective performance. It also leads to others' empathy and creating cultures where employees can bring their whole self to work.

What skills will be critical in 2030. Benjamin Laker, leadership strategist, share the skills leaders will need in the future. *(This is What Leadership will be in 2030, Benjamin Laker, Forbes).*

- Coaches—They will need to be coaches and understand how to motive and inspire their teams.
- Futurists—have a relentless view of trends and be connected to their networks
- Technology Teenager—teenagers always seem to be connected to the latest technology. Future leaders need to embrace the technology and be savvy and digitally fluent.
- Translator—masterful communicators. They listen and seek to understand. They understand the connection between verbal and nonverbal communication and can connect to people through all channels of communication. Listening and communication are two timeless aspects of great leaderships.

- Be Yoda—future leaders need to be emotionally intelligent like Yoda and develop their empathy and self-awareness. Empathy is at the heart of building great cultures and at the heart of the healthcare industry.

3.4 Leadership and Teams

Increasingly organizations/leaders look for a 'coach-consultant hybrid' for external support and to assist with solutions in challenging times [5]. Also, organizations are increasingly working with leaders to assist them in becoming more knowledgeable about coaching-approaches to management versus historical top-down, control/management approaches. In Forbes' description of this VUCA world (Volatility, Uncertainty, Complexity and Ambiguity) leaders are challenged to make significant changes in approaches, some highlighted in Appendix 1 [6]. Executive coaches assist leaders with these challenges by increasing awareness, drawing out ideas/option), generally staying 'behind the scenes' while providing new research, models and solutions, serving as a go-to-person for trust and support [7]. Additionally, health/wellness coaching expertise provides valuable assets to improved executive functioning and functioning of employees, particularly during stressful times such as these COVID pandemic challenges.

First, it is critical that the leaders of the team recognizes that they are also a MEMBER of the TEAM. Consequently, it is very important that leaders realize that they are constantly modeling 'team behavior' while in the leadership role. Consequently, how the leader manages self, is the role model for all team members whether a conscious decision by the leader, or not. 'Manage Your Energy, Not Your Time' by focusing on awareness/assessment of physical, emotional, mental, and spiritual energy [8]. In the 'crisis of the day/moment,' leaders too often think about their time . . . not their energy! Despite knowing about health, unhealthy habits develop without even noticing. First, it is important that the leader is aware of neuroscience perspectives and knowledge of circadian and ultradian rhythms relevant to leaders/executives. First—is the leader an owl or lark? What are the most productive time(s) for the leader, based on the person's circadian rhythm? [9]. Utilizing that circadian rhythm and recognizing the natural rhythm's of each of the key members of the team is also very important, particularly in consideration of best time to get 'quiet work accomplished and what are best time(s) for team meetings? One potential key is to plan ahead, attending to email/voicemail timing on the calendar to avoid constant interruption(s) and increase productivity (of both the leader and other key members of the team. This will also enhance 'trust' and recognition that the leader respects individual differences and is sensitive to unique needs of members of the team. This is particularly important with the increase in virtual meetings caused by COVID isolation, and many individuals balancing other demands—such as family/children demands, etc.

It is important within this changing world of being 'on' 24-7 with virtual meeting/work demands. Consequently, leaders need to not-only take care of self but work with team members to encourage integration of circadian timing issues, and encourage self and key members to take with time(s) for ultradian rhythm break(s) every 90–120 min into the daily calendar. Also, it is helpful if the leader makes it a priority to schedule the recommended social, physical and/or spiritual (ultradian) breaks including: connecting with teams and frontline workers with compassion/vulnerability to enhance their resilience, take a 'desk-exercise or mindfulness break', and/or create 'sweet spots' of positive emotions by expressing appreciation to others. These kinds of breaks can be invited during virtual meetings and/or done through role-modeling by leadership. Finally, encourage members of the team to value sleep and if it is a good fit for stress management, to use expressive writing to write down concerns/stories [10] for team member's personal resilience. Neuroscience indicates that human brain(s) and spirit(s) do not turn off at night and/or during breaks (when in default mode) but frequently come up with creative and/or spiritual solutions which are more effective than overworking a brain in constant 'task-mode'! [11].

Although mentioned previously in the earlier discuss regarding leadership, it is critical again that the leader BEGIN WITH TRUST using authenticity, self-awareness, recognizing that 'limiting mindsets' create challenges and can negatively impacting trust [12]. It is critical for leaders to become self-aware and address any of these limiting mindsets that can assist teams/organizations to move forward in times of difficulty/crisis. Other than recognized 'fixed and growth mindsets" (Dweck 2017), other 'mindsets' in the literature include: Promotion/Prevention, Open/Closed, Abundance/Scarce [13] and abundance/scarcity, break-the-roles/risk-averse, and long-term/short-term goals [14]. To build better team functioning, it is important that the leader and other key team members self-assess to become more self-aware of any limiting mindsets. Then (with TRUST among the members of the team, to assist each other to explore the presence of 'limiting mindsets.' If the leader is purposeful in choosing self-management and open/vulnerable (asking members to be honest and notice when a mindset emerges in the leader and each other, this process assists the team to work more openly with each other in individual and group self- management! When everyone on the team is purposeful in self-management, then the group as a whole can: (1) listening for key words/phrases habitually spoken related to the 'limited mindset'; (2) identify when a particular limiting belief/mindset' emerges; (3) identify when it emerged and possibly why, and (3), and (4) exploring new 'belief(s)' with new 'habit' words consistent with a purposeful shift to improve team/organizational resilience (McGuire 2018).

Another Team approach—where the leader purposefully focuses embracing more of a team coaching mindset than a 'team management approach' is addressed by Peter Hawkins in his book Leadership Team Coaching. Hawkins identifies five disciplines for systemic team coaching that are important for leaders who choose to lead with a coaching mindset to be more effective and to implement for better team functioning. These disciplines include: *commissioning, clarifying, co-creating, connecting,* and *core learning*. It is so important that team have a clear *commission* which includes a clear purpose and agreement of what defines team success. Second is *clarifying* where the whole team buy into the mission of the team which includes core values, vision for success and clarity about role expectations. For the team to buy into *co-creating*, the team must be clear according to Hawkins that the team outcomes result from more than the sum of their parts and that there are agreed-upon processes and behaviors to accomplish goals. Next is *connecting*, involving agreement related to managing partnerships together as a team, within the larger organization and beyond. Finally, the last and possibly the most important of Hawkins' five disciplines is *core learning*. *Core learning* involves the team reflecting on their own work and processes with a willingness to learn collectively and individually in order to ensure better team function. For team leadership to be effective, the leader can work with the team members from the beginning with a coaching mindset and walk team members through these five disciplines as an important approach to improve team functioning [15].

3.5 Leadership for Organizational Resiliency

Earlier in this chapter, the authors discussed the leader's and team's needs for awareness mindsets that can create leadership and team challenges. It is important to note, leadership to create organizational resilience goes beyond managing mindset(s) to being aware of the need for and preparing for future organizational change. Reliance on traditional hierarchical structure(s) and data-driven outcomes for success based on past performance presents VUCA challenges which again includes Volatility, Uncertainty, Complexity and Ambiguity [6]. One very important strategy advocated by Wagner

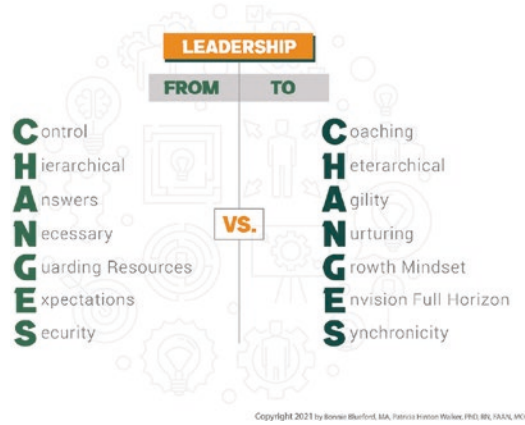
(2018) is for leaders to shift from Hierarchical to Heterarchical organizational

structure and management. This poses the important question 'Is Heterarchy the Answer to Crisis of Hierarchy?' (see Appendix 2, Graphic below). Heterarchical structures are a very important consideration for the current, very complex situations, particularly with the COVID Pandemic and leaders/teams/organizations being forces into virtual environments. This approach presents opportunities for front-line people to honestly feel empowered to pose possible solutions that would be helpful versus 'how we have traditionally done things around here'. This different approach also allows leaders to show true empathy/compassion by opening up dialogue within and across organizations rather than forcing individuals on the front line to ONLY contribute and share concerns 'up the hierarchical ladder'. It is so very important for leaders to recognize that, "Innovation Never Suffers from Lack of Ideas" [16] and be aware that previous 'limiting mindsets' may have prevented new ideas from being considered/implemented. Also, the freedom to share concerns, criticism, and new ideas to address front-line challenges not only opens up organizations, but improves front-line morale and feelings of belonging/acceptance.

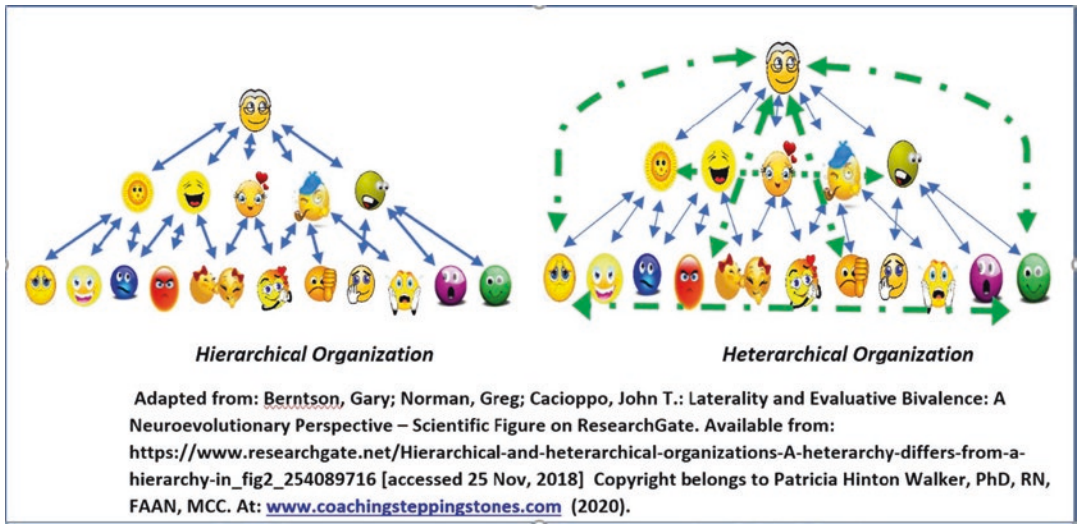
As emphasized earlier, leaders MUST focus on BUILDING TRUST, but it is critical that leaders are willing to show concern and some vulnerability. Also, the heterarchical structure allows leaders to demonstrate the 'power of vulnerability' [16]. However, it is important to note that leaders who overshare their own fears may cause lack of subordinates' confidence that challenges are being addressed [17]. However of increasing importance, leaders need to periodically openly seek subordinates' criticisms and concerns [18]. This continues to be a very important approach that builds resilience. Carol Pemberton (2015) calls it (resilience) a 'bank account that has a balance figure that can be drawn upon when needed' by creating meaningful interaction with frontline workers, openly seeking subordinates' concerns and 'on-the-spot' problem solving and new ideas. Leaders need to at least be willing to explore the switch from hierarchy to heterarchy in order to foster organizational resilience, using the heterarchical model with the courage of 'personal presence' by leaders can truly make a difference AND open the door for better organizational functioning setting the model for different approaches for future crises/pandemics!

Healthcare workers and caregivers sometimes face life and death situations every day. The pandemic has accelerated this reality of their critical role in society. Many times, they are trying to help others who have experienced a trauma or illness while at the same time trying to manage their own daily compassion fatigue. The prolonged "little 't' trauma" can take its toll. If wellness skills are incorporated into daily life, individuals can bump too far out of their resiliency zone (CRM) and become depressed and fatigued or angry and anxious. The key to building a thriving health care organization and workers is bringing in wellness skills to help employees learn how to be resiliency-informed where professionals believe people are resilient and have the compassion to enable them to learn new skills. Resiliency is about wellness and self-regulation skills, and it is based on science [19] (see Appendix 2).

Appendix 1: Leadership Changes



Appendix 2: Hierarchical Versus Heterarchical Organization



Adapted from: Berntson, Gary; Norman, Greg; Cacioppo, John T.: Laterality and Evaluative Bivalence: A Neuroevolutionary Perspective – Scientific Figure on ResearchGate. Available from: https://www.researchgate.net/Hierarchical-and-heterarchical-organizations-A-heterarchy-differs-from-a-hierarchy-in_fig2_254089716 [accessed 25 Nov, 2018] Copyright belongs to Patricia Hinton Walker, PhD, RN, FAAN, MCC. At: www.coachingsteppingstones.com (2020).

Health IT and Leadership Challenges

According to a recent Forbes article, healthcare tops the list of the most cyber-attached industries (Top 5 Industries at Risk of Cyber-Attacks, Forbes 2020). "Chronic underinvestment in cybersecurity has left many so exposed that they are unable even to detect cyber-attacks [or malware attacks] when they occur." (University of Illinois, 2020)." The New challenges include Malware and ransomware, cloud threats; misleading websites; phishing attacks; encryption blind spots; and employee error. Ensuring the security of healthcare systems will lay the foundation for the level of trust in healthcare.

Leadership in and of the technology and IT area(s) of any organization that uses the technology is difficult and is becoming more difficult. There are so many things about it that appear as magic to the uninterested, underinformed, and unfamiliar; consequently, for some it becomes understandably exhausting to make important and relevant executive decisions. Now to complicate things more, we must include the possibilities of pandemics, climate change, hacking, ransomware, and cyber espionage to the already difficult IT executive decision-making process. Additionally, integrating wearables which track and transmit consumer/patient health-related data to the cloud, both by patients themselves and providers require extended knowledge of complex systems. As mentioned previously the necessary transition to remote care will require an increased focus on consumer/patient collected data that tracks health, chronic care management (versus just treatment) and even citizen science-related data repositories for community-based health/wellness related data. Increasingly new senior housing will be 'wired' throughout the day and transmit data to the cloud for easy, ongoing evaluation—both by the patients themselves and by remote care providers. This level of monitoring can help patients with chronic conditions better manage their own health and as mentioned earlier, will shift some of the historical costs related to urgent care and emergency department visits. Finally, new complex systems including: store-and-forward telemedicine; software will facilitate asynchronous communication between consumers/patients and providers so that even photos, X-rays, messages and medical data can be exchanged. This will increasingly be relevant to 'smart homes' linked to provider systems for seniors, those with significant disabilities and

healthcare enabled housing for historically underserved populations.

The main mission of any IT section is to create and continue the mission-prescribed function which is and will be increasingly complicated by telehealth and robotics in this rapidly changing environment. That function is determined by the organization and, from an IT section perspective, the rest of the organization that depends on its information technology are its customers, including itself. The organization is, to one degree or another, dependent on the IT section to meet its customers' ever-changing requirements and to make those functions available upon customer (including internal customers) demands. And, the IT section is dependent on its customers' interaction to define their needs. Without a functional and smooth interdependency such as this, the organization will experience a degradation of mission performance. At the executive decision-making level, some aspects of IT may seem like magic, but there easily understandable foundational requirements of IT systems. Electrical power, software, hardware, data communications, human resources, and security should be considered in support of any organization's IT and other technological functions including new software and hardware for many systems that will need to adapt to the growing demand of telehealth, remote collaboration. (retrieved on 03/16/2021) from: https://www.intel.com/content/www/us/en/healthcareit/telemedicine.html#:~:text=Intel%20Provides%20a%20Foundation%20for%20Telemedicine%20Technology%20,enable%20manufacturers%20...%20%201%20more%20rows.

Obviously, electrical power must be provided, but its quality must be within normal limits and its availability should be congruent with the organization's needs. For example, if the hospital's mission is to provide services during natural disasters and the IT systems during that disaster are required, then acquisition, installation and testing self-contained power generating systems or contracting with a 3rd party for electrical power must be considered. The recent cold weather spell in Texas is a good example of this situation. "Many hospital staffers have stayed in the medical facilities all week—knowing there was no heat or water at home. At least hospitals have generators for basic electricity" (1).

Benign and functional software running on reliable and sufficiently fast computers, wired or wireless communication media, and/or other data equipment, e.g., bio sensors are necessary to an organization's IT section. If the software and/or its networking system has been maliciously changed or if the computers are insufficiently powerful enough to provide satisfactory services, then the organization's mission performance will degrade. In the case of malicious changes to an organization's software, it should be noted that those changes can occur due to the actions of malicious individuals/organizations or countries conducting criminal activity and/or denial of service activities. This list may include irate employees or hackers. Some more malicious attackers use ransomware which is "malware that requires the victim to pay a ransom to access encrypted file" (2). In contrast to ransomware, the malware attack against SolarWinds, Inc. was a significant and dangerous Cyber Espionage that, had it not been discovered, could have resulted in future debilitating Cyber Attacks, including ransom. Essentially, the sequence of events is summarized by an article published by Malwarebytes Labs where their Threat Intelligence Team said, "This scenario, referred to as a supply-chain attack, is perhaps the most devious and difficult to detect as it relies on software that has already been trusted and that can be widely distributed at once. Among the victims who received the malicious update are FireEye, Microsoft and the US Treasury and Commerce departments, making this one of the biggest cyber incidents we have witnessed in years" (3). A detailed technical explanation of the offending software can be found at CrowdStrike's website article (4).

Physical security of IT assets is also important and should not be overlooked by organizations' leaders. Physical security lapses can compromise mission performance as much as ransomware, fire, natural disasters or pandemics. "Information management security systems ensures information, no matter how it is transmitted, shared, or stored, is always protected in an appropriate

manner." So, protecting information from malicious physical access is as important as securing it from cyberattacks and the like. Leaders should consider the following elements of physical IT systems security:

Physical security policy
Campus, building, floor, room, asset security
Physical barriers
Fire, flood, intruders and equipment temperature
Card readers or combination locks
Entry/exit logs or video
Guards (5)

As indicated earlier, the IT section is dependent on its customers' interaction to define their needs. The effects of COVID-19 during the last year have placed particular emphasis on this aspect of healthcare IT systems. Cerner Corporation reported "…some of the ways health care providers are using data and Cerner tools to strategically schedule their workforce and help avoid a staffing shortage during the pandemic." Their customers were cited as needing the ability to visualize understaffed shifts, automate schedules during high demand times, track expenses that were not heretofore tracked, track teleworkers, and to track COVID-19 positive patients' movement through the healthcare system. "Better patient outcomes occur when you have the right caregiver, in the right place, at the right time" (6).

Sufficient qualified technical and supervisory IT staff are needed to continue operation of the organization's information system during normal and stressed times. Without them the organization will experience degrees of mission degradation. "a prolonged leadership void is too risky. It raises questions about a company's internal talent pool. Is it robust enough? How much attention has been given to developing internal talent, starting at the senior executive level? Are there ready candidates at every key position?" (7). Leaders must ensure that their organizations hire people with up-to-date skillsets unless their organizations are able to teach needed skills, or, through 3rd party teaching organizations, acquire those skillsets for their employees. CompTIA, Inc. suggests that "Digital operations are more important than ever, with many transformative changes accelerating over the past year. Fair treatment for all is an absolute mandate, making diversity, equity, and inclusion a top priority" (10).

The global IT industry is massive and affects most people in one way or another. "In 2020, the global information technology industry took a small step back in terms of overall revenue. As of August 2020, the research consultancy IDC was projecting global revenue of $4.8 trillion for the year, compared to their original estimate of $5.2 trillion. While the tech sector fared better than many other industries during the pandemic, it was not immune to cutbacks in spending patterns and deferment of major investments" (10). Due to good IT decisions made by leaders at many levels, people can now search for, order, and expect fast and reliable delivery of products with a few clicks/presses on their phones or personal computers. Information is available with little effort and time. Marketplaces are leveled now more than ever; small businesses can compete with larger corporations. Education and advice are just a few seconds away. And, with new digital creative tools like desktop 3D printing and milling for example, garage-level innovation and products can form the basis for thriving businesses and artistic expression. "There's no denying that we live in the age of technology. No matter what industry or aspect of life today we look at, technology influences it in some way or another. It's changed the way we look at and do everything…" (8). COVID-19 and its variants have caused us to change the way we work and interact with others. However, we do not currently possess the biological technology to eliminate that need for change in all future viral pandemics. Leaders can be thankful that our IT systems and anti-viral research were mature to the extent that they were when COVID-19 pandemic occurred, otherwise it could have been much worse, but leaders should be watchful.

This chapter began with a theme from another disruptive period, the 1960's. So, an oldie but goodie lyric from a Buffalo Springfield song (1966) comes to mind to complete the chapter's

theme, but the lyric needs to be updated to hold this chapter's context in mind. The parentheses are the authors':

There's something happening here
What it is ain't exactly clear
There's a man with a gun *(mouse)* over there
Telling me I got to beware
I think it's time we stop
Children, what's that sound?
Everybody look, what's going down?

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4 Promoting Informatics Workforce Development Through Global Initiatives

Man Qing Liang, Trisha Pongco, and Toria Shaw Morawski

Abstract

This chapter focuses on initiatives that aim to promote the development of the healthcare informatics workforce and discuss the importance of fostering global and interprofessional communities to drive innovation and technology worldwide. This chapter will showcase resources and tools for students, educators, and healthcare professionals co-developed by the Healthcare Information and Management Systems Society (HIMSS) global communities in partnership with other expert organizations. These resources will cover a wide range of health informatics topics—from core competencies recommendation frameworks to adoption models for imaging professionals. Finally, this chapter will describe the current state of the digital healthcare workforce and address the impact of COVID-19 on its development.

Keywords

Adoption model · Competency development · Education reform · Global workforce development · HIMSS TIGER initiative · Interdisciplinary community · Nursing informatics · Enterprise imaging

Learning Objectives

- Review the importance of global initiatives to promote health informatics workforce development
- Discuss current resources and tools for students, adult learners, educators, and health informatics professionals
- Understand the implications of COVID-19 on the healthcare workforce and its professional development
- Describe the roles, training and education, responsibilities, and barriers of the nursing informatics workforce

4.1 Introduction

Healthcare information systems have been pushed forward as a solution in the last decades to improve healthcare delivery quality, safety and efficiency [1, 2]. However, although incentivization has led to the rapid adoption of health information systems [3], there has been a gap in the

M. Q. Liang (✉)
TIGER Initiative, HIMSS, Montreal, Canada
e-mail: man.qing.liang@umontreal.ca

T. Pongco
Clinical Informatics, HIMSS, Brooklyn, NY, USA

T. S. Morawski
Professional Development, HIMSS, Schaumburg, IL, USA
e-mail: tshaw@himss.org

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development of an informatics workforce capable of contributing to the realization of the full benefits associated with this digital health transformation [4–7].

In 2016, the European Commission's (EC) Horizon 2020 research and innovation grant program, awarded funding to a Consortium to measure, inform, educate and advance the development of a skilled eHealth workforce through the European Union (EU) and United States (U.S.). The six organizations in the Consortium joined forces to deliver the EU*US eHealth Work Project [8].

Notably, this project identified the following gaps in training resources for the future generation of healthcare professionals [9]:

- Lack of knowledge and skills of faculty and educators
- Lack of knowledge and skills of healthcare professionals
- Availability of courses and programs
- Quality and quantity of training materials
- Difficulties from universities to meet the needs for practical and novel learning opportunities.

Therefore, to address these gaps, healthcare systems, professional associations, and universities must provide the necessary educational opportunities for learners and tools for educators [10]. Furthermore, because health informatics resides at the intersection of multiple disciplines, this demands buy-in from professionals across the healthcare workforce spectrum to address gaps.

To spearhead these efforts, HIMSS has fostered communities focused on harnessing the power of information and technology. Through its extensive network of 100,000 individual members, 480 provider organizations, 470 non-profit partners, and 650 health services organizations, HIMSS aims to identify best practices for the digital transformation of healthcare by offering a "unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics" [11].

Numerous HIMSS initiatives have been created to allow global members to co-create content as subject matter experts (SMEs) that the interprofessional communities consume. These initiatives include:

1. The HIMSS TIGER Initiative
2. The HIMSS Nursing Informatics Community
3. The HIMSS-SIIM (Society for Imaging Informatics in Medicine) Community

This chapter will present these three initiatives and discuss how they have cultivated a global interprofessional community focused on identifying best practices and resources in different areas of health informatics to develop tools focused on global workforce development needs and opportunities.

4.2 HIMSS TIGER Initiative

The Technology Informatics Guiding Education Reform (TIGER) Initiative was formalized in 2005 by a group of nurse leaders who lacked visible nursing representation at the first Office of the National Coordinator for Health Information Technology (ONC Health IT) conference. These TIGER pioneers organized diligently to create a grassroots initiative to ensure that the nation's strategy for health IT would integrate the nursing voice. They aimed to "develop a shared vision, strategies, and specific actions for improving nursing practice, education, and the delivery of patient care through the use of health information technology" [12]. Shortly after the creation of the initiative, key collaboratives were created to address priorities for the development of the U.S. based nursing informatics workforce. The work completed by these collaboratives from 2006 to 2014 culminated in the publication of numerous landmark reports, which provided recommendations on informatics competencies, usability and clinical application design, leadership develop-

ment, and other aspects of nursing informatics [13]. In 2012, TIGER's vision expanded globally with the establishment of a committee represented by volunteers from around the world. Additional information on the history of the TIGER initiative has been detailed in a previous publication titled "The Evolution of the TIGER Initiative" [14].

Previously a standalone foundation focused solely on nursing informatics, the TIGER Initiative transitioned into HIMSS in 2014. This transition came with a renewed focus on interprofessional health informatics, as the pioneers had the foresight to see where the field was headed. Today, TIGER is a global initiative and interprofessional community focused on education and reform, fostering community development and growth, and workforce development. TIGER "offers tools and resources for learners to advance their skills" and for educators to develop technology and health informatics curricula, as well as supplemental resources [15]. As shown in Fig. 4.1, resources and professional development opportunities are available for all learner levels regardless of discipline.

The following section will describe the resources and opportunities shown in Fig. 4.1.

4.2.1 TIGER Global Informatics Definitions

Responding to the need to curate global health informatics definitions, the TIGER Initiative published the *Global Informatics Definitions* document defining core health informatics terminology [16]. This document serves to provide context for various terms appearing in TIGER resources and was revised by members of the TIGER International Task Force to ensure that definitions were adapted to TIGER's global, interdisciplinary community [17]. Infographics in the document illustrate the rapidly changing field of informatics in the last decades, as well as the numerous disciplines at the intersection of biomedical informatics.

4.2.2 Global Health Informatics Guide

Inspired by the work of TIGER over the last 6 years, most notably by the EU*US eHealth Work Project, the *HIMSS Health Informatics Guide* "aims to acquaint those learning about health infor-

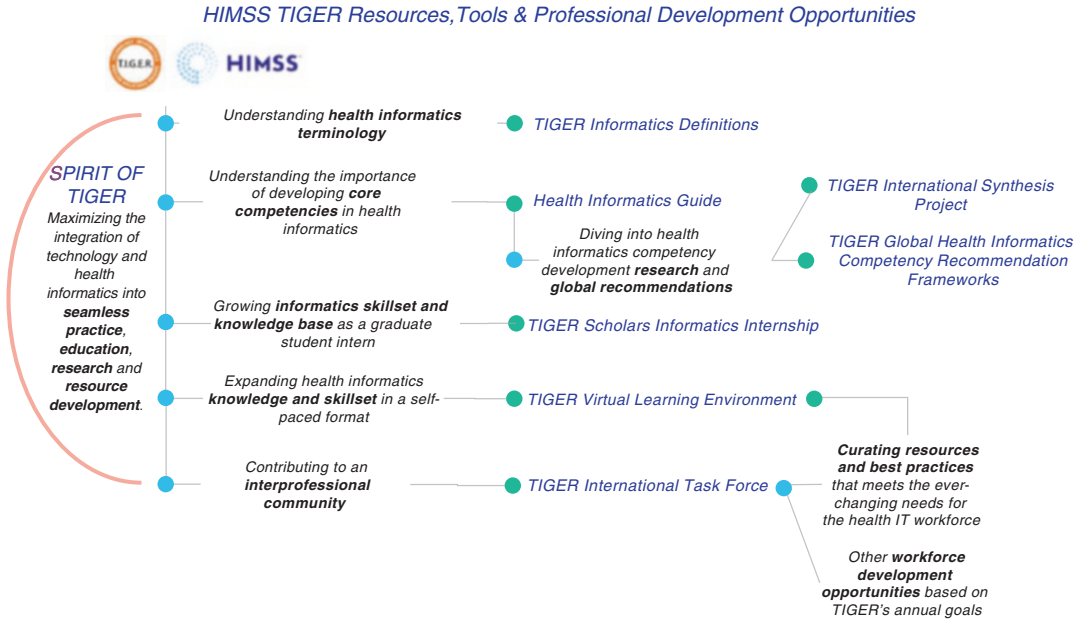


Fig. 4.1 HIMSS TIGER resources, tools and professional development opportunities decision tree

matics with a direct conduit on where to locate and how to leverage competency based tools and resources available from around the world" [9]. Regardless of where one is located, this Guide connects learners and educators alike to competency development focused tools and resources.

4.2.3 TIGER Scholars Informatics Internship

Every year, two interns (one domestic, one international) who are seeking a healthcare master's degree or doctorate are selected to participate in the program—supported by the HIMSS Foundation. The program aims to help students grow their informatics skillset and knowledge base as they prepare to graduate and pursue career opportunities. Program components include [18]:

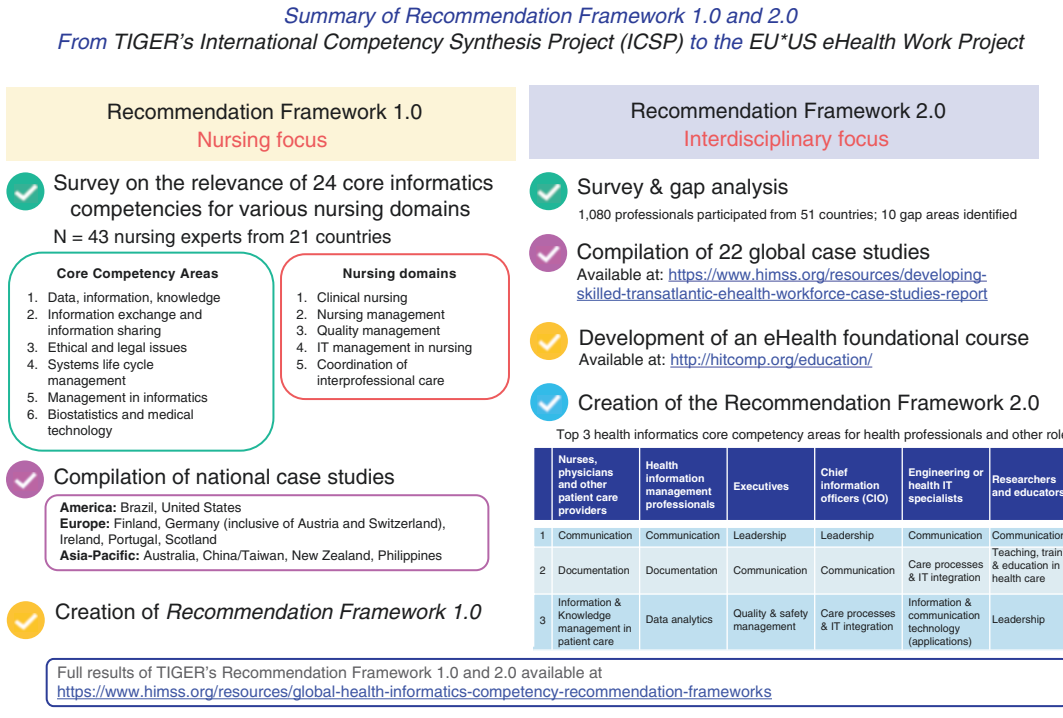
- Mentorship via the global TIGER volunteer network and HIMSS staff
- Opportunity to serve as a Program Assistant at the HIMSS Global Health conference
- HIMSS student membership
- TIGER Virtual Learning Environment (VLE) access to complete the courses tied to certificates of completion

4.2.4 TIGER International Competency Synthesis Project

In 2015, TIGER began compiling core recommended informatics competencies reflective of many countries, scientific societies, and research projects [19]. Figure 4.2 summarizes the outcomes from the TIGER International Competency Synthesis Project (ICSP) and the EU*US eHealth Work Project.

The project initially involved three phases focused on five nursing domains [(1) clinical nursing, (2) nursing management, (3) quality management, (4) IT management in nursing, (5) coordination of interprofessional care]:

1. Deployment of a survey focused on nursing informatics competencies



	Nurses, physicians and other patient care providers	Health information management professionals	Executives	Chief information officers (CIO)	Engineering or health IT specialists	Researchers and educators
1	Communication	Communication	Leadership	Leadership	Communication	Communication
2	Documentation	Documentation	Communication	Communication	Care processes & IT integration	Teaching, training & education in health care
3	Information & Knowledge management in patient care	Data analytics	Quality & safety management	Care processes & IT integration	Information & communication technology (applications)	Leadership

Fig. 4.2 Summary of the outcomes from the TIGER ICSP and the EU*US eHealth Work Project

2. Compilation of national case studies submitted by our global volunteers from Australia, Brazil, China/Taiwan, Finland, Germany (inclusive of Austria and Switzerland), Ireland, New Zealand, the Philippines, Portugal, Scotland, and the U.S.
3. Creation of the *Recommendation Framework 1.0* derived from case studies' findings, survey results, and stakeholder input. This nursing-centric framework aims to provide knowledge about informatics competencies, professional roles, priorities, and practical experience.

4.2.5 eHealth Competency Development: Synergy of Projects

Subsequently, *Recommendation Framework 2.0* was created to augment the focus from nursing towards a series of other professional roles [(1) healthcare professionals providing direct patient care, (2) health information management professionals, (3) executives, (4) chief information officers, (5) health IT specialists, (6) researchers and educators].

The TIGER ICSP and the EU*US eHealth Work Project joining forces to both further describe and validate this framework. The TIGER ICSP findings were leveraged as the foundation upon which the EU*US eHealth Work Project began.

The EU*US eHealth Work Project aimed to address the need, development, and deployment of workforce IT skills, competencies, and training programs. The project's overall goal was to create a legacy of digitally empowered health care professionals now and into the future.

A total of 33 core competencies were identified from the TIGER International Competency Synthesis Project (ICSP) Recommendation Framework.[1] Each competency will be aligned to an individual chapter in the fifth edition of *Nursing Informatics: A Health Informatics, Interprofessional and Global Perspective* also published by Springer Nature.

4.2.6 TIGER Virtual Learning Environment (VLE)

"Powered by HIMSS, the TIGER VLE is an interactive, online learning platform for academic professionals, students, adult learners, and clinical educators. This personalized learning experience—containing courses and webinars—expands knowledge and skillset in a self-paced format" [20]. Highlights of the education portal include courses tied to certificates of completion, a robust resource library, and a webinar archive.

By highlighting the work of open source collaborators, TIGER with SME from the VLE work stream, sift through information from around the world to curate content for subscribers. Subscribers can then easily leverage these resources to expand their knowledge base or integrate these resources and modules into classroom curricula and beyond.

4.2.7 TIGER International Task Force

The TIGER International Task Force (TITF) provides the global community represented by 29 countries with knowledge, leadership, and guidance to reform technology and informatics education by providing domain expertise through activities, projects, and collaborations. The TITF is further supported by work streams aligned to each year's goals. As of 2021, the TITF is comprised of five workstreams, including:

- **The Virtual Learning Environment (VLE)** Work Stream (WS): This WS is dedicated to refining the VLE offerings to ensure they are globally relevant and up to date. The workstream seeks to identify new resources that address gaps in competency areas.
- **The Global TIGER Network (GTN)** WS: The GTN represents a network of networks

[1]The 33 core competencies identified in the EU*US eHealth Work Project can be explored via https://www.himss.org/resources/global-health-informatics-competency-recommendation-frameworks.

that seeks to mirror the interprofessional, intergenerational workforce. The WS ensures that all past and current TIGER volunteers are up to date on TIGER's goals, projects, and resources.

4.3 HIMSS Nursing Informatics Community

The HIMSS Nursing Informatics Community was founded in 2003 in response to the ever-expanding role of the informatics nurse professional in health information and management systems. As the membership of nurses increased within the organization, this effort was highly encouraged to articulate a cohesive voice for informatics nurses at HIMSS. Currently, the HIMSS Nursing Informatics Community spans over 8000 members who provide the domain expertise, leadership and guidance to HIMSS activities, initiatives, and collaborations with the global nursing informatics community [21].

To spearhead initiatives, the community is led by the HIMSS Nursing Informatics Committee which is comprised of 12 distinguished nursing informatics leaders across the U.S. who hold roles in various hospital systems, market supplier organizations, academia, non-profit sector, government agencies, and more. The community and committee is supported by the HIMSS Nursing Informatics Education & Networking Task Force which serves as the forum for empowering leaders in the nursing informatics field.

Through a culmination of global endeavors by the HIMSS Nursing Informatics Community, nurses across the healthcare spectrum have continued to prove their value in impacting on the driving workforce of informatics. Recent publications from the HIMSS Nursing Informatics Community include the HIMSS 2020 Nursing Informatics Workforce Survey and the Chief Nursing Informatics Officer Job Description Document.

4.3.1 HIMSS Nursing Informatics Workforce Survey

Building upon research since 2004, the HIMSS 2020 Nursing Informatics Workforce Survey, completed by a total of 1359 respondents, provided insights on the workplace setting, nursing informatics training and education, and work experience (Fig. 4.3). The survey recommenced the demand of informatics nurses for the devel-

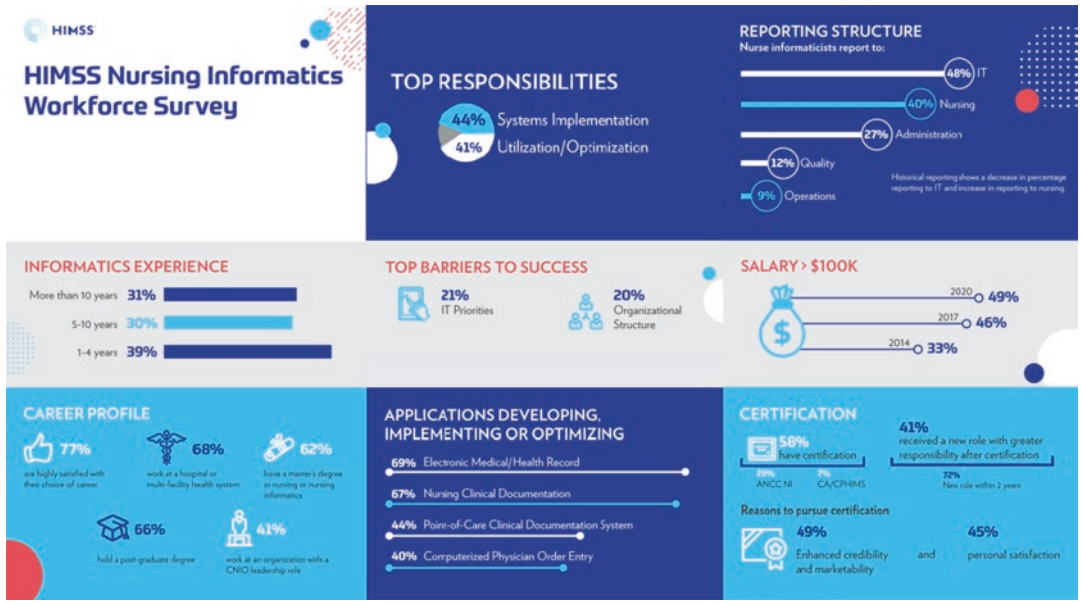


Fig. 4.3 Summary of the 2020 HIMSS Nursing Informatics Workforce Survey. (Adapted from: https://www.himss.org/resources/nursing-informatics-workforce-infographic. Used with permission of HIMSS)

opment, implementation and optimization of medical and health records, nursing clinical documentation, point-of-care clinical decision support and computerized practitioner order entry [22].

- **Workplace:**
  - Over two-thirds (68%) work for a hospital or multi-facility health system.
    More than half (53%) work at a Magnet-designated hospital,[2] and 41% work for an EMRAM Stage 6/7 hospital,[3] which has been associated with an increased value of informatics in health system achievements.
  - The majority of the remaining respondents identified working for a vendor/payer, government or military, or in an academic setting.
- **Training and education** also continued to be a priority as 2020 saw a significant rise in formal education.
  - The percentage of respondents who obtained a master's degree or PhD in nursing informatics increased to 37% compared to the 31% of respondents who achieved the same degree in 2017.
  - Individuals also strove to obtain certificates in nursing informatics, which rose from 20% in 2017 to 25% in 2020. The number of respondents with any certification expanded from 49% in 2017 to 58% in 2020.
  - If a certification was received, respondents were asked reasons that a certification was pursued. Enhanced credibility and marketability (49%), and personal satisfaction (45%) were the highest attributions to this section. All in all, certification was again found to have a high impact on respondents' career paths.
- **Work experience:** The workforce has also proven its growth as 14% of respondents reported having less than 1 year of experience in informatics in 2020 versus the 8% of respondents in 2017. Informatics nurses are also cultivating careers within their current roles as 38% have been in their current role for more than 5 years compared to the 31% of individuals in 2017 [22].
- **Chief Nursing Informatics Officers** (CNIOs) and Senior Nursing Informatics Executives continue to showcase their value within the interprofessional care team.
  - According to the NI survey, approximately four out of ten respondents have a senior nurse informaticist title, while 41% of nurse informaticists work in organizations that have a formal CNIO or other senior nursing informatics officer.
- All in all, data from this survey prove that the industry and career opportunities within nursing informatics have continued to grow year after year. Nurse informaticists are now forging their focus beyond EHR implementation and propitiously innovating the role as analysts, educators, policy developers, and more. Continuing education can keep nurse informaticists up-to-date with the pace of technology and guide them in providing high-quality patient care both clinically and technically.

4.3.2 Chief Nursing Informatics Officer Job Description Document

The growing number of CNIOs over the years have also led to many new positions with different titles. To streamline this role, members of the HIMSS Nursing Informatics Community and Committee created a standardized CNIO Job Descriptions Document that can be referenced for the competencies they must attain regardless of the specific job title [23]. The description document therefore provides recommendations for a C-Suite level CNIO or equivalent job description

[2]Magnet-designated hospitals are "organizations where nursing leaders successfully align their nursing strategic goals to improve the organization's patient outcomes". For more information, visit https://www.nursingworld.org/organizational-programs/magnet/.

[3]The Electronic Medical Record Adoption Model (EMRAM) developed by HIMSS Analytics is available at https://www.himssanalytics.org/emram.

including qualifications and experience, key responsibilities and reporting structure.

One of the highlighted examples within the document focuses on the strategic and leadership perspective. For any CNIO, it is vital to serve as a key strategic liaison for health IT efforts representing nursing and patient care team needs. The leader in this role must combine patient care, informatics concepts and change management knowledge to effectively address the information and knowledge needs of healthcare professionals and the patients they serve to promote safe, effective and efficient use of health IT in clinical settings [23]. Amongst other areas, they also act as the change agents in the identification, development, planning, implementation and value measurement of informatics strategies to support quality patient care outcomes and professional practice. It is essential to recognize this role in the growing interprofessional field of informatics from a global lens.

4.4 HIMSS-SIIM Enterprise Imaging Community

Enterprise Imaging refers to a set of strategies, initiatives, and workflows implemented across a healthcare enterprise to consistently and optimally capture, index, manage, store, distribute, view, exchange, and analyze all clinical imaging and multimedia content to enhance the electronic health record [24]. Through a number of initiatives, discussed below, HIMSS realized the significance of enterprise imaging and its potential to educate the health information and technology realm. Starting in 2015, HIMSS and the Society for Imaging Informatics in Medicine (SIIM) partnered with the vision to provide an effective point of connection for clinicians and IT professionals to engage and advance enterprise imaging strategies. Formally introduced as the HIMSS-SIIM Enterprise Imaging Community in 2019, healthcare professionals from numerous industries have joined this community to advance professional development with targeted imaging education, grow connections through networking, and collaborate to advance global imaging strategies [25]. The HIMSS-SIIM Enterprise Imaging Community has grown to house a multitude of healthcare professionals outside of the radiology space since its and includes hospital system executive leaders, clinical informaticists, cardiologists, imaging vendors, IT professionals, and more.

4.4.1 HIMSS-SIIM Enterprise Imaging Workgroups

Through several contributions and endeavors, the HIMSS-SIIM Enterprise Imaging Community continues to showcase the value of the growing field through various activities, as illustrated in Fig. 4.4. To date, over ten whitepapers have been created by enterprise imaging contributors with a readership spanning over 61,000 downloads. Topics range from the foundational, technical, and workflow and governance of enterprise imaging. Currently, three workgroups have been launched within the community for members to explore specific initiatives based on timely topics, such as Photodocumentation, Interactive Multimedia Reporting (IMR) and Data Standards Evaluation.

- The first workgroup centers on **Photodocumentation**, which is defined as any photograph used to record a medical condition. Currently, the primary tools are digital cameras and smartphones. This workgroup provides a multidisciplinary forum for discussion of the clinical and technical challenges and opportunities associated with Photodocumentation. The launch of this workgroup represents a new opportunity for the HIMSS-SIIM Enterprise Imaging Community as it reaches beyond the radiology environment and seeks to engage other subspecialties, expanding the reach of the community. These subspecialties include dermatology, pediatrics, family medicine, emergency medicine, orthopedic surgery, head and neck surgery, and telehealth practitioners.
- The second topic focuses on Interactive **Multimedia Reporting (IMR)**, which is defined as interactive medical documentation

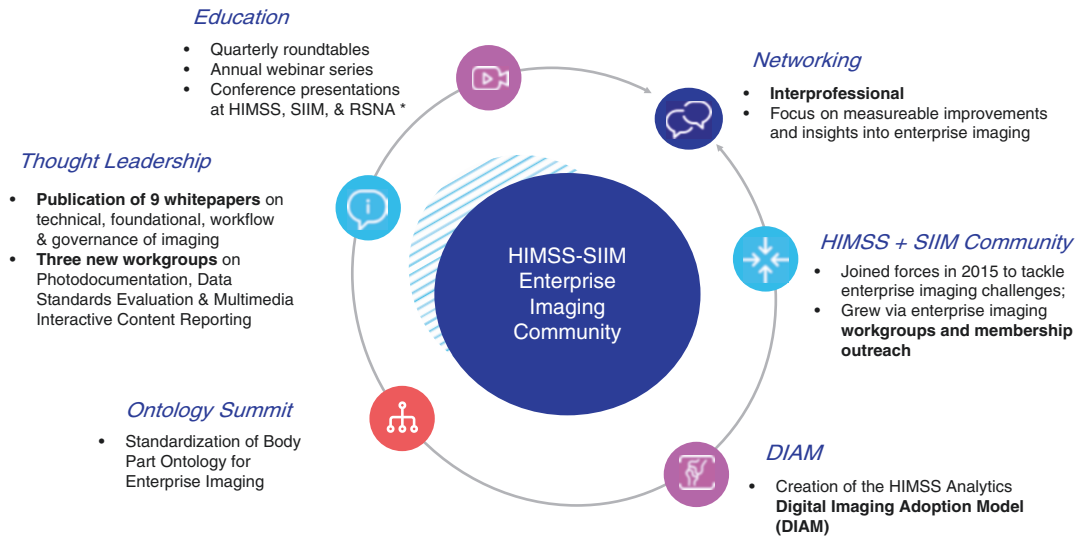


Fig. 4.4 Summary of the HIMSS-SIIM enterprise imaging community activities

that combines clinical images, videos, and/or image annotations with text, graphs, and/or tables, educational resources to optimize communication between medical professionals, and between medical professionals and their patients. The intent of this multidisciplinary workgroup is to develop a forum for discussion, sharing successes and challenges, and spurring innovation across many subspecialties concentrating on the clinical and technical aspects of this topic.

- The last, focusing on **Data Standards Evaluation**, analyzes existing nomenclature related to body parts and anatomic regions for purposes of multidisciplinary relativity and systems interoperability delivered both internally and externally across healthcare organizations.

4.4.2 HIMSS-SIIM Digital Imaging Adoption Model

As the community continued to exponentially shine through their whitepapers and workgroups, its positive engagement with the healthcare and IT community prompted them to curate a **Digital Imaging Adoption Model (DIAM)** in support with the Society of Imaging Informatics in Medicine (SIIM), the European Society of Radiology (ESR), and the European Society of Medical Imaging (EUSOMII) [26]. Essentially, the DIAM is a strategic roadmap to digital imaging maturity and allows consumers to identify and adopt the right digital strategy and improve health outcomes for patients. In the complex and continuously evolving environment of hospital imaging departments and imaging centers, there is a distinct need to deliver medical imaging securely, through the right channel, with the right context, and at the right time to the person [26]. Furthermore, numerous changes from the move to value-based care and increased use of mobile devices are now impacting the way clinicians across the board utilize digital imaging.

4.5 Fostering Global Alliances and Partnerships

As illustrated by the variety of initiatives and workgroups shared in this chapter, many unique domains and topics exist within health informatics. The creation of various specialized communities enables the mobilization of the entire

healthcare workforce to improve patient care through technology and informatics. Aspiring and experienced (health) informatics professionals have the opportunity to contribute to the development of resources and collaborate with global SMEs and stakeholders from various disciplines from around the world. By partnering with outside organizations, the work accomplished by community members can then be leveraged for use across the global healthcare ecosystem.

In addition to collaborative projects discussed previously (e.g., EU*US eHealth Work Project, HIMSS-SIIM DIAM), HIMSS has fostered informatics workforce development by partnering with other organizations to co-create resources and drive impact on a broader scale.

4.5.1 TIGER's Partnerships with Academic Institutions

Notably, TIGER has established memorandums of understanding (MoUs) with leading academic institutions around the world to develop courses, seminars, and workshops:

- National Yang Ming University (Taiwan)
- University of Texas at Arlington's Multi-Interprofessional Center for Health Informatics
- National Autonomous University of Mexico

These partnerships aim to support the global expansion of informatics education and knowledge for learners and educators of all levels. Forthcoming co-created courses will leverage TIGER's resources and competency recommendations derived from TIGER's recommendation frameworks tied to competency attainment. All offerings are aligned to certificates of completion.

4.5.2 HIMSS Europe Nursing Informatics Community

Similarly, HIMSS' Nursing Informatics' European counterpart, known as HIMSS Europe Nursing Informatics Community, was launched in 2019 in collaboration with the International Council of Nurses and Finnish Nurses Association with the goal of "supporting nursing professionals from across Europe with resources required to lead the next wave of digital healthcare transformation" [27]. This partnership was made possible with HIMSS' Partner Innovation Exchange (PIE) program, bringing together professional organizations, providers, non-profits, and academic institutions [28].

The HIMSS Nursing and Midwifery (England) Informatics Community, which falls under the HIMSS Europe Nursing Informatics Community, also launched in 2019 to bring together existing United Kingdom (UK) networks and combine the professional expertise of local nurses and midwives [29]. The Community aims to share best practices, improve information technology that enhances nursing and midwifery workflow and promote patient safety by focusing on "digital confidence rather than digital competence" [30]. Furthermore, by connecting the digital dots in the UK's nursing and midwifery ecosystem, the Community enables the creation of one unified voice to "influence national and regional digital strategy" [30].

4.6 Informatics and COVID-19

Although the need for a competent informatics workforce in healthcare has grown exponentially in the last decade, the COVID-19 pandemic has accelerated such necessity across all disciplines.

In 2021, in a context where the global shortage of nurses has worsened, the HIMSS Europe Nursing Informatics Community published demands for more significant investment to ensure nurses' professional and technological development. These demands include [31]:

- **Nursing informatics education**
  - "*Include informatics as a required specialty;*
  - *Update nursing curricula with mandatory nursing informatics educational courses and training in the higher education level.*"
- **Incorporating the role of chief nursing informatics officer**

- "*Introduce national advanced nursing informatics training schemes to onboard CNIOs for newly opened positions at health and care organizations.*
- *Impose digital nursing strategy to ministries of health and where appropriate, local and regional health authorities to be developed in collaboration with respective nursing associations*."
- *Launch higher education programs for undergraduate and postgraduate specialization in nursing informatics or incorporate the science of nursing informatics in existing health administration informatics, public health administration and related academic programs*.
- *Enable nursing-led hackathons and support nursing innovation by securing patents and training in application to patents as well as public or private investment in piloting nursing-led solutions*"

The need to support nursing innovations is also echoed in the National Academy of Medicine's "The Future of Nursing 2020–2030: Charting a Path to Achieve Health Equity" report [32]. Notably, the report recommends that "all public and private health care systems incorporate nursing expertise in designing, generating, analyzing, and applying data to support initiatives focused on social determinants of health and health equity using diverse digital platforms, artificial intelligence, and other innovative technologies" [33]. Examples of nursing-led initiatives created in light of COVID-19 include the use of standardized nursing terminology to help advance health care, knowledge discovery, and responsiveness to COVID-19 [34].

Furthermore, the growing nursing shortage and workload associated with the COVID-19 pandemic has highlighted the shortcomings in ensuring nurses' health and wellbeing [32]. Similarly, other health care professions, such as physicians, will also be facing similar shortage and wellbeing challenges in the coming decade [35].

Therefore, addressing healthcare professionals' burnout, psychological safety, and wellbeing, especially in resource-limited regions, is essential. Ultimately, the wellbeing of these critical workers will affect the quality, safety, and efficacy of the care they provide [32]. Information technology solutions have been identified as both a burden and a solution to clinician burnout. For instance, the use of electronic health records (EHRs) with low usability scores has also been associated with both increased nurses' and physicians' professional burnout [36, 37]. In addition, the nursing survey revealed that most nurses are excluded from hospital technology design or decisions [36]. Therefore, the nursing voice needs to be amplified to ensure that the technologies on which they depend to provide care delivery meet their needs [36]. Conversely, digital health tools, such as online diagnostics and symptom checkers, virtual nurses, professional workflow technologies, and intelligent workforce management information systems, have emerged as solutions to help alleviate nurse burnout [38].

The pandemic has also disrupted healthcare students' ways of learning with the use of a variety of learning platforms. The future healthcare workforce would benefit from "learning platforms that encourage flexible and interactive learning," as well as teamwork tools that enable efficient collaboration, data-sharing, and "data control in research and academic capacities" [39]. For instance, digital learning solutions, such as TIGER's Virtual Learning Environment (VLE), offer dynamic micro-courses and resources that learners of all levels can leverage. Furthermore, through the Informatics Educators Resource Navigator (IERN), integrated within the TIGER VLE, TIGER seeks to support informatics educators who are getting lost trying to navigate and understand a field that is so rapidly changing.

Informatics tools, such as real-time data analytics, secure messaging, and telemedicine, have become critical in helping combat the COVID-19 pandemic [40]. These emerging technologies have reinforced the need to strengthen informatics skills. Developing a competent, interprofessional workforce will enable all disciplines to be represented and contribute to the informatics ecosystem.

4.7 Conclusion

The ever-increasing use of electronic healthcare solutions has led to numerous exciting career opportunities within the health informatics field in the last decade. The COVID-19 pandemic has also aggravated shortages of healthcare professionals and increased our reliance on virtual solutions, yielding an even greater demand for a competent informatics workforce. Associations, such as HIMSS, aim to "reform the global health ecosystem through the power of informatics and technology" with numerous initiatives [11]. Aspiring professionals and educators from around the world have the opportunity to leverage various resources and tools from the TIGER initiative to advance their skills or to develop curricula based on best practices. Professionals from the entire healthcare spectrum are encouraged to contribute to initiatives by following their passions. Notably, HIMSS members have the opportunity to serve as volunteer or community member for one of the numerous communities or task forces to benefit from peer-to-peer networking opportunities and exchange ideas on challenges and solutions that affect their region (e.g., D-A-CH (Germany-Austria-Switzerland), Dutch, French, Italian, Japanese, Nordic communities, etc.) or area of focus (e.g., education reform, nursing, imaging, health equity, innovation, physician, telehealth, etc.) [41]. Individuals of all levels of experience, disciplines, sectors (e.g., healthcare institutions, academia, industry, etc.) and countries can make impactful contributions in reimagining the future of health and informatics.

4.8 Links to Online Material

HIMSS Technology Informatics Guiding Education Reform (TIGER) Initiative
• **HIMSS TIGER Landing Page** https://www.himss.org/tiger
• **Health Informatics Guide** https://www.himss.org/resources/health-informatics
• **TIGER Informatics Definitions** https://www.himss.org/resources/tiger-informatics-definitions
• **TIGER Virtual Learning Environment (VLE)** https://www.himss.org/tiger-virtual-learning-environment
• **TIGER International Competency Synthesis Project** https://www.himss.org/tiger-initiative-international-competency-synthesis-project
• **TIGER Global Health Informatics Competency Recommendation Frameworks** https://www.himss.org/resources/global-health-informatics-competency-recommendation-frameworks
• **TIGER International Task Force Landing Page** https://www.himss.org/tiger-international-task-force
• For questions, please email: tiger@himss.org
HIMSS Nursing Informatics Community
• **HIMSS U.S./North America Nursing Informatics Community Landing Page** https://www.himss.org/membership-participation/nursing-informatics-north-american-community
• **HIMSS Europe Nursing Informatics Community** https://www.himss.eu/communities/nursing-informatics-community
• **HIMSS 2020 Nursing Informatics Workforce Survey** https://www.himss.org/resources/himss-nursing-informatics-workforce-survey
• **Chief Nursing Informatics Officer Job Description** https://www.himss.org/resources/chief-nursing-informatics-officer-job-description
• **Online Journal of Nursing Informatics (OJNI)** https://www.himss.org/resources/online-journal-nursing-informatics
• For questions, please email: informatics@himss.org
HIMSS Society for Imaging Informatics in Medicine (SIIM)
• **HIMSS-SIIM Enterprise Imaging Community** https://www.himss.org/membership-participation/himss-siim-enterprise-imaging-community
• **HIMSS-SIIM Enterprise Imaging Community Landing Page** https://siim.org/page/himss_siim_wgp_inter
• **HIMSS-SIIM Workgroups** https://siim.org/page/himss_siim_workgroups

- **HIMSS-SIIM Collaborative White Papers** https://siim.org/general/custom.asp?page=himss_siim_white_pap
- **HIMSS-SIIM Webinars** https://siim.org/page/himss_siim_webinars
- **Journal of Digital Imaging** https://www.springer.com/journal/10278
- For questions, please email: enterpriseimaging@himss.org

Other Online Material

- **HIMSS Resource Center** https://www.himss.org/resources-all

Questions and Answers

1. Which resource should a learner leverage if they wish to expand health informatics knowledge and skillset in a self-paced format?
   (a) TIGER Informatics Definitions
   (b) Health Informatics Guide
   (c) TIGER Virtual Learning Environment
   (d) TIGER Global Health Informatics Competency Recommendation Frameworks

   Answer c. As shown in Fig. 4.1, the TIGER Virtual Learning Environment is an online learning platform offering a personalized learning experience to expand knowledge and skillset in a self-paced format.
2. Which nursing domain is not included in Recommendation Framework 1.0?
   (a) Nursing management
   (b) Clinical nursing
   (c) Nursing education
   (d) Quality management
   (e) IT management in nursing

   Answer c. As shown in Fig. 4.2, the nursing domains in Recommendation Framework 1.0 are clinical nursing, nursing management, quality management, IT management in nursing and coordination of interprofessional care.
3. Which of the following is false regarding the 2020 Nursing Informatics workforce survey?
   (a) The percentage of respondents who obtained a master's degree or PhD in nursing informatics decreased in 2020 compared to 2017.
   (b) 41% of nurse informaticists work in organizations that have a formal CNIO or other senior nursing informatics officer.
   (c) Over two-thirds of respondents work for a hospital or multi-facility health system.
   (d) The number of respondents with certificates in nursing informatics increased between 2017 and 2020.

   Answer a. The percentage of respondents who obtained a master's degree or PhD in nursing informatics increased to 37% compared to the 31% of respondents who achieved the same degree in 2017. The other statements are true.
4. Which of the following is not an activity of the HIMSS-SIIM Enterprise Imaging Community?
   (a) Webinar series
   (b) Publication of white papers
   (c) Networking
   (d) Membership outreach
   (e) Mentorship program

   Answer e. As shown in Fig. 4.4, the HIMSS-SIIM Enterprise Imaging Community offers webinar series and networking opportunities, publishes of white papers and participates in membership outreach activities. There is no formal mentorship program.
5. Which of the following statements is false?
   (a) The shortage of nursing professionals is expected to decrease in the coming decade.
   (b) Studies have shown an association between electronic health record (EHR) usability and professional burnout among US physicians and nurses.
   (c) Digital health tools could help alleviate nurse burnout.
   (d) Students can benefit from learning platforms that encourage flexible and interactive learning.

   Answer a. As described in the "Informatics and COVID-19" section, the shortage of nursing professionals is expected to increase in the following years. The other true statements are mentioned in the same passage.

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5 Preparing Clinicians and Patients for the Future of Virtual Medicine and Telehealth

Bridget C. Calhoun

Abstract

Telehealth and telemedicine used to be a small, specialized niche within the larger healthcare industry. Areas of medicine that were particularly conducive to this provision of healthcare involved patient:provider interactions that relied more heavily on the medical history and inspection, rather than auscultation, palpation and percussion of body parts. The COVID-19 pandemic, and associated social distancing recommendations, forever changed the healthcare landscape in 2020, and dramatically increased the utilization of telehealth/telemedicine. As consumers of healthcare, patients are now far more willing to participate in telehealth visits that can be conducted within the confines of their own homes, when appropriate. During the 2020 COVID-19 pandemic, the added feelings of safety and security felt at home, often outweighed the anticipated challenges with technology. Today, patients with chronic conditions are likely to have several pieces of equipment at home that can help facilitate telehealth visits and provide clinicians with objective patient data. Equipment such as a scale, blood pressure cuff, and pulse oximetry, glucometer and spirometry can provide clinicians with helpful information and contribute to important aspects of the healthcare visit, even when it is conducted remotely. In our current digital world, clinicians must be proficient with technology, knowledgeable about HIPAA compliant platforms and skilled in employing health informatics.

Keywords

Telehealth · Telemedicine · Technology
Virtual visits · e-health · Patient portals

Learning Objectives

- Describe how the pandemic changed the delivery of telemedicine.
- Explain what patients need at home to facilitate telemedicine.
- List some milestones in the history of telemedicine.

5.1 Introduction

Telehealth and telemedicine technology used to be limited to a small subset of medicine. What was once thought of as futuristic, is now a relatively common way to deliver healthcare. Recent events including the COVID-19 pandemic, and advancement and widespread availability of

B. C. Calhoun (✉)
John G. Rangos Sr. School of Health Sciences, Duquesne University, Pittsburgh, PA, USA
e-mail: calhoun@duq.edu

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technology, has expanded utilization of telemedicine into disciplines that weren't originally thought conducive to it. As the provision of healthcare changes, so must the education of current and future healthcare providers [1–3]. We need clinicians who are fluent in the languages of both medicine and technology. We need clinicians who can quickly adapt to expanding digital worlds, while still providing high-quality, patient-centered healthcare. Worldwide, there have been modifications to the training of future healthcare providers and simultaneous training opportunities for the current workforce. Collectively, these activities have allowed patient care to continue in highly efficient ways, even when patients and providers are in physically distant locations.

5.2 Background

The use of informal professional consultations via phone were quite common prior videoconferencing capabilities. Clinicians could seek assistance from other clinicians by simply calling them, but such communication was often delayed, consulting physicians had no way to bill for their services, and the overall model was deemed inefficient.

Some of the earliest visionaries in the field of telehealth identified the benefits of having videoconferencing capabilities within small, rural community-based hospitals that could be used to communicate with specialists and subspecialists who were physically located at different facilities, and often employed by large, academic teaching facilities in urban settings. Simultaneously, forward thinking clinicians realized that telehealth could be used in the home and other settings, by utilizing a telephone and/or personal computer. These two situations of innovative thinking launched today's prolific use of telehealth. For the purposes of this text, telemedicine and telehealth will be used interchangeably.

Initial use of consumer-based telehealth in the early 1990s included patient assessments which did not involve many components of the physical examinations. Assessments that were limited to history-taking and inspection, without the need for palpation, percussion or auscultation, could effectively be performed via distance [4]. Psychotherapy for example, was particularly conducive to this form of patient:provider interaction.

The acceptance of patient portals as a repository for medical records that were easily accessible helped pave the way for subsequent advances in telemedicine. The ability to correspond with clinicians electronically, via email, provided patients with added accessibility to those providing their care. The utilization of patient portals as a means to communicate with physicians or therapists provided confidence and reassurance that such email communication was secure and trustworthy. Logging onto the patient portal allowed patients to see components of their medical record, and independently, they could review results of diagnostic tests, submit requests for medication refills, and schedule appointments. One driving force for this was to improve patient satisfaction, and patients initially responded favorably. By 2017, approximately 90% of providers were offering patient portals as a service to their patients. Since the inception of patient portals, there have been conflicting studies about whether or not the activity of emailing clinicians via patient portals has led to fewer or more clinic visits. One consistent finding is that patients with higher out-of-pocket expenses are more likely to email providers.

Another important milestone in the field of telehealth was the availability of electronic prescription writing (ePrescribing) in 2003. This technology allowed for a more secure process of medication distribution by allowing communication directly between the prescriber and dispenser. Electronic prescription writing continued to gain popularity and broader adoption by both clinicians and patients. Patients in need of prescriptions didn't necessarily have to be seen in person, provided the medical practice had software capabilities to send electronic prescriptions to pharmacies.

The discipline of behavioral health led the way for telehealth throughout the mid 2000s. Not only were visits for common behavioral health conditions such as depression and anxiety an appropriate use of this technology, but the laws related to the prescribing of controlled substances also contributed to its popularity. For example, children or adults who are prescribed stimulants for Attention Deficit Hyperactivity Disorder (ADHD) often require a new prescription every 3 months. These clinic visits, which must occur four times per year, allow for a review of the patient's symptoms and an evaluation about how well the symptoms are controlled on the current dose of medications. Typically, the physical exam is limited to surveillance for side effects of the stimulants such as hypertension and weight loss. Patients are able to self-report weight, and in many cases, self-report blood pressure, perhaps after recently taking it at the grocery store, or recording at home with their own blood pressure cuff. Such interactions can easily and efficiently occur via videoconferencing, with a secure ePresciption sent immediately following the visit.

Nationwide adoption of telemedicine also reflected the broad demand by consumers, particularly among men who were interested in getting a prescription to treat erectile dysfunction. The evaluation that was indicated prior to prescribing sildenafil (Viagra), the first of the phosphodiesterase inhibitors, relied heavily on the medical history and little in terms of physical examination. Since many households had personal computers at the time, business-savvy physicians were establishing online practices that would permit the evaluation of men with erectile dysfunction and the subsequent prescribing of appropriate treatment. These practices had great potential and were lucrative. Physicians could dramatically expand their pool of patients, provided such visits were within the legal parameters and scope of practice of individual state boards of medicine.

In clinical-based or hospital-based telemedicine, advancements in technology soon permitted the capture of patient data in the form of pictures of skin lesions/wounds, or sounds of the heart or lungs into audio files, that could be shared digitally from one clinician to another. There were logistical and fiscal challenges with these advances. Specifically, questions were being asked such as: were the shared video and audio files secure and could patient confidentiality be ensured? Were the files being retained in secure formats? Were breaches of confidentiality possible, or even likely? Could remote physicians bill for their consultative services?

5.3 Security and Privacy

Interactions with patients, whether they occur in-person or remotely must demonstrate privacy compliance of patient data as well as data security. This requires a deep and thorough understanding of what protected health information is, and how it is effectively protected. The 1996 Health Information and Privacy and Affordability Act (HIPAA) was designed to modernize the protection of health-related information and safeguard patient privacy. Since then, there have been updates including the HIPAA Privacy Rule in 2003, the HIPAA Security Rule in 2005, the HIPAA Breach Notification Rule in 2009, and the Omnibus Final Rule in 2013.

Telehealth complicates data security. Health systems and physician practices must ensure that when patient data is transmitted, it is fully encrypted. Knowing that telemedicine visits are often recorded, the healthcare industry must now consider how the recording is to be retained, and how patient privacy is maintained. Additional consideration must be given to how hospitals, clinics and physician practices can provide data security for the long-term, while still making patient records accessible to those who should have access now, and in the future. All healthcare facilities and physician practices must demonstrate "good faith efforts" in protecting medical related data. One important component of HIPAA compliant software is that it secures health protected information from hackers, or anyone external to the institution. Additionally, the software is to include breach notification systems, so in the event of a breach, appropriate measures

can be taken to contain the breach. One of the biggest challenges with HIPAA compliant software is the need to protect information from employees who may have access to it, but aren't legally entitled to it.

Federal law requires health systems and institutions to comply with all patient privacy and confidentiality regulations. As such, internal audits are required so organizations can preemptively identify vulnerabilities in their software platforms and data security practices. Health systems must ensure that they have secure messaging and secure recordings during patient:provider visits, whether they occur in person or remotely. Additionally, when video files, audio files and/or digital images (such as photographs acquired during the visit) are uploaded onto a cloud, data storage must be secure there as well.

5.4 Telemedicine Education

In order to have synergy among the members of the healthcare team, all members must have some training and appropriate exposure to telehealth equipment, and a strong comprehension of how visits will be conducted. In some ways, the preparation of physicians and mid-level providers who are diagnosing and treating remotely will be different than the nurses providing patient education, and the physical therapist leading clients through therapy and rehabilitation. But, it is important to appreciate that many of the founding principles of patient engagement transcend individual disciplines.

Canada and other technologically-advanced countries have embraced and advanced telehealth in an organized and comprehensive way. Within Canada, there was a concerted effort to train physicians, nurses and pharmacists so that each would become proficient in the practice of telehealth and collectively, they would be a better prepared generation of healthcare providers [5]. The Association of Faculties of Medicine of Canada established a program in 2011 which was to improve clinical practice by helping medical students and resident physicians in their use of digital health technologies [5]. The Canadian Association of Schools of Nursing worked to establish a culture within nursing education to integrate nursing informatics and professional practice [5]. The product of this initiative was a list of Nursing Informatics Entry-to-Practice Competencies for Registered Nurses. The Association of Faculties of Pharmacy of Canada worked to better prepare pharmacy students to work within technology-enabled environments related to the use of digital health, curricular design and educational processes.

The American Association of Medical Colleges (AAMC) has recognized the need to better prepare future physicians for providing virtual care. Prior to 2019, there was not an emphasis on telemedicine and telehealth in the curriculum for physicians. Nor was there an emphasis in the education of nurse practitioners, physician assistant, physical or occupational therapists or speech pathologists.

The COVID-19 pandemic served as an impetus to modernize medical and nursing education. In many cases, student rotations were canceled due to the need to de-densify patient care environments and to protect students from becoming infected with SARS-CoV-2, which is the causative organism of COVID-19. This abrupt and inconvenient disruption in medical and health sciences education forced universities to modify existing curricula and incorporate more telemedicine into training programs. Universities had the responsibility to provide opportunities for students to develop valuable skills in the field of telemedicine. Many training programs quickly created formal rotations in telemedicine that didn't exist in the past. Remote patient encounters satisfied training requirements so students could immediately apply instructional information into experiential learning for academic credit. It is likely that medical schools and health sciences training programs will retain the newly created telemedicine rotations, even when the COVID-19 pandemic is over.

Currently, the AAMC is attempting to universally improve the preparation of future physicians by developing competencies for telemedicine. Once these competencies are established, they will be integrated into the curricula in all medical schools in the United States.

5.5 Telemedicine Models

In the last two decades, telehealth has continued to advance, and now can be stratified into three distinct models:

1. Individual patients interacting with clinicians or therapists from their home. This model is referred to as **home-based telemedicine**.
2. Urgent evaluation of acute problems by a clinician who is not the primary care provider. This most similar to an in-person urgent care evaluation, but for problems that can be assessed and managed without diagnostic studies such as poison-ivy, conjunctivitis, tinea infection of the skin, urinary-tract infection, upper respiratory conditions and cellulitis. This model is referred to as **ambulatory-based telemedicine**.
3. Interactions between clinicians of one healthcare facility who are assessing a patient, and consulting in real-time with an expert at a distant location for an opinion. This model is referred to as **facility-based or hospital-based telemedicine**. A second type of facility-based telemedicine can involve Interactions between staff of a health facility, such as a long-term care facility and getting guidance and treatment orders from a clinician at a different physical location, such as after-hours or when the clinician is on-call. Such assessments and interventions occur in real-time. An example of this involves a long-term care facility that doesn't typically have a physician on-site all the time, but may need a prompt evaluation of one of the residents of the facility. Typically, the necessary evaluation goes beyond what can be discussed over the phone.

The ultimate goal of all of these models is to increase access to high-quality care in a time-efficient manner. Regardless of which of these models clinicians will be working in, the fundamental principles remain the same. Clinicians must collect as much information as possible, establish rapport in order to maximize the sharing of information, comply with all HIPAA laws and accurately document the encounter in the medical record.

5.6 Consent Procedures

Patients must provide consent for treatment regardless of whether the care is provided in person or remotely. Traditionally, this is in a written form, and completed during each appointment with a healthcare provider. For virtual settings, obtaining consent for treatment can be done with the digital exchange of signed documents in advance of the visit. The procedure for obtaining digital consent in advance of the visit can be particularly helpful for patients with low literacy, poor vision or other conditions that may require them to have assistance from a family member or caregiver. There are times when verbal consent can be given, however, verbal consent requires a witness. It has been proposed that digital consent forms are better secured than the traditional paper forms used during in-person visits, and therefore some facilities obtain the signature for consent electronically, even when the healthcare visit occurs in person.

Since the importance of strong communication in healthcare has been well-established, it is recommended that clinicians don't view digital consent as a replacement for a conversation about consent to treat. Clinicians must remember that informed consent is a process, and not just a form to be signed. This is particularly true when clinicians are consenting patients for a future invasive procedure. The process of obtaining informed consent must still include a discussion of why a procedure is being performed, what the procedure is, potential risks, potential benefits as well as any alternative treatments. This conversation should also include how treatment will evolve, if appropriate.

5.7 Reimbursement

Healthcare in the United States is disproportionately funded by Medicare, Medicaid, dual Medicare-Medicaid plans, Medicare Advantage and the large commercial health insurance plans. Regardless of the funder, the reimbursement for physician services is determined by the length of the visit, the extent of the assessment, and the

complexity of medical decision making. This architecture holds true in the virtual world as well. Visits are coded by diagnosis, evaluation and management and/or procedures and subsequent billing reflects the substance of the visit in its entirety. The Center for Medicare and Medicaid Services (CMS) is one of the primary driving forces in terms of reimbursement for healthcare. The physician fee schedule used for providing remote healthcare has gone through several revisions, which includes revisions for telehealth visits. Telemedicine visits are not reimbursed at the same rate as in-person visits, and it would behoove clinicians to become familiar with the appropriate fee schedule in advance to conducting virtual visits [6].

In the mid 2000s, most Medicaid programs provided some coverage for telehealth services. Since 2020, all individual state Medicaid programs provide coverage for telehealth services. Growth of telehealth services is closely monitored by the CMS. The COVID-19 pandemic forced rapid utilization of telehealth and the CMS reported a 63-fold increase in telehealth services in the time period of March 2020 through July 2020, compared to use from March 2019 through July 2019 [7].

The Coronavirus Preparedness and Response Supplemental Appropriations Act (CARES Act) served as an important milestone and advanced the field of telemedicine. The CARES Act expanded the list of eligible services that have been approved to be delivered via telehealth. Public Law No. 116-136 (March 27, 2020). The website for the Centers for Medicare and Medicaid Services (CMS) is a valuable resource and provides the most up-to-date information. The CMS is not just valuable resource for coders and billers, it is a site that is beneficial for clinicians too [6].

As clinicians are expanding their knowledge of telemedicine, they must also be aware of professional practice issues such as, what are the laws about treating patients across state lines via telehealth? In response to the COVID-19 pandemic many states have loosened or eliminated restrictions for practicing medicine across state lines, but it is currently unknown when those restrictions will be reinstituted. Clinicians must also be informed about their current malpractice insurance and whether or not it covers virtual visits, and if so, to what extent does it provide coverage.

5.8 Home-Based Telemedicine

Telehealth and telemedicine technology have many attractive aspects including patient and clinician safety, prompt attention to acute medical issues and the elimination of travel time to the visit. Patients with underlying conditions that increase their susceptibility to infections allows them to remain in the safety of their own home, thereby limiting exposure to other people and outside environments. Patients may also have physical limitations that could make in-person visits more challenging. For example, for patients who are wheelchair dependent, showing up in person for a brief, 10 min clinic visit for a routine medication refill assessment may not be the best use of time. There is also a cost-benefit for these patients if they can switch to a virtual visit. Benefits may be in the form of decreased costs since they do not have to invest money into transportation, parking or bus fees.

When conducted in the patient's home, telehealth visits allow the clinician to have a small glimpse into the living environment. Clinicians can take advantage of this opportunity and potentially identify hazards in the home, such as someone smoking when a patient is on supplemental oxygen or the presence of multiple pets in the home when treating patients for environmental allergies. In emergent situations, the clinician may be able to contact emergency medical services while staying in contact with the patient and providing necessary guidance and instructions.

The Veterans Administration is a leader in home-based primary care programs, which encompass primary care, preventative care, urgent care and/or palliative care. Home-based primary care programs pair patients with providers who evaluate the patient on a regular basis. One of the greatest advantages of this model is

regular assessments that can promptly identify changes in health status. Ideally, these regular assessments can lower overall healthcare expenditures by promptly addressing problems, before complications arise and decrease the need for evaluations in emergency departments. This model works particularly well for chronic disease management. Conditions such as congestive heart failure, asthma, hypertension, generalized anxiety disorder, attention deficit and hyperactivity disorder are particularly fitting for this type of care. The monitoring and management of these common problems require periodic assessments which can be performed remotely, and interspersed with in-person visits when a more extensive physical examination can be performed. This model also allows for continuity in care and the establishment of long-term relationships between patient and provider, which can lead to improved patient outcomes and patient satisfaction. Regularly occurring visits also allow for preemptive monitoring such as an increasing blood glucose level that doesn't yet meet the criteria for diabetes mellitus and is amenable to modifications in the diet. Examples such as this demonstrate how frequent monitoring of patients with chronic conditions can decrease hospital admission and readmission rates.

Healthcare personnel who may be involved in home-based primary care programs include physicians, nurses, physician assistants, nurse practitioners, social workers, therapists, pharmacists, emergency medicine technicians and therapists.

While extremely beneficial to some, in-home assessments may be more difficult for others. There was initial concern that those with of lower socioeconomic status would be significantly disadvantaged in the form of *access* to healthcare as the utilization of telemedicine expanded. Specifically, there were concerns about the individual or family that did not have computer access or reliable connectivity. Thankfully, modern cell phones have full capabilities for a virtual healthcare visit, so those concerns have been minimized. Telemedicine may continue to improve access to healthcare as those with lower socioeconomic status and limited transportation don't have as many barriers.

Reasonable concerns still exist about the patient of advanced age, who is likely is afflicted with multiple age-related medical conditions, and/or who fears or struggles with current technology. Among healthcare providers, there is a common concern for the "invisible homebound", referring to a subset of the population who are not seeking regular healthcare, but who were probably in need of care. These individuals may be homebound due to immobility, low endurance, physical limitations, poor cognition, etc. Unfortunately, it is often something catastrophic that gets these individuals to seek care. Home-based primary healthcare is a way to prevent more individuals to becoming among the "invisible homebound".

Now that more medical practices are equipped to conduct telehealth visits, and more clinicians are skilled with remote patient interactions, it is predicted that telehealth visits will continue to increase in popularity. The COVID-19 pandemic illustrated the benefit of telehealth in terms of the safety of the healthcare workforce. Frontline workers, including healthcare employees, are at an increased risk for communicable diseases. Allowing for remote patient:provider interactions removes the possibility of infection acquired from the patient, whether it be something as familiar as the common cold, or something as potentially life-threatening as COVID-19.

During the height of the COVD-19 pandemic, there was particular fear of exposure to the virus by pregnant mothers. This provided more further expansion of telemedicine to this patient population. During these visits, expectant mothers could self-report their weight and be instructed to measure the fundal height, which is the size of the uterus which corresponds to the fetal development. The measurement is recorded at the top of the pubic symphysis to the top of the uterus. This measurement is part of the physical examination for every expectant mother and patients can be taught to take this measurement by using a standard tape measure found in the home. Other important components such as the blood pressure and assessment of lower extremity edema can be performed as well. Patients can report their symptoms and advice given by the clinician.

Discussing the details of the birth plan could also be discussed without the mother leaving the safety of her own home.

5.9 Ambulatory-Based Telehealth

The convenience of urgent care centers has been demonstrated by the rapid growth of urgent care facilities. There are approximately 10,000 urgent care facilities in the United States, which represents a growth of 50% since 2013. In some cases, urgent care needs can be appropriately addressed in virtual arenas. Patients can be evaluated and treated in very time efficient manners. The ability to be evaluated by a healthcare provider for urgent conditions from the home is highly attractive and there are many conditions that this is appropriate for. Presumptive diagnoses for common conditions such as urinary tract infections, conjunctivitis, cellulitis, fungal skin infections, poison ivy, etc., can be made without the need for diagnostic tests and thereby are effectively managed in an outpatient setting and eliminate the need for the patient to physically travel to the clinic. If the presenting problem is emergent or more serious and requires immediate intervention, the patient can be promptly referred to the local emergency department for appropriate care.

5.10 Technology

Patients participating in telemedicine visits must have access to a device that has a camera and compatible audio. The patient must also have proficiency using the device. If not, it is ideal to have someone with the patient who can assist and troubleshoot when necessary. It is helpful when patients can anticipate challenges in connectivity and even practice in advance maneuvering through the system or operating the system. Use of a device with a larger screen is ideal, but many patients are able to participate in a virtual visit using just a cellphone. In some cases, patients may have medical equipment in the home that can be used during a telehealth visit, when that is the case, patients should be told to have the equipment ready and ensure its working properly before the visit.

5.11 Orientation for the Visit

In advance of the visit, patients should be given some basic instructions about how to log on, how far in advance of the visit they should log on, and what the screen will look like when they successfully connect. Patients should also be told how long the visit is expected to last and what, if any equipment or records they should have on hand. Specific details related to the reason for the visit should also be shared. For example, if a patient has hypertension, they should be instructed to have their list of daily blood pressure recordings on hand as well as their blood pressure cuff. If a person performs fingerstick glucose testing, they should have the daily results ready to share. Regardless of the reason for the visit, patients should have a list of current medications on hand. In some cases, it is appropriate to perform medication reconciliation which is when together, patients and providers count pills as a way to monitor compliance with medications. Therefore, patients should know if they need a list of medications, the actual medications or both for the visit.

Clinicians should be as prepared as possible by reviewing each patients' chart in advance of the visit. Ensuring that the chart is complete with results of any diagnostic testing or medical imaging that was performed is crucial to making the visit run as efficiently as possible.

5.12 Performing the Visit

Telemedicine visits should be conducted as similarly as possible to in-person visits with regard to demonstrating respect to the patient. Clinicians should dress in a similar way to how they dress for in-person visits. The environment of the clinician should be quiet with minimal background noise and no distractions. Clinicians must also remember to keep these conversations as private

as possible, eliminating the chance that others can overhear the conversation/interaction. Many clinicians prefer to wear a headset during telehealth visits as a way to maintain privacy. If clinicians are participating in telehealth visits from within their own homes, they are expected to find a quiet area where they will not be interrupted.

In order for patients to continue to embrace telemedicine, clinicians must be intent on demonstrating respect and maintaining all privacy and confidentiality laws. Similarly, when the visit is underway, the clinician must be aware of anything that can impact the privacy of the visit, such as a family member, household guest or delivery person in the background.

It is understandable that clinicians may question their ability to establish a rapport with a patient when the visit is conducted through a computer screen. Clinicians are reminded that good rapport begins with a personal introduction, clear speech at an appropriate rate, language that is understandable by the patient and good eye contact. Fundamental principles of verbal communication remain the same whether the visit is in-person or remote. Clinicians must be attentive and not interrupt the patient when he/she is speaking and demonstrate good listening skills.

Non-verbal communication is also important during virtual visits. Consistent eye-contact throughout the visit, a comfortable, but not too causal body position is recommended. Clinicians should be aware of facial expressions they make and understand how they may be perceived by a patient.

Like most visits, the clinician must first get the chief complaint, or reason for the visit. For new patients, this may take extra time, but for established patients, this may become routine. Either way, the clinician must collect relevant information about the health concern, condition or compliant. The clinician should be patient and attentive while collecting this information. During the visit, it is advised that the clinician have real-time access to the patient's electronic medical record. Ideally, the clinician's workstation will have two monitors: one to visualize the patient, and the other to visualize the patient's electronic medical record (EMR). It is not unusual for the clinician to toggle back and forth between the EMR screen and the one with the patient. This may be confusing for the patient as it may appear the clinician is reading the screen, or distracted by something else. The clinician should inform the patient that a second screen is being used in order to have the patient's medical history and test results readily available.

For new patients, the introduction is very important. Many medical practices and facilities require the clinicians to wear their nametags and ensure they are visible to the patient during a telehealth encounter. Clinicians should know the rules of their employer before conducting these visits. This is particularly important for physician assistant, nurse practitioners and other non-physicians. The patient should be clear what type of clinician they are seeing, and there should be no assumptions that telemedicine visits are performed exclusively by physicians.

Clinicians have always been trained to optimize their observational skills, but this is particularly important during virtual visits when important patient data will be gathered verbally and by observation. Clinicians must be particularly attentive to the patient's verbal communication, including voice quality, rate of speech, choice of words, descriptors used for medical complaints, and coherency of speech. Similar attention must be paid to non-verbal cues including posture, emotional responses, facial grimacing, eye-contact, etc. Other subtle signs may be evident to the clinician during the visit such as the patient with decreasing visual acuity trying to get closer to the screen or the person with decreasing hearing acuity asking the clinician to repeat things. Seeing the patient in visible distress may even require the dispatch of emergency personnel to the home.

Evaluating patients in their home environments can also provide insight to how well, or how poorly their physical space supports their current medical condition and medical needs. Is the home clean or cluttered? Are there fall hazards? Is there appropriate lighting and temperature control based on how the person is dressed? If a person is having to administer their own injections, there should be good lighting. If a per-

son is having to change their own dressings, there should be a clean area to do that.

Clinicians should encourage the patient to take notes during the visit so they can reference them later or share the details of the visit with family members or caregivers. Clinicians should have patient education materials that can be shared with the patient during the visit and emailed to the patient after the visit.

Patients should be asked if anyone else is present for the visit and for patients with chronic conditions, it is often helpful to know what role this person plays in the patient's life.

5.13 Physical Examination

Clinicians use a combination of four different techniques to perform a physical examination. Inspection, auscultation, percussion and palpation are used to identify abnormalities in body systems. The various components of the physical examination are more important for some body areas than others. For example, examination of the skin requires inspection and palpation rather than auscultation. However, auscultation is a crucial component in the examination of the lungs.

In addition to what is observed clinicians can also utilize any home medical equipment that may assist in parts of a physical examination. Common items may include blood pressure cuffs, a scale, pulse oximetry and a thermometer. Patients with chronic conditions will likely also have equipment unique to their diagnosis. For example, patients with asthma should have spirometry and patients with congestive heart failure should have been given a prescription to get a pulse oximeter, in many states, patients may be permitted to purchase them without a prescription, although having a prescription will likely lower the amount each patient will have to pay for it.

Throughout the visit, the clinician can inspection for many things including, jaundice, rashes, tremors, symmetry of the pupils, facial drooping, signs of active infection such as erythema, swelling or discharge/drainage from a wound or previous surgical site. Palpation describes the examination technique of physically touching the body. Obviously, palpation cannot occur during a telehealth visit. However, there are times when clinicians can ask for assistance from the patient for parts of examination that includes palpation. For example, if a clinician wanted to assess for pitting edema, which is performed by putting pressure on the skin of the lower extremity to see if a visible indention remains when the pressure is removed, the clinician can instruct the patient to do it and either describe the result or show the result to the clinician by adjusting the position of the camera. Similarly, if the clinician wanted to assess skin temperature of a specific area or whether pain or discomfort is elicited when an area of the body is touched, the patient can step-in and report the findings back to the clinician.

Throughout the visit, communication must utilize basic principles of simple language, repetition of important topics, use of anatomic drawings or other teaching strategies. When treatment is necessary, patients must be clear on what they are being treated for, and what the goals of treatment are. The teach back method, which provides patients with an opportunity to explain details from the visit back to the clinician as a way to demonstrate understanding, should be employed. If there are decisions that must be made, clinicians should follow best practices for shared decision making and provide ample time for patients to make decisions. At the end of the visit, the patient should be thanked and a final opportunity to ask questions or clarify information should be provided. Follow-up plans and contact information should be provided prior to disconnecting.

5.14 Other Utilization of Telehealth

Now that clinicians are more proficient at conducting telemedicine visits and patients are more inclined to participate in them, there will be other opportunities for utilization. For example, during times of Inclement weather, patients may prefer to have a virtual visit, if possible. If patients have unreliable transportation or limited mobility, they

may request virtual visits. For routine pediatric visits, when vaccinations are not being administered, children can participate in virtual visits and possibly lessen time away from school.

5.15 The Future of Telemedicine

In order to establish best practices, clinicians must optimize care while using modern technology. Clinicians will be further directed to make quicker and more accurate decisions to benefit patients. The future of telemedicine remains extremely bright. Future advancements in telehealth will likely involve the integration of artificial intelligence. Current telehealth requires the interaction between patients and clinicians, however, with advancements there may be more algorithms to help expedite the diagnosis and treatment of patients. The term "big data" is being used more and more often in the context of medicine. Data that are super-precise can be beneficial for any industry, and in healthcare, data that are super precise may help clinicians best treat patients, allowing for longer lives and improved quality of life. Artificial intelligence that can incorporate knowledge from scientists, researchers, clinicians and software developers can advance medical care. Using patient originated data, prognostic patterns can be identified and predictive algorithms can be developed to aid in prompt and accurate diagnosis and treatment. Data analytics within the healthcare industry provides endless opportunities to curate data whether derived from biological specimens, diagnostic procedures, prescribed medications, physical examinations, surgical outcomes, claim data, compilation rates, morbidity and mortality rates, etc. It is likely that telemedicine will continue to advance the broader field of medicine in ways we cannot yet imagine.

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Privacy and Security

6

Darren Lacey

Abstract

Privacy legal doctrines have changed substantially over U.S. history from property to notions of self-projection and autonomy. Privacy in information management includes several fundamental protections and responsibilities to be applied in nearly every legal privacy regime. The HIPAA privacy rule reflects privacy principles with some specific applications in healthcare. Information security is a distinct discipline with deep roots in the military and intelligence. The HIPAA security rule focuses on several major controls in physical and technical security. Security practice, however, requires deeper attention to evolving technologies. In recent years, security frameworks have increasingly focused on modeling threats and testing security controls against common threat scenarios.

Keywords

Privacy · Confidentiality · Integrity · Availability · Consent · Authorization · Encryption · Cipher · Threat · Firewall · Intrusion · Risk management

D. Lacey (✉)
Johns Hopkins University and Johns Hopkins Medicine, Baltimore, MD, USA
e-mail: dll@jhu.edu

Learning Objectives
Readers should be able to:

- Define and explain functional information management principles and concepts of privacy protection.
- Apply high level security theory to HIPAA security practice.
- Match high level security controls with emerging concepts in threat and risk

6.1 Introduction

The networked information technology revolution progresses unabated while evidence of its inherent insecurities continues to mount. Any server connected to the Internet is nearly certain to be scanned and prodded within hours of connection. New forms of malicious code—viruses, worms and spyware—are introduced daily. Vulnerabilities in major applications and systems are exposed at nearly the same rate. There are almost no limits to the speed, size and scope of cyber-attacks, and many of us have the uneasy feeling that the ensuing damage could be catastrophic. We fear that the Internet could come undone at any time—possibly from intentional attack or from the sagging weight of a remarkably complex communications system.

Yet so far, he Internet has proven surprisingly resilient. Whatever security concerns we might

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have, every major industry sector—including healthcare—has embraced computer technology and the Internet [1]. As other chapters in this volume illustrate, a new era in medicine is dawning, built on integrated delivery systems, electronic health records, telemedicine and improvements in diagnostics and decision support tools. Information technology has begun to transform medical care and public health in likely permanent ways, all in the middle of an insecure cyber-space.

As information systems became ubiquitous in the seventies and eighties, so grew a large and increasingly professional labor force and set of practices that together have formed what is now called health informatics. A few years later information security has seen much the same growth, including increasing specialization, a focus on data analytics and systems usage. And just as informatics grew organically out of the business needs of myriad organizations, information security practice has evolved largely from the bottom up. And it is in this context that we will discuss the role of security in health informatics and emphasize its complex relationship with privacy doctrine and changes in the health field.

6.2 Privacy

Advances in technology are usually followed by changes in the law, and few legal concepts have seen changes as dramatic as personal privacy. The rapid rise of information technology and the Internet has accelerated changes in many of our common conceptions of privacy. Just as older technologies such as photography and audio recording led to a contraction of the private space, more powerful and pervasive tools of cyber-space are diminishing personal privacy to the vanishing point.

Supreme Court Justice Louis P. Brandeis and attorney Samuel Warren raised concerns about privacy rights in an 1890 law review article, one of the most comprehensive and provocative cases on the topic to the present day [2]. Most of what has been written on privacy—before 1890 and since—has focused on the relationship of the individual and the state. Civil investigations, abortion laws and criminal search and seizure are examples of incursions, whether justified or not, by the government into the personal space of citizens. The arguments of the Brandeis and Warren paper are applicable in nearly any setting where privacy rights may be infringed, whether by the government or the actions of private third parties.

It is the non-government aspects of privacy, whereby individuals or organizations potentially violate the privacy rights of their neighbors, that were of particular interest to Brandeis and Warren and that are of interest today. It is here that we begin to understand the responsibilities that those outside of the government owe to the privacy concerns of patients, customers, and employees.

Throughout the eighteenth and nineteenth century, courts drew a clear distinction between public and private personae and their attached rights of privacy. One's private actions—those inside the home or office—were considered sacrosanct, and the courts disallowed reference to such actions in civil actions and greatly circumscribed what could be discussed even in criminal cases. Personal journals, notes, diaries and even letters sent under presumed confidence were generally seen as beyond the scope of legal discovery or publication by others. While the private realm received almost categorical protection in law, what one did or said in public received almost none. The distinction between public and private lives began to dissolve with increasing complexity in commerce: consumer and credit markets and professional services in law, medicine, and accounting, among others. It became apparent that few activities could be easily reduced to solely public or private selves, and traditional understandings of privacy, causing laws to lose force [3].

Brandeis and Warren attacked traditional theories of privacy on two fronts. First, they suggested that a traditional justification, "domestic setting," could not be sustained across a wide range of locations and circumstances in which private information could be recorded or disclosed. Second, they disputed the widely held belief that privacy violations were the result of

some form of trespass. Brandeis and Warren point to many cases where courts would prevent publication of personal papers even where there is no claim of trespass, thus suggesting that courts recognized in deed if not always in word how privacy protection had outgrown its foundations.

They contended that "trespass theory", whatever relevance it might have had in the past, would almost certainly undermine privacy claims in the future. They foresaw that "recent inventions" such as photography and sound recording would make possible surveillance without breach of property rights at all. They argued that as the realm of the observable grows, in practice the realm of privacy contracts. Rather than asking how certain information was originally obtained, the more fundamental inquiry should be on information content itself, that something inherent to word or deed may trigger privacy protection. A great deal of private information is disclosed voluntarily to all manner of individuals and organizations. Such disclosures are not "domestic occurrences," nor are misuse or disclosure the result of "trespasses." Should the mere fact that one discloses information to someone voluntarily say, a hospital or bank—negate all claims for privacy going for forward?

For all their objections to privacy doctrine of the time, Brandeis and Warren were unable to propose a well-thought out alternative. They presented an elegant turn of phrase by stating that privacy is, "the right not merely to prevent inaccurate portrayal of private life, but to prevent its being depicted at all" [4]. They understood this formulation could not be sustained in practice, and immediately started to backtrack with respect to public figures, political issues, etc. The simple fact is that an open and free society must allow for the occasional—and usually more than occasional—airing of private information. They knew this and struggled unsuccessfully to introduce a test that would balance privacy with other rights, like press, speech, and a general need to use some private information in commerce and everyday life.

Recent scholars have built on these ideas and several support privacy by appealing to contemporary sociological theories of identity [5]. In tribal or small agrarian societies individuals have numerous opportunities to make themselves known, to demonstrate through continuous interactions a nuanced picture of their character and personality. Today, our relative anonymity means we have a more difficult time succeeding in "impression management," putting individuals "in danger of being judged, fairly or unfairly, on the basis of isolated bits of personal information that are taken out of context" [6].

Under this view, the current state of privacy law is a dangerous muddle—not clear enough to predict results—yet with each new privacy "violation", expectations are reset, resulting in continuing diminution of our private space. To check this inexorable decline in privacy, Daniel Solove distinguished types of privacy and their sociocultural contexts, employing a functional matrix of information types and potential uses [7]. This approach is demonstrated in the current state of privacy regulations.

In the absence of clear direction from courts, federal and state legislative branches have become increasingly active in regulating privacy. The period of the last fifty years has seen a patchwork of federal and state privacy laws and regulations covering individual privacy rights and responsibilities of those collecting information. The first significant advances took place in the 1970s with passage of the federal Fair Credit Reporting (finance) and Privacy (government data use) Acts. These laws brought to fore standard ways of handling data, especially private data, and established an emerging set of requirements, the Fair Information Practice Principles (FIPP). Computer technology was addressed in the Electronic Communications Privacy and Computer Security Acts during the 1980s. Congress addressed privacy of library records, book purchasing and video rentals, and issues regarding research and academic freedom. Subsequent legislation addressed financial services (the Gramm-Leach-Bliley Act), business records (Federal Trade Commission and the European General Data Protection Regulation) and medical records (HIPAA). These laws recognize, in ways that common law does not, that private information is commonly disclosed for

many purposes and that the use of such information should be administered according to reasonable standards.

6.3 HIPAA and FIPP

Throughout the remainder of the chapter, security and privacy will be discussed in terms of the most important piece of legislation on the topic in the healthcare field, the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Public Law 104-191, Final Rule: 45 CFR Parts 160 and 164 (January 25, 2013)) [8]. HIPAA was enacted to simplify and standardize healthcare administration and in so doing facilitate greater portability of health insurance coverage for people changing jobs or experiencing other life changes. A persistent obstacle to health insurance portability has been inconsistent and conflicting coding and billing standards. Title II of HIPAA requires providers and insurers adopt standard code sets and methods for electronic interchange.

Since early in its legislation, questions have existed as to whether HIPAA standards, in assuring portability, would also undermine the privacy and confidentiality of patient records [9]. With all records in a standard and intelligible form, attackers, once having accessed patient information, can read and aggregate such data from multiple organizations easily. In standardized environments, attackers need only learn taxonomy and semantics once and then apply this knowledge for each attack, rather than having to learn a unique taxonomy for each system. This emergence of "scalable" attacks (which can be multiplied with little additional effort) has concerned many in health care. In response, requirements for privacy and security standards (developed by the U.S. Department of Health and Human Services) have been incorporated into HIPAA. The "Privacy Rule," finalized in 2002, required compliance by all "covered entities" (e.g. providers, insurers, health plans, and information clearinghouses) by 2003. The "Security Rule," finalized in 2003, required compliance by covered entities by 2005. Major changes, to encourage the use of electronic health records, were incorporated into HIPAA in 2009 as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted through the American Recovery and Reinvestment Act (Public Law 111-5) [10]. And again, when the need for greater technical standardization raised the privacy and security stakes for electronic health records, legal and regulatory requirements ratcheted up technological expectations.

The HIPAA Privacy Rule includes several industry specific requirements, yet the overall structure being familiar to those in the privacy advocacy community, its vocabulary and taxonomy in place for over 50 years. Fair Information Practice Principles (FIPP, not to be confused with Federal Information Processing Standards or FIPS) have provided business and government a model for assessing information handling and privacy. Widely known in government, it is understood in the commercial sector principally through its progeny (such as the Internet privacy standard, P3P). Every major effort in privacy owes some debt FIPP, a relatively straightforward statement of privacy principles intended to underscore the responsibilities of entities in collecting personal data.

6.3.1 Notice/Awareness

The first principle, in priority and importance, is *notice*. Individuals disclosing data ("Discloser(s)") should be informed of the information practices of those receiving data ("Collector(s)") before disclosing any personal information. Disclosers must receive notice before they can make informed decisions on disclosure and its extent re: personal information. According to FIPP, Disclosers should be provided notice of the following:

- Identity of the Collector
- Uses for the information collected
- Potential recipients of the information
- Nature of the information
- Whether providing information is voluntary
- Steps taken by Collector to ensure confidentiality, integrity and quality of information.

Under HIPAA, covered entities are required to provide to patients a "Notice of Privacy Practices"

that meets the privacy requirements set forth in this principle. The Notice is the primary privacy control measure for the main activities of healthcare entities: patient treatment, payment and operations ("TPO"). For other activities undertaken by health care entities, such as research, marketing or fund-raising, notice is by itself insufficient—and covered entities must obtain Discloser consent.

6.3.2 Consent

Notice defines subject matter and participants. *Consent* takes the next step by providing the Discloser an opportunity to establish her preferences regarding use and disclosure of personal information, particularly secondary uses beyond those contemplated at time of disclosure. For example, a patient discloses personal information when visiting a physician, and the physician would provide notice of the physician's set of privacy practices, or that of the physician's office, clinic, hospital or payer. Using FIPP terminology, HIPAA considers treatment, payment and operations as *de facto* contemplated uses of information in the healthcare setting. If a collecting physician has another use in mind—for example, medical research, hospital fundraising, or disclosure to a public health clearinghouse—she must first obtain patient consent ("authorization" in HIPAA parlance) for these intended uses. A good portion of the Privacy Rule involves determining when authorizations are required from patients and how these should be processed and maintained. While it may be desirable to require authorization and consent by all patients for any intended use, healthcare providers have been quick to point to the effort and costs involved. Where covered entities intend to use aggregations of patient data—a common occurrence in many hospitals or clinics—obtaining and processing patient authorizations presents significant administrative burdens.

Consent generally comes in two forms: *opt-in* or *opt-out*. Authorization under HIPAA requires affirmative steps (signing a form) by the Discloser to allow certain uses of personal information, an *opt-in*. In an opt-in world, nothing is permitted—that is, the Collector may not collect or use personal information—until the Discloser does something to remove the prohibition. Opt-ins do not always require a signature or other documentary evidence. In many cases, a click box at a Web site may be adequate to indicate an affirmative statement of choice.

Opt-out requires affirmative steps to *prevent* collection and/or use of personal information. In an opt-out world, every reasonable use or practice is permitted—that is, until the Discloser acts to set limits or prohibitions. In some cases, opting out is easy—for example, removing checks from check boxes on a Web page—in others it requires effort. Several years ago, financial institutions were required to send consent forms to their customers regarding disclosure of personal information between business associates Consent notices were sent by mail to nearly all customers, and many customers received several notices from the same bank or financial services company. To opt out (i.e. disallow information from being shared with an affiliate) customers were required to perform a concerted action: call a phone number, return the consent form by mail or fill in a Web form. Predictably, few people took the trouble to opt out, and information sharing continued much as it had prior to the change in the law.

6.3.3 Access/Participation

Under this principle, a Discloser has the right to review his/her personal information to ensure accuracy and completeness. A driving forces behind the HIPAA Privacy Rule has been a growing interest among patients in the transparency of patient records and the right of patient review [11]. Access can give a patient a sense of ownership of his/her medical record and be an effective check on integrity and accuracy. As an example of access rights, the Johns Hopkins Heath System discusses these in its standard Notice of Privacy Practices:

- *Right to inspect and copy*. With certain exceptions (such as psychotherapy notes, informa-

tion collected for certain legal proceedings, and health information restricted by law), you have the right to inspect and/or receive a copy of your medical information.
  - We may require you to submit your request in writing. We may charge you a reasonable fee for copying your records.
  - We may deny access, under certain circumstances, such as if we believe it may endanger you or someone else. You may request that we designate a licensed health care professional to review the denial.
- *Right to request an amendment or addendum*. If you feel that medical information we have about you is incorrect or incomplete, you may ask us to amend the information or add an addendum (addition to the record). You have the right to request an amendment or addendum for as long as the information is kept by or for Johns Hopkins.
- We may require you to submit your request in writing and to explain why the amendment is needed. If we accept your request, we will tell you we agree and we will amend your records. We cannot take out what is in the record. We add the supplemental information. With your assistance, we will notify others who have the incorrect or incomplete health information. If we deny your request, we will give you a written explanation of why we did not make the amendment and explain your rights [12].

These policies seek a balance between the rights of patients to see and amend information with the complexities of a hospital's operational environment. Interestingly, patients are not given the right even by request to delete information in a record even if that information is incorrect. To maintain the integrity of records and patient safety, records may only be marked and supplemented with corrections, not erased or deleted.

6.3.4 Integrity/Security

FIPP combines the idea of integrity, preserving accuracy of data, with security (discussed in detail below), and includes a great deal more.

6.3.5 Enforcement/Redress

This last element considers real-world mechanisms for ensuring compliance with standards through enforcement and recourse. *Enforcement* focuses on the Collector, usually involving an enforcement entity and a set of procedures that arise when there is a question of non-compliance by a Collector or affiliate. *Recourse* focuses on the rights of those potentially wronged as a result of non-compliance. Mutually reinforcing, the former addresses the overall compliance environment for an organization or sector, and the latter considers justice in individual cases. Both enforcement and redress can rely upon (1) self-regulation, (2) private remedies, and/or (3) government enforcement. For example, healthcare entities self-regulate enforcement through internal or external audits, certification procedures and adoption of industry-wide standards of care. The federal government enforces HIPAA through the Office of Civil Rights in conjunction with the U.S. Department of Justice for HIPAA Privacy issues and the Center for Medicaid and Medicare Services (CMS) for HIPAA Security matters. U.S. state governments also have enforcement arms for privacy and security.

6.4 Information Security

Information security draws from at least four distinct disciplines.

- Much of what we consider information security began with the mathematical field of *cryptography* [13]. Historically, information security was primarily concerned with building and breaking ciphers and encryption algorithms. Today, with practically unbreakable encryption widely available, the discussion has focused on the quality of implementation in real-world systems. Sensible security is therefore within commercial reach of organizations that do not have the resources or expertise to engineer cryptographic or other security primitives. There are widely available technical tools and corresponding practices to assure security.

- The next discipline is *information management*. Matching the sensitivity of specific data to an individual user or level of clearance (e.g. confidential, top secret) is a formal process known as multi-level security (MLS) [14]. MLS was created to solve the problem of sharing information from many sources and with many purposes among individuals and organizations when the data "owner" cannot be made aware of all potential recipients or uses. Security clearance and certification processes were established to form baseline *controls* for sharing information. MLS connects security of information to its physical, personnel and systems counterparts, and it forms the technical basis of the HIPAA Security Rule. The focus of HIPAA is not on information systems *per se*, but on the value and attendant risk of the underlying information, the value of which can vary according to its form, content and possible uses [15]. Healthcare information security professionals consider the likelihood that potential attackers may find value in such information.
  - Is a particular piece of information valuable to the collecting organization? If not, why then is it being collected?
  - If collected information does indeed have internal value, would it be valuable to anyone else, specifically a thief, a blackmailer or other bad actor?
- From these determinations, a data classification scheme that adjusts security based on internal value and risk posed by potential value to others. Information systems can likewise be classified according to these classification schemes, reflecting the structure of MLS.
- The third discipline (and the one most familiar to many readers) is *computer and component network security*. The rise of networks and the Internet has made computer security central to contemporary informatics. The rise of modern computer security is almost entirely a function of the rise of networked computing. The vulnerability to attacks from remote computers through the Internet increases their likelihood exponentially, expanding the pool of possible attackers and the means of attack. These attacks can be made through intrusion, malicious software, inappropriate access, data loss, denial-of-service attacks, etc.
- Finally, information security draws from the fundamental need to protect body and property, an idea so broad and elemental that it can hardly be confined to a single discipline. As information has become a vital asset for individuals and organizations, the importance of securing it has grown accordingly. While threat and risk profiles may change, national security experts have identified the following layers of security, each of which has direct influence on information security:
  - Physical security—protection of physical objects
  - Personal security—protection of people
  - Operations security—protection of operational or administrative activities
  - Communications security—protection of primary means of communications (such as phones, radio)
  - Network security—protection of network components and content
  - Information security—protection of information and information assets [16].

HIPAA follows this model and addresses security controls through physical, administrative (Personal and Operations) and technical security (Communications, Network and Information).

6.5 Characteristics of Information Security

Security under HIPAA includes technical and managerial practices, with corresponding tools that protect both a system and the information therein from unauthorized access and/or misuse. More broadly, security often is defined as the state whereby systems are generally working for their intended purposes and that they are resistant to intentional attacks and unintentional misuse. Many security professionals introduce security with a standard set of elements, with terminology

arising from its initials, "CIA" (Confidentiality, Integrity, Availability/Accountability):

6.5.1 Confidentiality

Information can only be accessed by authorized individuals, and in turn it is not made available or disclosed to unauthorized individuals. This idea is closely related to privacy but is narrower in scope, as it only addresses user access not the raft of legal and policy issues surrounding privacy. Confidentiality means that only those with a "need to know" can access certain information.

6.5.2 Integrity

Information is complete and uncorrupted and has not been modified by unauthorized individuals. More broadly integrity can refer to the quality of the information, its readability and usefulness. For example, poor handwriting that results in an inaccurate transcription of a diagnosis or prescription constitutes an integrity problem that information systems are designed to address.

6.5.3 Availability

Information can be accessed by users when needed and is correctly formatted for use. One of the main reasons for implementing information technology in the first place is to expand availability of information to those who do not have physical access to paper records. The World Wide Web, electronic health record and e-mail have all expanded availability of information. Security and availability failures can result in interruptions of this service usually by disrupting user access to machines or networks.

Improving security means enhancing one or more of these hallmarks of well-running systems. In some cases trade-offs are made between two or more considerations. For example, limiting user access to certain files can improve confidentiality, but often at the cost of availability. Another important security property is not immediately apparent in the systems performance, but is equally important in terms of overall security:

6.5.4 Accountability

Information access and usage can be attributed to unique individuals. When a clinician signs changes to a patient record, she is ensuring accountability. When a user accesses an application and leaves an auditable trail regarding his activities (e.g. records, viewed, created, modified or deleted) the system has tools to ensure accountability. These mechanisms are not only important in their own right; they are instrumental for improving the CIA and security of any application or system.

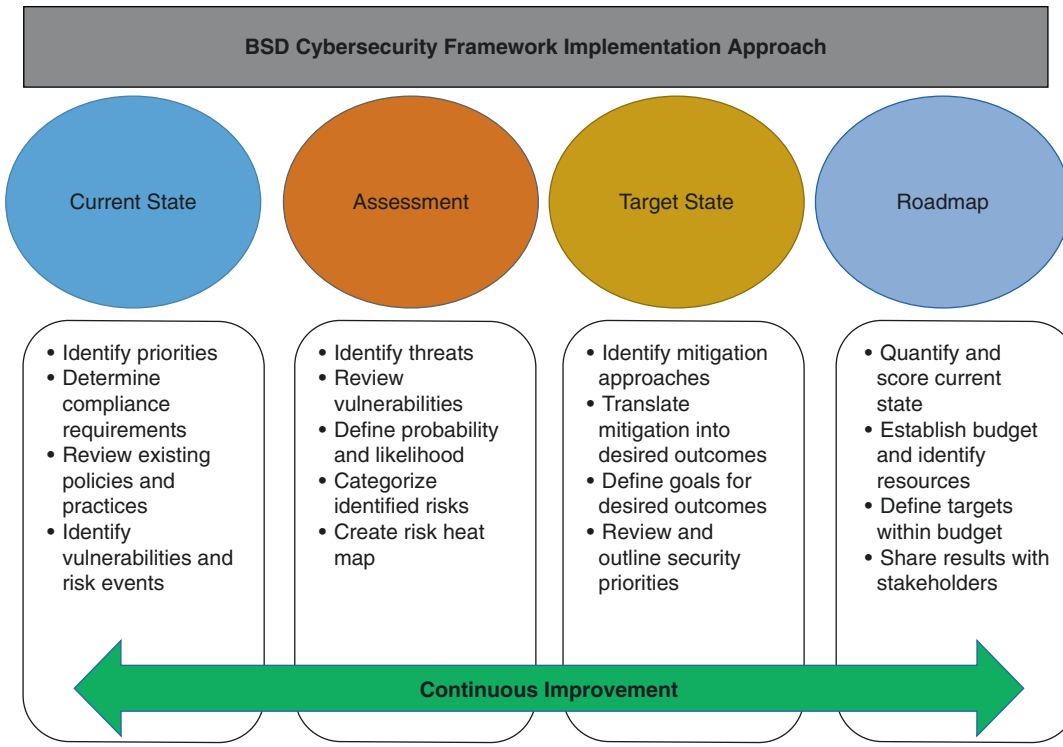
6.6 NIST

The National Institute of Standards and Technology (NIST) has been designated as the principal information security and assurance agency for the civilian-sector U.S. federal government. NIST has published a series of guidance documents in its 800 Special Publications series for planning, implementing and evaluating information security technologies and practices. NIST recommends that effective information security (here called "computer security") has the following characteristics:

1. Computer security should support the mission of the organization.
2. Computer security is an integral element of sound management.
3. Computer security should be cost-effective.
4. Computer security responsibilities and accountability should be made explicit.
5. System owners have computer security responsibilities outside their own organizations.
6. Computer security requires a comprehensive and integrated approach.
7. Computer security should be periodically reassessed.

8. Computer security is constrained by societal factors [17].

In recent years, NIST introduced a cross-industry framework for evaluating information security, the *Cybersecurity Framework* [18]. Unlike most other privacy and security frameworks, NIST CSF does not use a binary checkbox approach. Instead, it opts for a maturity model whereby each control and family of controls can be rated on a continuum of effectiveness. Maturity models in information security are especially useful, because at no point does one achieve "security." It is a continuous process of invention. As we consider information security over the remainder of the chapter, consider how controls can be matched towards the overall security process.



National Institute of Standards and Technology

6.7 HIPAA Security Rule

Unlike the HIPAA Privacy Rule, which concerns all identifiable patient data whether in paper or electronic form, the security rule addresses only electronic patient data—electronic protected health information (E-PHI). Nonetheless, the security rule actually addresses a wider range of issues than the privacy rule, several of which would seem to have little direct relation to privacy (e.g. disaster recovery, integrity controls, etc.). The security rule provides for flexibility and diversity of approaches by allowing covered entities to plan and develop individual security programs within broad guidelines. Yet this needed flexibility comes at the cost of vague standards of care. The security rule tries to ameliorate this lack of clarity by distinguishing between "required" and "addressable" standards for specific controls. Yet this distinction amounts to less than what first meets the eye. Nearly every required control is oriented towards process and general objectives, and there is little guidance on the details or substance of these processes. Addressable controls, on the other hand, are more granular, yet even there, standards are unclear.

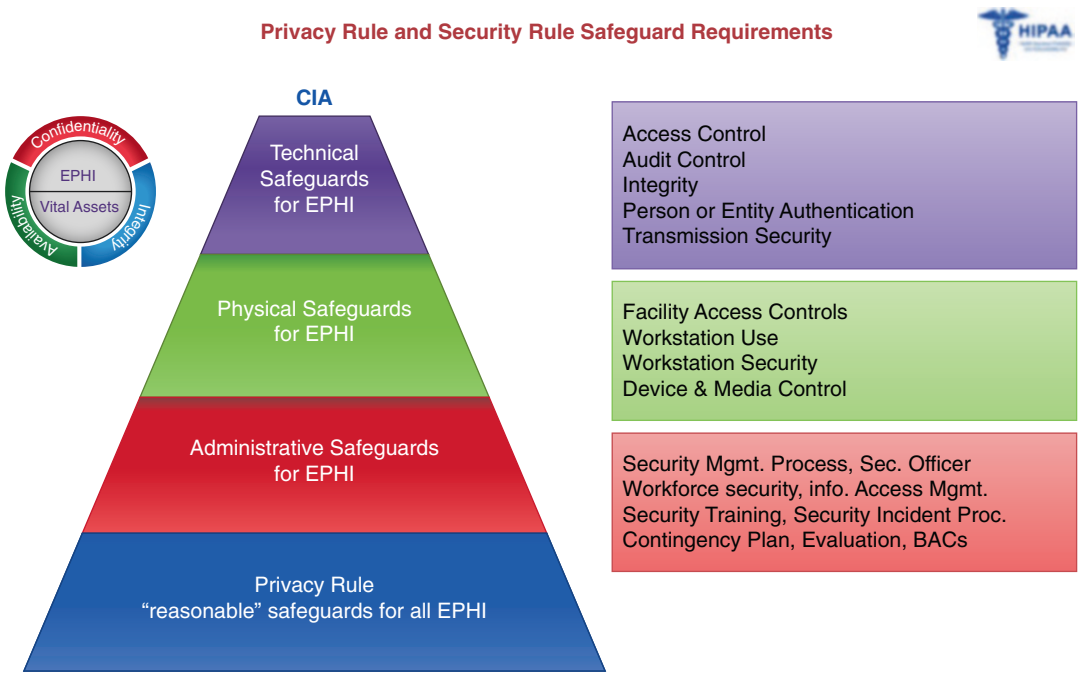
The required provisions of the security rule could be summarized as follows: a covered entity must assess the value and feasibility of implementing a series of controls appropriate for its environment and document its strategic and tactical decision-making process. While there is likely to be some emerging consensus regarding how certain required controls such as risk assessment and incident response procedures are implemented, whether a specific control actually meets HIPAA requirements is still usually unclear. The body of enforcement actions and advisories by the federal government has helped clarify some controls, but standards at the leading edge of security practice remain vague.

6.8 Risk Assessment and Management

The security rule requires that each covered entity adopt security practices that it considers reasonable given the level of risk and institutional capabilities. By discussing information security in terms of risk assessment, HIPAA is well within the mainstream. An entire industry has grown up around ISO 17799, OCTAVE, NIST and a number of other risk assessment methodologies [19]. Risk management typically starts with a formal risk assessment in order to establish an effective security strategy and then incorporates controls and metrics throughout a security systems life cycle. CMS describes the relationships between the two concepts thusly:

> Risk analysis is the assessment of the risks and vulnerabilities that could negatively impact the confidentiality, integrity, and availability of the electronic PHI held by a covered entity, and the likelihood of occurrence Risk management is the actual implementation of security measures to sufficiently reduce an organization's risk of losing or compromising its electronic PHI and to meet the general security standards [20].

HIPAA emphasizes both risk assessment and risk management as cornerstones of an effective security program:



6.8.1 Organization and System Purpose

For information security in general and HIPAA in particular, it is best to think of systems broadly, as encompassing one or more IT applications, administrative processes, and underlying infrastructures. Articulating the purpose of these systems sets the stage for assessing risk. System purpose indicates which of the CIA security elements (confidentiality, integrity and availability) are most critical in a particular instance and determine the data collection needs of the organization or system. It is both good privacy practice under FIPP and general security practice to collect and maintain the least amount of data, the "minimum necessary," required to achieve the system's business purposes.

6.8.2 Threats

Threats are external dangers to an asset and exist whether an organization implements any security controls or not. The most common and well-known threats arise from malicious code, such as viruses and worms. The most extensive family of threats relate to intrusion—including those resulting from exploitation of system vulnerabilities by external hackers and using these to take control of software or hardware or to intercept network traffic. The two categories above are in many ways the archetypes of computer security. While not as visible perhaps, other threats are just as serious, such as those arising from equipment malfunction, physical theft, environmental hazard and inappropriate use by system insiders.

6.8.3 Vulnerabilities

Unlike threats, defenders have some say in the type and scope of its vulnerabilities. Vulnerabilities are the holes in a system—administrative, technical and otherwise—that subject an organization to threats. Security controls are directed towards addressing one or more vulnerabilities, and it is common for accounts of vulnerabilities to be mirror images of recommended controls. For instance, failure to lock server closets is a vulnerability, and the corresponding control would be to lock server closets as a matter of practice. It is not difficult to see that vulnerabilities are often simply the absence of certain controls.

6.8.4 Calculation of Risk: Likelihood * Damage

The standard approach to addressing risk is to multiply the likelihood of an incident by the amount of damage such an event would cause. Unfortunately, there is a dearth of data in nearly every organization as neither the likelihood nor damage of information security events is settled. At best, most risk assessment methodologies can identify a few quantitative metrics and supplement those with more qualitative accounts of risk factors. More effective incident reporting and widespread information sharing may begin to give security professionals a better sense of the likelihood of attacks. On the other side of the equation, damages for security/privacy incidents can now be estimated from enforcement and court actions. The recent rise of organizational extortion by attackers spreading malware or stealing data is changing the cost calculus regarding damages.

6.8.5 Risk Mitigation: Reducing Likelihood

Risk mitigation, the main part of risk management, includes controls of two primary types: reducing likelihood of attacks and limiting damage from such attacks. In both cases, security controls are linked to identified threats and vulnerabilities and implemented according to the requirements of the system and overall security strategy.

6.8.6 Risk Mitigation: Limiting Damage

All systems break on occasion. A secure system is resilient when such a break causes damage that is manageable not catastrophic. A broken system—an intrusion, theft or virus—is not by itself a violation of HIPAA security. It becomes a problem when the incident results in a loss or disclosure of PHI. Current security practice is to assume that internal systems have been compromised, that the perimeter has been broken. There is an adage about organizations that over-emphasize perimeter security are like candy bars—hard and crunchy on the outside, soft and chewy on the inside. Nowadays organizations work to harden the soft parts—quickly identify breaches, impede attackers and rebuild systems quickly.

6.8.7 Cost Effectiveness of Controls and Priorities

It is nearly as difficult to measure the cost effectiveness of controls as it is to quantify risk. While it is sometimes clear what a control will cost—in money, personnel resources, attention of management—assessing the effectiveness of controls against that investment is difficult. One general rule for information security is that strong policies, incident response capabilities and training of users and administrators are usually among the most cost-effective controls and best security investments.

On occasion one hears the following business "wisdom"—that which cannot be measured will be ignored. Risk assessment and management struggle with this charge to measure the value of security investments. In the absence of reliable data security professionals focus their concerns on the impact of known threats and vulnerabilities. The practice of risk assessment now relies upon the experience and analogical reasoning of security professionals, and it is usually involves a combination of the knowledge of best practices and intuitive understandings of risk thresholds. The field moves so rapidly that security professionals are generally in a perpetual state of surprise regarding the next tranche of threats and potential impacts. We are always in danger of fighting the last war and are therefore wary of rigid methodologies and purely statistical reasoning. While there is reason to believe that that the quality of risk data will improve, it would be surprising if security decision-making becomes appreciably more formal than it is today.

6.9 Security Controls: Major Concepts

6.9.1 Access Control

There is no more important concept in the HIPAA Security Rule than access control, which means ensuring that only authorized individuals are allowed to access (i.e. read, create or modify) E-PHI. The treatment of PHI under HIPAA is in many ways analogous to the treatment of classified information in defense and intelligence organizations grounded in MLS. HIPAA seems to focus first on the protection of confidentiality and integrity, and secondarily address other security concerns. Like classified models, HIPAA emphasizes the role of human resource-related requirements of workforce clearance, separation of duties, need to know and minimum necessary. Both privacy and security rules are in effect access control standards with a few additional items included as needed to preserve information and systems integrity.

In information security practice access control consists of two processes: authorization**,** the right of a user to access an electronic system, and authentication, the process by which an authorized user proves her identity. The former process is principally administrative in nature, and even in cases where authorization is handled through automation it is almost always a human decision—such as hiring an employee—to grant access to a system. The latter is usually technical in nature, including things like passwords and tokens. Not every user requires access to every part of a system or record, and good security seeks to limit access by mapping job functions to access roles. This

type of authorization process is known as role-based access, and it requires careful planning and granular controls. Most systems currently use a somewhat less rigorous approach, identity-based access, which generally gives full access to any user that meets a threshold test for need-to-know.

Authentication is the more technical side of the access process. It uses one or more factors to ensure the identity of users. The factors are often referred to as:

- Something you know (e.g. passwords, pass numbers (PIN's), query and response mechanisms)
- Something you have (e.g. keys, tokens, credit cards)
- Something you are (e.g. fingerprints, facial or voice recognition.

Authentication is strongest when it utilizes more than one factor, "multi-factor" authentication. For example, a token combined with a PIN number would be much stronger than one factor or the other by itself. It would be possible to guess a PIN or steal a token, but to accomplish both would be more difficult for any potential thief. Nonetheless, passwords remain the primary form and often the only method of authentication for many systems. They have the advantage of portability across platforms and familiarity for users, but their problems are manifold. Security professional disagree on whether passwords should be assigned from a central source, required to follow difficult syntactic rules (e.g. interchanging alphanumeric characters, etc.) given minimum or maximum length or changed regularly by users [21]. About the only control on which there is wide agreement is that applications should lock users out after some small number of unsuccessful authentication attempts. This is an effective defense against attackers compromising a system by guessing passwords, using a dictionary or what is called a brute-force attack where every possible letter/numeral/character combination is shuffled through. In recent years, many attacks involve not the password itself but the encrypted representation of the password, or "hash," stored on the compromised system or in memory. Such attacks are based less on the quality of the password than on how the victim system manages low-level authentication tokens.

Authentication is one of the few areas where the HIPAA security rule requires a specific control – each user must have a unique ID for access to E-PHI. Implementing this standard is more difficult in practice than it might first seem. There are many applications capable of storing E-PHI including word processing documents and spreadsheets, many of which can be protected by requiring password access. These applications (such as Microsoft Excel) can require that passwords be used to open documents, but there can only be one password per file. If more than one person is authorized to access the file, the only option is to share one identity and password, a seeming violation of HIPAA. Still even a shared password provides some protection and seems preferable to leaving a file on a server or workstation open for any user to access. One must therefore choose between complying with the specific requirements of the security rule (i.e. one identity per user) and providing additional security on a potential E-PHI record (i.e. encrypting a file with a single password).

6.9.2 Physical Controls

Under HIPAA, physical security is broadly understood to include safeguards against unauthorized access to physical locations, storage of data and to the many threats posed to data from environmental hazards like flood, electrical surges, etc. Physical and environmental security refers to measures taken to protect systems, buildings and related supporting infrastructure against threats associated with the environment.

As in most areas, physical security under HIPAA is principally an access control issue. The obligation is to control access first to high risk areas—server rooms, networking closets, etc.—and then to consider lower risk areas that might house workstations or other devices. There are a number of unremarkable controls that organiza-

tions can implement—key and automated locks, guards, video surveillance and escorts of visitors are examples. It is also required to prepare for physical hazards, in order to prevent or mitigate damage and improve recovery efforts. Interestingly, the HIPAA security rule considers in some detail disaster recovery and business continuity planning, subject matters with little apparent direct relationship with the privacy concerns in the HIPAA privacy rule. This indicates that the security rule was established to cover all major areas of security not simply those supporting privacy. Disaster response is a critical component of any security program as systems under stress are often the most vulnerable to attack. Moreover, several controls intended primarily to assist disaster recovery also serve other important security purposes. For example, the security rule emphasizes the need for data back-up and recovery. In many organizations back-ups are used first to help recover systems from a failure—sometimes caused by physical hazards but more often by hardware or software failure. Data back-up procedures have other secondary, privacy-enhancing benefits, including the critical role of back-up data in investigating security and privacy compromises. Thus, a good security control applies both to physical and electronic threats, serving multiple purposes of prevention, mitigation and recovery.

6.9.3 Encryption

Encryption is among the best-known and most important information security elements. Cryptography is a mathematical operation, and contemporary cryptographic algorithms fall into two major categories: symmetric and asymmetric. In symmetric algorithms, encryption and decryption algorithms (or keys) are the same. This is private key cryptography, which depends upon keeping keys away from unauthorized individuals. Access to keys may be restricted through authorization and authentication of users, but private key cryptography has severe limitations when there are many intended recipients. In asymmetric algorithms, on the other hand, encryption and decryption keys are different. This is public key cryptography, which depends on two keys, a public key (available to everyone) and a private key (known only to the key holder).

An example of asymmetric cryptography works:

> Using symmetric/private key cryptography, Alice would send a message to Bob by using a key to encrypt the message and then ensure that Bob has the same key for decrypting it. The security of the message is a function of how well Alice distributes the key to Bob and to no other unintended recipients. If Alice needs to send secret messages to many people on a daily basis, key management quickly becomes a near impossible task.
>
> Using asymmetric/public key cryptography, Alice can now choose to encrypt the message using Bob's public key—available through, say, a directory of keys—but only Bob can decrypt the message, as he is the only person with the private key paired with his public key. If another person receives the encrypted message, even with full knowledge of the public key, decrypting would be impossible without the corresponding private key. Thus, Alice can send as many secure messages as she wants to anyone with a public key pair, and she need not distribute keys or send any additional information about herself or the nature of the message. She can also broadcast messages much more readily by encrypting according to the public keys of each intended recipient without compromising security by over-using one key or needing to issue multiple keys.

While public key cryptography has made security in complex environments like the Internet possible, challenges remain. To maintain security, a public key system must assure the correspondence between public and private keys and between key pairs and key-holders. There are myriad opportunities to impersonate keyholders, to alter information about keys or otherwise disrupt the operation of system using public keys. Security and assurance cannot be effectively maintained without an organization and processes trusted by users, an "infrastructure." The sophistication and complexity of assuring public key systems, a Public Key Infrastructure (PKI), has become one of the principal challenges for information security practitioners.

6.9.4 Network Security

Network security is one of the cornerstones of practical information security. In fact, many people erroneously consider information security and network security to be synonymous. Many of the most common and damaging attacks occur through network traffic—viruses, intrusions, denials of service. Without local networks and the over-arching network infrastructure, the Internet—threats to information confidentiality, integrity and availability would be far less serious. By the same token, it is the centrality and ubiquity of the network that has made the most recent advances in IT possible.

There are manifold uses of networks—Web sites, local area networks, e-mail, distributed applications, etc.—and the range of security requirements is just as diverse. Networks that support Web pages may also support applications handling millions of electronic health records. Designing a network architecture that provides maximum flexibility for the former while providing strong protections for the latter has become an increasingly challenging and complex task. The rise of the Internet has provided impetus for network security and improved tools to accomplish the task.

6.9.5 Firewalls and Intrusion Detection/Prevention

Network security begins with perimeter defense. The most common source of viruses, worms, malicious software and hacking intrusions is the Internet. A secure organization first attempts to keep intruders out of its internal domain and the assets residing therein. A firewall sits on the perimeter of the network and monitors packet (the constituent elements of communications across the Internet Protocol, IP) traffic—including source, destination, types of packets, attachments, ports and conceivably any component of traffic. The firewall is the point of ingress/egress for the network and it can accept, reject or tag traffic based on a set of pre-defined policies. For example, the firewall may reject all traffic received from a certain source IP address, or it may only reject traffic from that IP address with certain types of attachments or directed towards certain ports on a destination machine inside the network. In recent years, firewalls have become sophisticated in detecting and preventing application fingerprints, thus blocking malware on open ports and often restricting the kinds of applications that can be run in the network.

Perimeter defense is important, but good security assumes that attackers will at some point succeed in penetrating the network. The goal of security programs is to build resiliency in the face of threats that may frequently compromise the network perimeter. Thus, all enterprise firewalls and many other enterprise network tools, include intrusion prevention systems (IPS) to identify, alert and block intrusions. Intrusion prevention is a real-time process, but intrusion detection can be asynchronous, driven by operational practices of checking logs, process or system files with tools that monitor activity for indications of unauthorized access or activity. In addition, most firewall strategies now monitor intra-network communications much as they do on the perimeter. The combination of internal and external firewall policies are continuously adjusted to address threats and organizational security posture and culture.

6.9.6 Device and User Security

Network intrusion prevention is scalable and usually cost effective, but it is a coarse control. Enterprises require defense-in-depth in addition to the perimeter and network segments. The increasing “zero trust” approach treats each device on the network as an external device, the network interrogating role each user/device pairing, with each device answering questions regarding its security posture and behavior. In practice, devices have installed agents that continuously monitor activity and threat, in much the same way that a firewall monitors network behavior. While anti-virus software has been

ubiquitous since the 1990s, security endpoint agents have superseded it and improved dramatically and increasingly include threat profiling, mobile capabilities and machine learning. To enrich behavioral analysis, user activity—including location, authorized user roles and applications accessed—is assessed as part of its security posture. In recent years, there has been increasing attention to the security of medical devices. NIST [22] and the Federal Drug Administration [23] point regulatory and operational challenges to applying security updates as factors in the difficulty of addressing device vulnerabilities.

Encryption, firewalls, intrusion detection and anti-virus agents were all contemplated at the time of the adoption of the HIPAA security rule. One could argue that the compliance burden can be met by effectively adopting and maintaining currency with each of the controls above. Yet the past two decades have demonstrated that a raft of newer technologies should be adopted in order to mount a sensible defense against evolving threats. An extension of the security rule is needed to help evaluate next-generation controls. One response has been the introduction of the NIST Cybersecurity Framework, discussed above, that would provide a model for identifying goals and objective for an organization's security posture. Another approach is to turn the process on its head and focus not so much on information management goals, but on responding directly to threats.

6.9.7 Attack Methodologies

Information security breaches may be unintentional (e.g. sending a document through email to unintended recipients, loss of a laptop storing E-PHI), but the most damaging compromises have arisen from directed attacks. The Website hosted by the Department of Health and Human Services that catalogues HIPAA security breaches over the 500 individual reporting threshold has seen a steady increase in the fraction of records compromised through attacks from other causes (https://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html). Attacks on healthcare organizations are increasingly common and damaging. From a risk perspective, healthcare organizations are expanding their security programs beyond the components contemplated in the HIPAA Security Rule. What follows is a description of the stages and elements of typical attacks. By breaking the attack down into a set of processes, defenders can identify controls, technical or otherwise, that may effectively check an attacker at each stage. Controls evolve rapidly but the trajectory of most attacks have remained consistent.

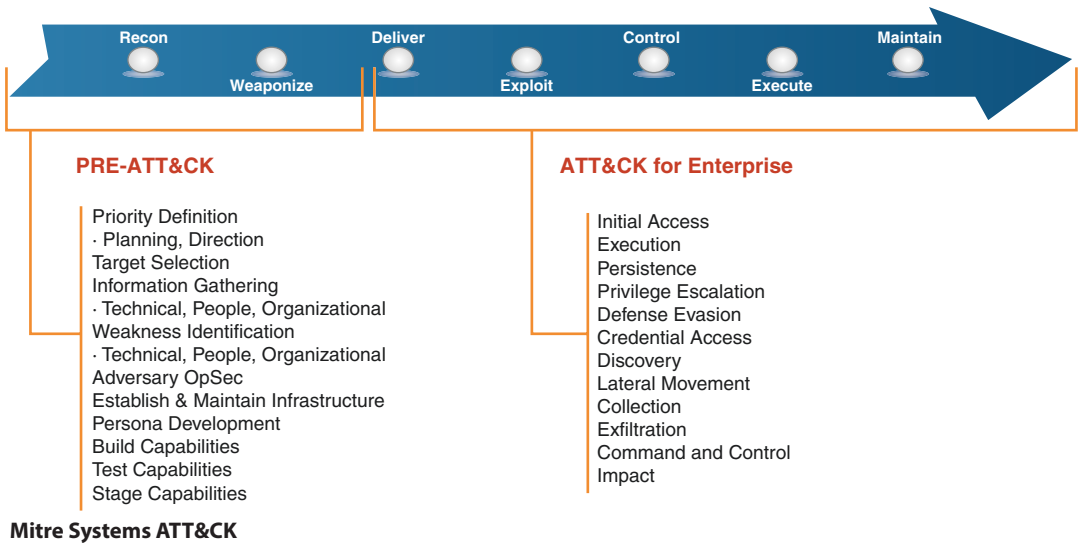
Lockheed Martin, a major U.S. government contractor, has formulated a model called the "cyber kill chain" [24] that demonstrates the stages of typical attacks on enterprises:

1. *Reconnaissance*—an attacker may surveil a system for weeks or months prior to committing resources to an attack. It will gather open-source intelligence on network openings, users and business operations. It is common for attackers to use social media and advanced search engine functionality to build a target profile.
2. *Weaponization*—the kill chain contemplates that malware will be involved in most attacks, and that the attacker will identify or develop code to carry out an attack. It is rare that an attacker need develop code *de novo,* as there are many no-cost customizable tools available.
3. *Delivery*—injecting malware into a target system typically involves malicious email (phishing), attacks on Web sites or Internet facing systems (e.g. networking, remote access protocols). Increasingly attackers will embed malware into third party update tools or other widely used software.
4. *Exploitation*—once malware is delivered, the attacker seeks conditions whereby the target system can be compromised, including specific vulnerabilities or network configurations.

5. *Installation*—exploitation code is typically lightweight, with few functions so that it can run quietly and evade detection. Once a target system is exploitedan attacker may deliver a secondary payload that typically includes additional functionality.
6. *Command and control*—once functional malware is installed, an attacker will typically establish a command and control (C2) channel to the target system.
7. *Actions on objectives*—with C2 established, the attacker may conduct automated actions, such as network scans, data copying, system disruption or begin "hands on keyboard" actions using the compromised system as a jumping off point for lateral movement in the network or connecting to other systems.

There are many permutations to the cyber kill chain, and there is every reason to believe that attack methodologies may change. For example, secondary payload installation may happen earlier in the process, or installation may iterate over several small installations. Yet this model provides an analytic framework for security planning and evaluating security controls.

Mitre Systems, another major government contractor, led a security community-wide effort to build on some of the concepts introduced by the frameworks like the cyber kill chain. The result is a more encyclopedic model for security incidents, one that covers many of the kill chains permutations and includes threat and adversary information. The ATT&CK model [25] includes both a risk assessment framework and step-by-step approach to typical attacks. It includes hundreds of individual components and is too complex to cover here. Due to its comprehensive nature and focus on threat, it is a major step forward in security practice. For example, while penetration testing has been a common practice for many years, ATT&CK provides a context and objectives for directed testing of components individually in complex environments. Defensive techniques such as honeypots (i.e. systems with no other purpose than to attract attackers that might be on the network) and deception (i.e. creating system artifacts to confuse and distract attackers) can be formalized and assessed according to the ATT&CK methodology.



Mitre Systems ATT&CK

6.10 Conclusion

As in nearly every area of information technology, security tools are advancing rapidly. The sophistication of the threat environment demands the vigilance and preparation of information security professionals. It is unlikely that the underlying regulatory/technical structure of HIPAA privacy and security will change substantially, so organizations are responsible for sensible application of risk management, access control and security monitoring in order to achieve reasonable security across their operations and as necessary to help protect patient privacy and care.

6.11 Web Resources

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National Institute for Standards and Technology, Special Publications 800 Series. https://csrc.nist.gov/publications/sp800

Electronic Privacy Information Center. https://www.epic.org/

Department of Homeland Security, Cybersecurity and Infrastructure Security Agency. https://www.cisa.gov/

Open Web Application Security Project. https://owasp.org/

Health Information Sharing and Analysis Center. https://h-isac.org/

Questions and Answers

1. What are the main differences between privacy and security practices and how would healthcare organizations meld these two approaches?
   a. Privacy practices follow a lifecycle of data collection, storage, use and disposal. It requires interactions between the custodian/collector and the subject. Securing private data is a part of sensible privacy controls. Security, in its current forms, is primarily threat-based and involves a defense-in-depth approach against an active adversary. Healthcare organizations typically administer privacy as they would other risk management and administrative activities, while security is highly technical and often involves information technology departments, contractors and vendors.
2. How has security practice changed since the inception of the HIPAA Security Rule in the early 2000's?
   a. The HIPAA security rule was based on a combination of all-hazards data protection (e.g. disaster recover, floods) and concerns of the military/intelligence community of the time (e.g. access control, encryption). As threats have evolved, so has the emphasis of most security programs. Malware and multi-stage attacks against IT infrastructure require a threat/risk model that is more dynamic than the original security rule controls. Healthcare organizations should emphasize resiliency in the face of continuous attacks.

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Interoperability: Current Considerations

7

Hans J. Buitendijk

Abstract

Interoperability enables electronic data access and exchange within and across healthcare applications and organizations. As emerging technologies, regulation, standards, and network evolution converge toward nationwide interoperability, there are barriers and challenges that must be addressed to reach that goal.

Keywords

Health information interoperability · Health Level 7 · 21st Century Cures Act · Information dissemination · Data sharing · Electronic data exchange · Health Information Portability and Accountability Act (HIPAA) · Networks Coordination of care · Privacy · Standards and regulations · HL7 Fast Healthcare Interoperability Resources (FHIR) · Trusted Exchange Framework and Common Agreement (TEFCA)

Abbreviations

AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AIMS	APHL Informatics Messaging Services
APHL	Association of Public Health Laboratories
API	Application Programming Interface
ASC	Accredited Standards Committee
CA	Common Agreement
CCD	Continuity of Care Document
C-CDA	Consolidated CDA
CCDS	Common Clinical Data Set
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDC	Centers for Disease Control
CDS	Clinical Decision Support
CMS	Centers for Medicare and Medicaid Services
DME	Durable Medical Equipment
DRS	Designated Record Set
eCR	Electronic Case Reporting
EHI	Electronic Health Information
eICR	Electronic Initial Case Report
FAST	FHIR at Scale Taskforce
FHIR	Fast Health Information Resources
EHNAC	Electronic Healthcare Network Accreditation Commission

Interoperability is rich in acronyms. This abbreviations list provides a quick reference of those used in this chapter

H. J. Buitendijk (✉)
Chester Springs, PA, USA

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EHR	Electronic Health Record
GDPR	General Data Protection Regulation
HIE	Health Information Exchange
HIMSS	Healthcare Information Management Systems Society
HIN	Health Information Networks
HISP	Health Information Service Provider
HL7	Health Level 7—A standards development organization
IHE	Integrating the Healthcare Enterprise
LEAP	Leading Edge Acceleration Project
LRI	Laboratory Results Interface
NATO	North Atlantic Treaty Organization
NCPDP	National Council for Prescription Drug Programs
NHIN	Nationwide Health Information Network
NPPES	National Plan and Provider Enumeration System
NQF	National Quality Forum
NwHIN	Nationwide Health Information Network
ONC	Office of the National Coordinator
PULSE	Patient Unified Lookup System for Emergencies
QHIN	Qualified Health Information Network
QTF	QHIN Technical Framework
RCE	Recognized Coordination Entity
SAMHSA	Substance Abuse and Mental Health Services Administration
SDO	Standards Development Organization
SHIEC	Strategic Health Information Exchange Collaborative
SVAP	Standards Version Advancement Process
TEF	Trusted Exchange Framework
TEFCA	Trusted Exchange Framework and Common Agreement
TDRAAP	Trusted Dynamic Registration and Authentication Accreditation Program
USCDI	US Core Data for Interoperability

Learning Objectives

The objectives of this chapter are to enable the reader to:

- Define interoperability and explain its importance within US healthcare and articulate/list critical components needed to achieve it.
- Define/describe current reach and scope, progress and frontiers in US healthcare organizations.
- Suggest how the impact of interoperability between systems might be measured and interpreted.

7.1 Introduction

Healthcare interoperability is a capability of computer systems to exchange data and connect different departments and organizations to support clinical, administrative, and business processes. Early interoperability focused on sharing patient demographic data with laboratory and imaging information systems, enabling communication of electronic orders and test results, linking them to coding and billing data. In the early 1990s, information sharing started extending across organizations, with the development of health information exchange (HIE), and now involves sharing clinical encounters data, immunizations, and claims among many other types, for multiple purposes and stakeholders.

Thus, the definitions and focus of work on interoperability definitions has continued to evolve, expanding the scope from local (intra-organizational) to regional (inter-organizational), and now to nationwide sharing of clinical, financial and public health data.

7.2 Definition

Definitions of "interoperability" have evolved over time

- Webster defines "interoperability" as the "ability of a system (such as a weapons sys-

tem) to work with or use the parts or equipment of another system."

- NATO expands the concept[1]: "to act together coherently, effectively and efficiently to achieve tactically, operational and strategic objectives." Furthermore, "interoperable solutions can only be achieved through the effective employment of standardization, training, exercises, lessons learned, demonstrations, tests and trials."
- In 2005, the Commission on Systemic Interoperability (CSI) defined interoperability as "the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged."[2]
- In 2006, a presidential order defined "interoperability" as "the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered."
- In 2007, Health Level Seven (HL7®) provided in 2007 further defined three aspects[3]:
  - Technical interoperability—the most basic, hardware-based form of interoperability
  - Semantic interoperability—the ability of information shared by systems to be understood… so that non-numeric data can be processed by the receiving system
  - Process interoperability—an emerging concept that has been identified as a requirement for successful system implementation into actual work settings
- The Healthcare Information Management Systems Society (HIMSS) provided a progression of definitions in 2005, 2013, and 2017, and currently defines it as "the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally," recognizing four levels[4]:
  - Foundational (Level 1): Establishes the inter-connectivity requirements needed for one system or application to securely communicate data to and receive data from another
  - Structural (Level 2): Defines the format, syntax and organization of data exchange including at the data field level for interpretation
  - Semantic (Level 3): Provides for common underlying models and codification of the data including the use of data elements with standardized definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user
  - Organizational (Level 4): Includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities and individuals. These components enable shared consent, trust and integrated end-user processes and workflows
- The 21st Century Cures Act,[5] enacted December 13, 2016, established that "The

[1]North American Treaty Organization. Interoperability: connecting Nato forces. 2020. https://www.nato.int/cps/en/natolive/topics_84112.htm. Accessed 24 February 2021.

[2]Commission on Systemic Interoperability. Ending the document game. Recommendations. https://endingthedocumentgame.gov/PDFs/Recommendations.pdf.

[3]HL7. Coming to terms: scoping interoperability for health care. 2007. https://www.hln.com/assets/pdf/Coming-to-Terms-February-2007.pdf.

[4]HIMSS. Interoperability in healthcare. https://www.himss.org/resources/interoperability-healthcare.

[5]US Congress. 21st Century Cures Act. 2016. https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf.

term 'interoperability', with respect to health information technology, means such health information technology that:

– (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
– (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
– (C) does not constitute information blocking as defined in section 3022(a)."

This definition put focus on two important concepts: "without special effort" and "does not constitute information blocking" (see "Information Blocking")

These definitions identify the critical aspects that address essential goals, to connect:

- Providers to their patients' records/data for direct clinical care
- Patients to their own health records/data and to empower control over sharing of that data
- Public health agencies to patient records/data to manage population health
- Healthcare organizations and payors to clinical, administrative and insurance data for transactions, payment and operations (TPO)
- Researchers to identified and deidentified patient data for ethical human subjects and health services research

7.3 Current Landscape

Interoperability is shaped by the efforts of private and public/regulatory stakeholders. Initially driven by technical and internal business needs of healthcare organizations, interoperability extended to meet the shared needs of multiple organizations for payments and care coordination. To align these shared needs for data exchange, regulatory initiatives became necessary to align, promote, and accelerate data exchange at local, state, and national levels. Parts of the "landscape" include standards development organizations (SDOs), regulators to promote electronic collaboration across developers, healthcare provider organizations, payers, and others.

Interoperability, its policies and regulations affect many healthcare domains, processes and communications. Some themes are:

- Privacy
- Transactions
- Document Exchange
- Services
- USCDI/EHI/DRS
- Nationwide Networks
- Coordination of Care
- Patient Engagement
- Public Health

This list is not intended to be exhaustive, and there are examples herein and in other chapters. What follows are illustrations of the current state of interoperability with discussion of the magnitude of efforts still ahead on the road to nationwide interoperability.

7.3.1 Privacy

Privacy is critical to interoperability. According to Healthcare Insurance Portability and Accountability Act (HIPAA) rules,[6] covered entities and their business associates must maintain the privacy of a patients' records in sharing data with other parties, including "who electronically transmit health information in connection with certain transactions", health plans "that provide or pay the cost of medical care", and health care clearinghouses "that process nonstandard information they receive from another entity into a standard."[7] The 42 US Code of Federal

[6] HHS. Summary of the HIPAA privacy rule. https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

[7] CMS. Are you a covered entity. https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity.

Regulations Part 2 (42 CFR Part 2 = Confidentiality of Substance Use Disorder Patient Records) provides specific guidance on permissible sharing of substance use disorder patient records. Updates in July 2020[8] addressed a number of provisions ranging from applicability and re-disclosure, consent requirements, research, medical emergencies, consent requirements and a number of other provisions that reduced the variations between HIPAA and 42 CFR Part 2. In addition to federal statute and regulations, states have adopted privacy policies and regulations as well that create further requirements on how data may or may not be able to be shared. All must be considered, in combination with a patient's consent directives, to govern how patient data may or may not be shared.

Interoperability standards and profiles should enable data privacy to be preserved as it is shared in accordance with these policies directives across federal and state policies and regulations, as well as the patient's wishes. Standards and profiles for communication/documentation of disclosure and consent involves the following steps:

1. Define policies for identifying, labeling and managing data for disclosure and consent
2. Document patient consent directives
3. Label data in accordance with the policies and consent directives
4. Share documented directives
5. Manage and re-disclose received data

7.3.1.1 Define Policies for Identifying, Labeling and Managing Data for Disclosure and Consent

This is pragmatically done by healthcare organizations for local disclosures, but uniform documentation of the relevant policies across HIPAA, 42 CFR Part 2 and state specific privacy policies for widespread (inter-regional and national) adoption has not been accomplished.

7.3.1.2 Document Patient Consent Directives

HIPAA, 42 CFR Part 2 requires the capture and recording of patient consent directives and wishes with respect to privacy. The HL7 CDA® R2 Implementation Guide: Privacy Consent Directives, Release 1 as well as the HL7 FHIR® Consent resource enable computable documentation of a patient's directive that may extend or reduce data sharing as permitted by federal and state law.

7.3.1.3 Label Data in Accordance with the Policies and Consent Directives

The HL7 Healthcare Privacy and Security Classification System (HCS), Release 1 establishes a set of labels for tagging data enabling automated evaluation of well-defined privacy policies and patient consent directives. The HCS is used across a number of national standards (HL7 v2, HL7 CDA, and HL7 FHIR) to consistently and accurately tag data in messages, documents, and data accessed through FHIR resources at the appropriate level of granularity, e.g., a document as a whole or individual sections or entries.

The 2015 Certification Edition Cures Update sections in the ONC's final rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*[9] (21st Century Cures Rule) includes criteria addressing the ability to label for both documents and data accessed through application programming interfaces (API). However, some progress has been made in automating labeling of data enabling policy-defined sharing/disclosure/re-disclosure. Until uniform documentation of policies described in Step 1 has been established that enables mostly automated labeling of the data, adoption will be limited in the absence of clarity and consistency at a national level on which labels to use in support of what policies.

[8]HHS. Fact sheet: SAMHSA 42 CFR part 2 revised rule. https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html.

[9]Federal Register. 21st century cures act: interoperability, information blocking, and the ONC Health IT certification program. 2020. https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

7.3.1.4 Share Patient Consent Directives

There is not a clear consensus on an approach and infrastructure with respect to sharing a patient's consent directives One option is to send the directive with documents/transactions, the other being to store directives in a central location (such as an HIE or another network approach). Each has its benefits and difficulties. Current efforts include:

- Carequality,[10] an organization that established a national trust framework and a set of interoperability standards enabling cross-network data sharing, provides a guidance in its Query Based Document Exchange implementation guide[11] how a requester can assert patient consent, e.g., verbal consent has been obtained or a consent directive is on file and can be requested.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) has developed a FHIR R3 based Consent2Share[12] tool to capture and enable sharing using HL7 FHIR based APIs. However, the reference to Consent2Share was removed from ONC's Interoperability Standards Advisory with the 2021 edition.[13]
- The San Diego Health Connect's ONC LEAP Computable Consent Project under an ONC 2019 Leading Edge Acceleration Project (LEAP) grant[14] aims to simplify consent management and ensures interoperable services for the following four use cases: (1) privacy consent, (2) medical treatment consent, (3) research consent, and (4) advance care directives." The project is targeted to complete late 2021.
- Shift (formerly known as PP2PI (Protecting Privacy to Promote Interoperability))[15] is a project to address further implementation guidance to enable a usable and nationally scalable consent management approach around nationally accepted use cases as further described in their whitepaper.[16]

7.3.1.5 Manage and Re-disclose Received Data

After data has been received from a source, consent directives must continue to be honored. Thus, all labeling rules must persist and apply to subsequent transactions, i.e., permissions to re-disclose to another organization. This is directly affected by the infrastructure chosen for sharing patient consent directives.

Further collaborative efforts are essential to advance policies, standards, technologies, and infrastructure for comprehensive, yet practical consent management that assures HIPAA, 42 CFR Part 2, state, and individual patient consent directive compliance with respect to privacy, with the goal of automating consent processes as much as possible.

7.3.2 Transactions

The HIPAA Administrative Simplification rules reference the ASC X12 and NCPDP standards for claims and e-prescribing transactions, with the ASC X12 5010 standard currently applying to claims submission and the NCPDP SCRIPT 201771 standard covering prescription and medication history transactions.

[10] Carequality. www.carequality.org.

[11] Carequality. Query-based document exchange implementation guide. 2018. https://ceq-project.s3.amazonaws.com/wp-content/uploads/2018/09/30162842/Implementation-Guide-v1.1-Effective-3-27-18.pdf.

[12] FEI Systems. Consent2Share version 3 deployment guide. https://bhits.github.io/consent2share/downloads/3.5.0/C2S_Deployment_Guide_3.5.0.pdf, https://gforge.hl7.org/gf/project/cbcc/frs/?action=FrsReleaseBrowse&frs_package_id=303.

[13] ONC. 2021 interoperability standards advisory. https://www.healthit.gov/isa/sites/isa/files/inline-files/2021-ISA-Reference-Edition.pdf.

[14] ONC. LEAP 2019 – San Diego regional health information exchange. https://www.healthit.gov/techlab/ipg/node/4/submission/2591.

[15] PP2PI. Protecting privacy to promote interoperability workgroup. https://www.drummondgroup.com/pp2pi.

[16] Protecting Privacy to Promote Interoperability Workgroup: Whitepaper. https://www.drummondgroup.com/wp-content/uploads/2021/08/pp2pi-white-paper-june-2021.pdf

Other transactions have been the focus of state and national rulemaking, both nationally and state level, e.g., laboratory results reporting (for laboratories, providers and public health agencies), syndromic surveillance, and immunizations. HL7 v2 messaging standards have been widely adopted to support these transactions, although variations at the state level by agencies, as well as the variety of implementations already in place supporting provider-laboratory connections continue to create challenges. For example, a laboratory results reporting standard using the HL7 v2 based Laboratory Results Interface (LRI) interface guide[17] was included as a standard for EHRs by the ONC in 2014 but without a matching implementation requirement for reporting laboratories. Consequently, variations persist.

The *Direct Protocol* through ONC's certification program enables secure messaging between two parties using solely a HISP (Health Information Service Provider) that manages the transport and security of the messages. *Direct messages* can contain simple text and/or documents and other data sets. The protocol supports care transitions, case reporting, and is part of a newly developed IHE profile, IHE 360×[18] that enables closed loop referrals.

An HL7 FHIR-based Bidirectional Services eReferral implementation guide[19] was published enabling referrals using either FHIR messaging or RESTful services between healthcare organizations and community health centers which typically do not support HL7 v2 or HL7 CDA and C-CDA.

7.3.3 Document Exchange

Documents are snapshots of relevant data as pulled together or composed by a user for sharing in human-readable format while allowing for encoding of structured and narrative content. These are persistent, in contrast to transactions, which are typically purged after receipt. To define a clinical document, HL7 specifies six characteristics as part of the Clinical Document Architecture standard[20]:

1. Persistence: A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements
2. Stewardship: A clinical document is maintained by an organization entrusted with its care
3. Potential for Authentication: A clinical document is an assemblage of information that is intended to be legally authenticated
4. Context: A clinical document establishes the default context for its contents
5. Wholeness: Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document
6. Human readability: A clinical document is human readable.

Initially the Clinical Document Architecture standard left much room for interpretation on how to represent the content of document. Other industry initiatives aimed to define the content of a document as well, such as the Continuity of Care Record (CCR).[21] Through a series of progressions and collaborations, the Consolidated Clinical Document Architecture (C-CDA) Implementation

[17] HL7. Laboratory results interface, release 1 STU release 3 – US Realm. 2012. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279.

[18] IHE. 360 exchange closed loop referral (360X), Rev. 1.1. https://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_360X.pdf.

[19] HL7. Bidirectional services eReferrals (BSeR) FHIR Implementation Guide, 2020-03-02. http://hl7.org/fhir/us/bser/history.html.

[20] HL7. HL7 clinical document architecture, release 2.0, ANSI-approved HL7 standard, Section 1.1. Ann Arbor, MI, 2005. https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7.

[21] ASTM International and the Massachusetts Medical Society, HIMSS, AAFP, AAP, AMA, AHCA, the Patient Safety Institute and the National Association for the Support of Long Term Care. Standard Specification for Continuity of Care Record (CCR) (Active standard). ASTM International. 2012.

Guide R2.1, plus a companion guide, emerged providing guidance on how to represent 13 document types of which three are named in ONC's 2015 Certification Edition Cures Update (Continuity of Care Document, Referral Note, and Discharge Summary) to support the US Core Data for Interoperability (USCDI—see section USCDI/EHI/DRS), while others (e.g., Care Plan) are named in other CMS initiatives.

Since documents effectively represent payload of either transactions or services, document exchange standards are essential to enable submission, querying and retrieval of documents, whether formatted as CCRs, CCDs, C-CDAs, pdfs, or other formats, within and across care communities. The IHE Document Exchange profiles[22] are the de facto standards for document exchange and sharing through health information exchanges (HIEs) and national networks, while the use of FHIR-based document exchange is emerging. Additionally, the Direct Protocol is widely used as well for directed document delivery inside, across, and outside networks.

7.3.4 Services

Web services technologies have enabled internet and mobile technologies to interact with external data sources. The ability to exchange smaller, targeted packages enabled stateless, a-synchronous communication integrating multiple data sources, thus accessing data as needed rather than having to change large data sets. One of the typical examples to clarify its potential is the ability for an app on a smartphone to interact with a variety of data sources to gather data and put a rich user interaction together such as obtaining a map from on source, gas stations and restaurants nearby from another, and presenting it to a user to show nearest gas stations and restaurant stops. But whether the interactions are in support of consumer-focused apps on a smartphone or b2b, business-to-business interactions between systems supporting small to large organizations, this approach enables an entirely new way to solve interoperability challenges.

The aforementioned healthcare interoperability standards, particularly transaction focused standards, within this environment were not well suited for this new approach. The introduction of the Fast Healthcare Interoperability Resources (HL7 FHIR) standard[23] set out to restructure healthcare data definitions for interoperability at a more granular level to support the new needs for Web Services (such as RESTful APIs), starting in 2011.

In 2013, AHRQ published A Robust Health Data Infrastructure,[24] also known as the JASON report. It recommended industry to use public APIs and open standards, interfaces, and protocols that promote interoperability. ONC's 2015 Certification Edition subsequently introduced the requirement for API support for an initial set of data, the Common Clinical Data Set[25] (CCDS). Use of specific standards was not required, however, the APIs had to be open for anybody to use, thus requiring appropriate technical specifications to be provided by the certified EHR. However, a private sector initiative, the Argonaut project built an implementation specification using HL7 FHIR to support the CCDS data set, which was subsequently adopted by various EHR vendors to certify their software to ONC's API criteria. That in turn enabled various consumer App developers to begin connecting their apps more easily and consistently thus starting to fulfill the goals of the JASON report.

Through 2019 the HL7 FHIR standard matured sufficiently and gained substantial traction, enabling ONC to name HL7 FHIR R4 and specifically the US Core R3 implementation guide (evolved from the early Argonaut

[22] IHE. IT infrastructure technical framework, Revision 17. https://www.ihe.net/resources/technical_frameworks/#IT.

[23] HL7. HL7 FHIR, all releases. http://www.hl7.org/fhir/.

[24] AHRQ. A robust health data infrastructure, 2013. https://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf.

[25] ONC. Common clinical data set (CCDS). https://www.healthit.gov/sites/default/files/topiclanding/2018-04/2015Ed_CCG_CCDS.pdf.

specifications) to support RESTful API based access to the CCDS successor, the USCDI data set.

By December 31, 2022, all certified EHRs must support APIs using these standards, and many already started to make HL7 FHIR R4 APIs available well before the deadlines. At the same time CMS introduced a new rule in 2020 focusing on payers to establish as series of APIs to enable payer-to-payer, payer-to-consumer, and payer-to-provider data exchange based on the same HL7 FHIR standards.

It is critical to appreciate that HL7 FHIR based interoperability need not be restricted to RESTful APIs used for messaging or other methods as well. HL7 FHIR is in fact uniquely positioned to enable consistent syntax across transactions, documents, and services.

With the focus on HL7 FHIR®, new use cases are now being considered, including the following initiatives (HL7 FHIR Accelerators[26]) to advance:

- **Argonaut**: general advancement of the HL7 FHIR standard
- **CARIN**: consumer apps such as Blue Button for payers and real time benefits checking
- **CodeX**: common data elements for oncology
- **Da Vinci**: payer-provider transactions such as prior-authorization, clinical and claims data exchange, notifications, gaps in care and quality measures.
- **Gravity**: social determinants of health use cases.
- **Vulcan**: bridging clinical care and clinical research and strategically connect industry collaboratives.

All build on, expand, and constrain HL7 FHIR to facilitate and support specific use cases while maintaining consistency within the standard.

[26] HL7 FHIR Accelerators. http://www.hl7.org/about/fhir-accelerator/index.cfm.

7.3.5 USCDI/EHI/DRS

The 21st Century Cures Act[27] describes the need for interoperability for electronic health information (EHI), including the provision against information blocking of such EHI, but does not define its scope. ONC defines EHI to mean electronic protected health information (e-PHI) to the extent that it would be included in a designated record set (DRS) as defined in the HIPAA Privacy Rule,[28] other than psychotherapy notes or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding, and regardless of whether the actor is a covered entity.

Not only did the 21st Century Cures Act set the outside scope EHI (all data to be considered EHI), subsequent rule making also set a minimum scope of data within EHI that certified software needs to support with interoperability capabilities using HL7 CDA C-CDA documents and HL7 FHIR based APIs, and for assessing information blocking claims. The minimum scope is defined through the introduction of the USCDI standard.[29] Through regulatory updates the scope of USCDI will increase over time. Although the intent of USCDI at this point is only to address core data for interoperability that all certified software must support, for interoperability to occur without special effort for all EHI, standards must become available and agreed to for all EHI. In what form, how many regulatory iterations and over how many years has yet not been established.

[27] ONC. 21st Century Cures Act: interoperability, information blocking, and the ONC health IT certification program. 2020. https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

[28] CMS. The HIPAA privacy rule. https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.

[29] ONC. US Core Data for Interoperability (USCDI). https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.

USCDI v1, introduced in the 21st Century Cures Rule, represents an incremental expansion over CCDS adding initial provenance data, to better understand the source of the data shared, and clinical notes to address narrative summary data that frequently was not or insufficiently included in documents and APIs. Certified EHRs are required to support USCDI v1 by December 31, 2022 for documents and APIs. USCDI v1 also provides the initial scope for information blocking until October 5, 2022, after which the scope will be the full EHI data set.

The USCDI v2 draft was proposed in January 2021 and subsequently published July 8, 2021. USCDI v3 was published in July 2022.

To reduce the impact of extending the USCDI and using more current versions of standards referenced in the 21st Century Cures Act Final Rule through regulatory updates, the 21st Century Cures Act also includes a new, sub-regulatory process, the Standards Version Advancement Process (SVAP), that enables yearly updates to any standards referenced in the 21st Century Cures Rule. A newer version of a referenced standard must be approved by ONC to be included in SVAP. Adoption of standard versions referenced in SVAP are voluntary and are not required to stay current on certification. However, if one were to adopt the more current version allowed under SVAP every year, then by the time the next regulatory update is published (presumably using the then most current version of the standard at that time) the uptake is limited as it was spread over time. In that context, yearly updates to USCDI are expected to be included in the SVAP updates to enable continuous evolution between regulatory updates necessary to establish a new floor for standards support and introduce new standards.

As much as ONC defined the scope of EHI, the reference to the designated record set definition left ambiguity as to the exact scope of EHI. As highlighted by AHIMA in its Fundamentals of the Legal Health Record and Designated Record Set[30] that "there is no one-size-fits-all definition for the legal health record and designated record set", the actual scope of the data within a designated record set is very much in the hands of the provider. The provider has the opportunity and responsibility to define the specific scope of their designated record set. In particular, the definition of the designated record set in 45 CRF 164.501includes "(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals." which can yield variations in what could be considered a designated record for a particular one specialty practice vs. another specialty practice vs. a large health system. Until there is clear awareness of what a provider includes in their designated record set and/or further alignment on the specific scope, this will continue to create challenges for the requester of data what they can expect (an information blocking challenge), and for HIT to manage the variations in definitions to determine on behalf of the provider what data to provide to a requester (an interoperability challenge). Particularly the information blocking challenge can be expected to create mis-aligned expectations on what data is actually available.

7.3.6 Information Blocking

The 21st Century Cures Act introduced the concept of "information blocking" which is the prevention of interoperability "for a legitimate purpose specified by the Secretary [of HHS]" as defined by the 21st Century Cures Rule for eight exceptions[31] or reasons:

1. Preventing harm
2. Privacy
3. Security
4. Infeasiblity
5. Health IT performance
6. Content and Manner
7. Fees
8. Licensing

[30] AHIMA. Fundamentals of the legal health record and designated record set. http://library.ahima.org/doc?oid=104008.

[31] ONC. Information blocking exceptions. https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf.

The first five focus on reasons for not fulfilling requests to access, exchange or use EHI, while the last three focus on conditions or barriers to interoperability. Organizations subject to information blocking claims include providers, HIT vendors, health information networks/exchange, and other organizations holding EHI. Initially, starting April 4, 2021 and up through October 5, 2022, the scope of the data subject to information blocking claims applies only to USCDI v1 data. Even though USCDI v2 was published July 8, 2021, that does not change the scope of information blocking until October 5, 2022. After October 5, 2022, the scope of information blocking provisions apply to all EHI that an providers and organization hold.

7.3.7 Nationwide Networks

In 2004, ONC started an initiative to enable a nationwide interoperability framework using a Data Use and Reciprocal Support Agreement (DURSA) and a set of agreed to interoperability standards. Initially known as NHIN,[32] then NwHIN and Healtheway, it is now known as eHealth Exchange.[33] This framework enabled participants to exchange documents consistently from-point-to-point using the IHE Document Exchange profiles.

In 2012, DirectTrust™[34] was initiated to enable implementation and deployment of Direct Protocol based secure messaging. The Direct Protocol was created in response to early discussions in ONC's HIT Policy Committee and Standards Committee to enable email-based exchange as a way to accelerate nationwide exchange of data based on existing internet protocols. DirectTrust established an accreditation process for Health Information Services Providers (HISP) to support the Direct Protocol and sharing of Direct Address information.

In 2013, the CommonWell Health Alliance[35] of HIT vendors established a framework and a network infrastructure, including a record locator service, to enable and broker document exchange.

In 2014, Carequality,[36] a trust framework of standards and a connection agreement for cross-network access and national-level data exchange was formed, allowing multiple stakeholders (beyond healthcare providers and exchanges) to join, accelerating adoption.

In 2015, the managing organization of HealtheWay/eHealth Exchange and Carequality initiatives, started to operate as The Sequoia Project[37] culminating in 2018 with a corporate restructure. This enabled The Sequoia Project to further focus on broader promotion of nationwide interoperability, addressing key challenges such as information blocking, data use and content quality, and emergency preparedness under the Interoperability Matters initiative.

The value of Carequality's trust framework was underscored during the COVID-19 pandemic when an agreement between APHL and eHealth Exchange, enabling electronic case reporting without point-to-point data sharing agreements, was extended with Carequality to cover all Carequality implementers and their participants. Ramping up critical case reporting became much easier to ramp up.

National networks have seen exponential growth, exchanging over a hundred million documents each month, enabling healthcare organizations and consumer-focused applications to access more patient's data anywhere in the country. Regional HIEs continue to expand network initiatives as well through SHIEC[38] (Strategic Health Information Exchange Collaborative), such as the Patient Centered Data Home, which connects patient data across multiple HIEs, thus informing a patient's "home" HIE about data being available for that patient. As of January 2021, 45 HIEs are participating in this program, further enhancing access to patient's data at a national level.

Network capabilities will continue to expand, including using HL7 FHIR standards to enable and extend interoperability. Networks such as CommonWell already enable HL7 FHIR based document exchange. Carequality published an

[32] NHIN. https://www.healthit.gov/sites/default/files/what-Is-the-nhin%2D%2D2.pdf.

[33] eHealth Exchange. https://ehealthexchange.org/.

[34] DirectTrust. https://directtrust.org/.

[35] CommonWell Health Alliance. https://www.commonwellalliance.org/.

[36] Carequality. https://carequality.org/.

[37] The Sequoia Project. https://sequoiaproject.org/.

[38] SHIEC. https://strategichie.com/.

HL7 FHIR based implementation guide in December 2020 enabling individual data element and large data set exchange as well. These (cross-)network initiatives and collaborations will be building on the many HL7 FHIR based APIs already exposed by providers, payers, and potentially other data sources. Once the networks have the essential foundation in place to support HL7 FHIR based access and exchange, the many new interoperability use cases being developed, particularly through the various HL7 FHIR Accelerator initiatives, have the opportunity to build on the national networks to more rapidly expand and scale as well.

The 21st Century Cures Act also addressed the need for a national, trusted exchange framework and common agreement. That framework, also known as TEFCA, is under development and will be discussed further in the Outlook section.

7.3.8 Coordination of Care

A key use case of interoperability is care coordination. Coordination can be done actively, using workflow management standards such as those for laboratory, imaging, referrals, prescriptions, etc., or passively, sharing data by way of documents mostly to enable the receiver to compile a more complete clinical record of the patient enhancing clinical decision support. Most of the focus has been on passive coordination as CMS started the Meaningful Use Program. ONC included both the CCR and HL7 CCD specifications in the first Certification Edition in 2011. Over time, through collaboration across the industry, the HL7 CDA C-CDA implement guide, with association companion guides, has emerged as the single standard to generate structured documents in support of care coordination documents, using IHE Document Exchange and the Direct Protocol as the vehicles to share those documents.

In 2020, CMS introduced a rule[39] that, starting May 1, 2021, would require a hospital that uses HL7 v2.5.1 ADT based messaging to send an electronic notification upon admission, discharge and potentially other events to all applicable post-acute facilities, suppliers and a patient's primary care provider. CMS did not specify any standard format for the event notifications, although it did clarify that faxes would not satisfy the requirement. Industry initiatives have been considering how to enable event notifications beyond the use of HL7 v2.5.1 ADT messages as those have limited reach to external organizations given the infrastructure requirements to support such messages. Examples of standards that support event notification:

- DirectTrust provides guidance[40] using the Direct Messaging approach with HL7 v2 as payload to capture the admissions or discharge message that triggered the event, plus further documentation, e.g., HL7 CDA C-CDA documents where further supporting information is of interest is included.
- Da Vinci provides an HL7 FHIR R4 messaging based notification capability.
- HL7 is enhancing its FHIR based pub/sub capabilities in FHIR R5, while working on back-porting it to HL7 FHIR R4 to enable pre-adoption before FHIR R5 is published and adopted.
- Carequality has a project in progress using this approach.
- Various HIEs are exploring/expanding HL7 v2 ADT based notification to providers already connected to their HIE.
- SHIEC's Patient Center Home approach supports event notifications.
- Various HIT vendors provide solutions using HL v2 ADT feeds to trigger and route notifications using Direct Messages or other formats.

At this time, it is unclear which approach will emerge as the front runner to be adopted in future rulemaking, or whether network solutions will

[39] CMS. Interoperability and patient access for medicare advantage organization and medicaid managed care plans, state medicaid agencies, CHIP agencies and CHIP managed care entities, issuers of qualified health plans on the federally facilitated exchanges, and health care providers. 2020. https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf.

[40] DirectTrust. Event notifications via the direct standard. https://directtrust.org/standards/event-notifications-via-direct.

emerge bridging the different formats to enable nationwide event notifications.

CMS also introduced the requirement for providers to publish their electronic endpoints in the National Plan and Provider Enumeration System (NPPES) as a single source of contact information for data sharing. However, this would not cover all possible endpoints necessary to address all potential stakeholders in care transitions of care (payers and suppliers of potential interest) for event notification. ONC's FHIR at Scale Taskforce (FAST) promotes a national infrastructure of a set of federated directories, each of which provides contact information for different types of stakeholders. FAST is working with HL7 to develop implementation guidance for interacting with such a directory structure. In the absence of such an infrastructure, expanding the reach of electronic care coordination will remain a challenge.

Currently millions of documents per month flowing for care transitions, and interoperability initiatives are increasingly focusing on improving content, optimizing data sets and streamlining receiver-side record curation and reconciliation of external data with internal data. Additionally, dynamic care planning and coordination across disparate providers participating in the same care team continues to be a future goal. For now, sharing relevant current state data through documents remains the state of the art with closed-loop referrals and prior authorization gaining increased focus to manage complex, cross-provider and payer workflows.

7.3.9 Patient Engagement

Interoperability development is also empowering patients to access their medical record and manage their health. Much work is still needed to enable patients to have full access to and control of all their health data, regardless of the source of their data. Patient portal-based electronic health records, combined with online access using the internet-based app ecosystem, stimulated by ONC's HIT/EHR requirements and CMS' incentives have started opening up electronic access to one's data.

Currently, certified EHRs enable patient access via patient portals, scoped to the CCDS data set and formatted as HL7 CDA C-CDA documents when downloaded, and frequently using Direct messages to share those documents with anybody with whom the patient wishes to share that data. APIs are available for the same CCDS data set and various EHRs use Argonaut HL7 FHIR to enable apps to connect consistently across EHRs. By 2023 we can expect improved consistency and ease in connecting across providers as APIs using the HL7 FHIR R4 standard, in combination with the HL7 FHIR US Core, OAuth and OpenID specifications, have been deployed.

For data not yet included in USCDI but part of the larger EHI data set, the EHI Export requirement for certified software will enable electronic access to extended data sets, albeit without having agreed to standard specifications. I.e., the approach being taken for EHI Export is similar to that when ONC introduced APIs into their certification program. Likewise, while the ability to receive patient generated data is a certification criterion, no standards have been identified yet. HL7 recently started the Patient Engagement workgroup that is working with interested stakeholders to identify the gaps and drive development of the relevant standards for these and other data of particular interest of patients.

7.3.10 Public Health

In 2020, the COVID-19 pandemic demonstrated the importance of interoperability in public health to track and present current states, analyse patterns and trends, manage response, and prepare next steps.

Progress had been made to connect providers with local, state, and federal public health authorities in support of syndromic surveillance, laboratory reporting for reportable tests, and immunizations using HL7 and CDC developed standards. ONC included these standards in their certification editions, while CMS' Meaningful Use program began to encourage adoption of these capabilities. However, participating provid-

ers did not need to adopt all capabilities, most notably visible in the adoption of electronic case reporting, for which a specific standard was also not referenced.

The combination of nascent electronic case reporting adoption, data requirement variations across existing state and federal reporting created substantial challenges to respond when the pandemic struck. The pandemic also highlighted a gap in the amount of data necessary to understand the magnitude, patterns, comorbidities, and other factors influencing the spread, those mostly at risk, and where to focus. Public health jurisdictions at all levels started to identify additional data necessary to understand and manage the pandemic. For providers needing to report to jurisdictions in different states, and HIT developers enabling reporting in different states, the challenges increased even further as new reporting requirements, understandably all needed immediately, required jurisdiction specific development and deployment rather than one national level development and deployment effort. Given the variations across states, one software update could not be deployed to all states.

Efforts to gather data beyond syndromic surveillance, laboratory reporting, and immunizations were along two lines:

- Alternative methods using existing technologies and networks to access the additional relevant data
- Accelerating adoption of electronic case reporting

7.3.10.1 Alternative Methods

The alternative methods used HL7 CDA C-CDA CCD documents to get as much data as possible, using existing networks and Direct messaging, as ordered by public health jurisdictions. Carequality also established an emergency use process whereby jurisdictions could request documents under existing permitted purpose of treatment.

States also started adding data to existing transactions. These requirements added burdens and challenges as the existing transactions were never designed to support those requirements. For example, adding new electronic demographic data or intake questions at time of ordering/performing a given test created additional work for systems to collect, transmit, maintain, and include in reports. The data would have fit very well in case reports, but those were not electronically transmitted.

7.3.10.2 Accelerating Adoption of Electronic Case Reporting

HL7 had established the Electronic Initial Case Report (eICR)[41] and Reportability Response[42] implementation guides based on HL7 CDA, and The Digital Bridge[43] initiative had started to promote and drive adoption. The Centers of Disease Control (CDC) and APHL established the eCR Now initiative to work with jurisdictions, providers, EHR vendors, and national networks to accelerate adoption of HL7's eICR case report. The APHL/AIMS hub was positioned to enable a hub for a single point of submissions that in turn would filter HL7 eICR content based on the target jurisdiction and route it accordingly.

APHL established a data sharing arrangement with eHealth Exchange to enable participants to submit case reports without data sharing agreements between each provider and APHL. Carequality worked with eHealth Exchange to extend this data sharing agreement across all Carequality implementers and their connections.

While EHRs could trigger and create case reports within the EHR workflows, CDC at the same started development of an open-source app, the eCR Now FHIR App, to take advantage of FHIR based APIs to populate the HL7 eICR and communicate the report to APHL/AIMS. Initial deployments are expected to start early 2021.

By the end of 2020, virtually all public health jurisdictions were able to start to receive HL7

[41] HL7. Public health case report, release 2—US Realm—the electronic initial case report. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=436.

[42] HL7. Reportability response, release 1, STU release 1.0 – US realm. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=470.

[43] Digital bridge. https://digitalbridge.us/.

eICRs through the APHL/AIMS hub, while deployments started to accelerate.

In 2021 CMS did propose and finalize required adoption of four electronic reporting capabilities: syndromic surveillance, laboratory reporting, case reporting, and immunization reporting. In particular, inclusion of case reporting will greatly enhance the availability of critical data, not only in normal times, but particularly when responding to a pandemic.

In addition to more clinical data, there was also a need for operational data on capacity and resource utilization during the pandemic, information not necessarily derivable from existing data already shared, and was typically managed in systems not used for public health reporting, e.g., bed management, human resources planning, and inventory management. Data collection tools were therefore deployed using spreadsheet submissions and manual data entry methods using portals such as TeleTracking.

This gap led to the start of the HL7 SANER project to define HL7 FHIR based implementation guides that would enable query definitions for the measures of interest (including computable query expressions), reporting formats, and the relevant APIs to exchange/access the measure definitions, submit the reports, and/or using HL7 FHIR based APIs to access the source data to generate the measures. A need also emerged for interoperability to enable population health research using real-world data. As requests for patient level data started to be made beyond public health orders, establishing the necessary data sharing agreements with appropriate provider and patient consent outside of public health jurisdiction authorized requests become a key challenge, including having to realize that HIT vendors do not have data sharing rights to the data they manage for a covered entity under a business agreement that some researchers believed they did. Therefore, establishing the necessary data sharing agreements and consents in accordance with 45 CFR 46, Protection of Human Subjects consequently takes more time than a pandemic affords to rapidly get access to relevant real-world data to start key exploratory research.

An approach used by the Mitre COVID Healthcare Coalition uses a distributed query approach where participating providers' HIT would generate de-identified, aggregated reports to answer research questions. This approach reduces the complexities of obtaining the necessary consents, yet still resulted in relevant insights based on real world data. It also demonstrated the challenges with obtaining comparable data based on common data definitions, generally a problem with exploring real world data across varied systems, and indicated that a federated approach, similar to the one taken by the HL7 SANER project might provide a path for supporting real world (and real-time) data based exploratory research.

7.4 Outlook

As progress in nationwide interoperability development moves forward, the horizon also expands.

7.4.1 Privacy

While a fully aligned and consistent national privacy framework in the foreseeable future is unlikely, substantial progress can be made in the consent management space. Key challenges will include:

- Defining practical, computable policies that enable jurisdictional policies and patient consent directives that are usable by providers and patients alike.
- Identifying the roles of HIEs, networks, and EHRs to enable the necessary sharing using either accessible, shared repositories and/or passing along the directives with the data.

There are two projects in particular to track that focus on operationalizing the already available HL7 standards that enable standardized expressions of privacy policies and patient consent directives plus necessary tagging of data to manage data sharing according to these policies and directives. The San Diego Health Connect's ONC LEAP Computable Consent Project is focusing on computable patient consent directives, while PP2PI aims to take a holistic approach across critical use cases to enable national scaling, thus consistency of policy and directive

encoding. Both exemplify that much work is still needed to enable scalable privacy and consent management at a national level across a large variety of organizations and IT solutions that hold patients' EHI.

Increased patient mobility, especially at a global level, will further influence the design and implementation of infrastructures for patients to mediate access to their data where provider-to-provider exchange, even with patient consent, is not permitted. Increasing attention needs to be given to international regulations, such as the European General Data Protection Regulation[44] (GDPR) that impacts how a receiver is expected to manage patient data whether the receiver is already subject to GDPR or not in their country.

7.4.2 Cross-Organization Workflow Coordination

ePrescribing, laboratory test ordering and results reporting are clear examples of cross-organization workflow coordination where much progress has been made. New cross-organization workflows of interest include closed-loop referrals, prior-authorizations, and durable medical equipment (DME) or post-acute care ordering. Efforts to date have yielded initial implementation guidance[45] and early pilot and deployment activity. Clinical Decision Support (CDS) Hooks,[46] a specification enabling a "hook"-based pattern[47] for invoking decision support from within a workflow, that can work with SMART[48] Apps (HL7 FHIR based or not), will also be an important capability to enable and streamline cross-organization workflow coordination within the EHR or another IT's workflow.

In late 2020, CMS proposed rules to reduce technical burdens associated with prior-authorization[49] referencing the Da Vinci implementation guides supporting the prior-authorization workflow. The rule was not fully finalized at the start of 2021, but we should expect increasing interest and incentives to progress these workflows. Various solutions, including SMART apps using the FHIR based Da Vincie implementation guides for prior-authorizations, are starting to be deployed.

7.4.3 USCDI/EHI/DRS

Expansion of the USCDI towards the full scope of EHI and DRS is expected to continue even though USCDI after October 5, 2022 will not set the scope for information blocking. It is expected to set scope for interoperability standards, in particular the HL7 FHIR US Core and HL7 CDA C-CDA implementation guides.

It is quite conceivable that in the next 2–3 years a number of the HL7 CDA C-CDA based documents are starting to be available as FHIR documents instead. Such a transition would further ensure data shared as part of a document or through services would be fully aligned and consistently expressed in terms of syntax and semantics. As we expand standards support for all of EHI, whether for purposes of access and sharing individual data, documents, or large data sets (e.g., those needed for EHI Export capabilities), such consistency is critical to improve and maintain high data fidelity in interoperability.

7.4.4 Nationwide Networks

ONC has drafted a Trusted Exchange Framework (TEF), Common Agreement (CA) and Qualified Health Information Network (QHIN) Technical

[44] European Union. General data protection regulation, 2016. https://gdpr-info.eu/

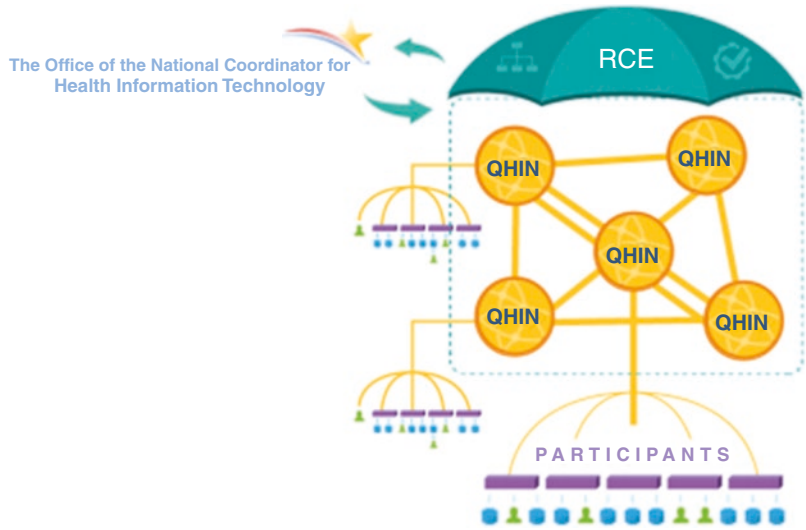
[45] See HL7 post acute orders implementation guide (http://www.hl7.org/fhir/us/dme-orders/history.html), Da Vincie Prior-authorization implementation guides (coverage requirements discovery—http://hl7.org/fhir/us/davinci-crd/history.html; document template and rules—http://hl7.org/fhir/us/davinci-dtr/history.html; prior-authorization support—http://hl7.org/fhir/us/davinci-pas/history.html), HL7 Bidirectional Services eReferrals Implementation Guide (http://hl7.org/fhir/us/bser/history.html), and IHE 360× closed loop referral (https://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_360X.pdf).

[46] CDS Hooks. https://cds-hooks.org/.

[47] Hooking. https://en.wikipedia.org/wiki/Hooking.

[48] SMART Health IT. https://smarthealthit.org/.

[49] https://www.cms.gov/files/document/121020-reducing-provider-and-patient-burden-cms-9123-p.pdf.



Source: ONC—Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. 2019. https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf

Framework (QTF) which defines QHINs, their responsibilities and technical infrastructure to enable interoperability between QHINs. A QHIN would be made up of participant organizations (e.g., health information networks, health information exchanges, provider organizations, health IT developers, payers, federal agencies) that would be interoperable with each other and to organizations in other connected QHINs:[50]

In this scheme, a central Recognized Coordinating Entity (RCE) would implement and monitor compliance of QHINs with the CA and QTF. This role was awarded to the Sequoia Project which is developing, with input from other stakeholders, the next iteration of TEFCA and the QHIN Technical Framework. By early 2021, this next stage was still pending.

Challenges still to be addressed are: how existing infrastructures will transition into the projected TEFCA infrastructure and how much of what is effectively already providing the targeted TEF capabilities (such as the Carequality specifications for cross-network document exchange and the DirectTrust capabilities for messaging) will remain. Early drafts indicate a strong resemblance with the current infrastructure in place.

Once TEFCA is finalized, adoption will be voluntary, with participation/adoption may be obliged by contractual requirements for membership in a QHIN. Networks have already expressed intent to become QHINs if TEFCA will be a practical and reasonable way to connect, adds value and expands accessibility to clinical records when the first phase of TEFCA is finalized.

In 2022 final documents were published for the common agreement, QHIN Technical Framework, and associated Standard Operating Procedures (SOP) with some yet to to be finalized. Then networks can start to apply to become a QHIN and initial connections under TEFCA be established.

While FHIR based access and exchange, whether FHIR based document exchange, FHIR based data element and data set level access and exchange, or FHIR documents, is not part of the initial phase, the expectation is that rollout of the TEF in conjunction with vendor implementation of FHIR-based APIs supporting the 21st Century Cures Rule, will enable substantial expansion of interoperability beyond the now traditional messaging and document exchange paradigms, firmly moving the healthcare industry into an era of service-based interoperability after this first phased.

[50] Trusted Exchange Framework and Common Agreement, Draft 2. 2020. https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf.

In December 2020, Carequality issued the first version of an exchange implementation guide[51] for national network level FHIR-based data access, followed by a second draft in July, 2021.[52]

7.4.5 Coordination of Care

Moving forward, questions of data quality and usability will be at the forefront with respect to care coordination. Specifics with respect to completeness, correctness and currency of information documented and transacted for care coordination will be a key focus shaping development. Both the source of the data and the receiver of the data will have a stake in this.

7.4.5.1 Source

Data quality assurance by the source for care transitions/coordination entails maintaining correct availability (right destination), encoding (right content and standards), completeness (right size and amount) for the purpose. Examples include:

- A collaboration between CommonWell and Carequality[53] focusing on a structured, "right-sized" encounter summary that balances narrative, encoded, and quantitative data.
- A data usability project started by The Sequoia Project in 2020 to explore how to further improve clinical content to facilitate health information exchange.
- An already available CDA Validator tool from ONC to measure conformance to the standards.
- Expansion of HL7 FHIR based access to data to further enable "right-sizing" of data.

7.4.5.2 Receiver

Data usability assurance by the receiver for care transitions/coordination entails integrating the external data received with the internal data with the least amount of effort, enabling the resulting data to be used in context in various workflows and views such as clinical decision support, trending, highlighting, etc. Examples include:

- Extracting data from documents to go beyond isolated viewing capabilities to using the actual content for review/analysis in context with internal data and for clinical decision support
- Simplifying and automating the curation and normalization process, minimizing clinicians de-duplicating data, reconciling, sorting, and organizing the data

7.4.6 Patient Engagement

The introduction of APIs, especially HL7 FHIR based APIs have wide industry support to facilitate healthcare data access. Existing security standards, such as OAuth and OpenID, enable a secure environment in which to expand development of apps for access within a trusted framework where consumers, providers, and payers are comfortable and confident that the consumer apps represent the consumer thus accessing the right person's data, and that the consumer is aware of how their data is used.

Trusted and accountable collaboration is required for this environment. The CARIN Alliance[54] is an effort in establishing a code of conduct for developers and focusing on consumer identification and authentication to drive adoption of consumer health apps. At the same time the Electronic Healthcare Network Accreditation Committee (EHNAC) is working on a Trusted Dynamic Registration and Authentication Accreditation Program (TDRAAP)[55] while national networks[56] are also exploring a trust framework encompassing consumer apps to increase scalability of connections to the patient's health data.

[51] https://carequality.org/wp-content/uploads/2020/12/Carequality-FHIR-Implementation-Guide.pdf.

[52] https://rce.sequoiaproject.org/wp-content/uploads/2021/07/QTF-V1-Draft.pdf.

[53] https://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf.

[54] https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/.

[55] https://www.ehnac.org/tdraap/.

[56] See also earlier references to Carequality's FHIR implementation guide.

7.4.7 Public Health

The pandemic has identified many challenges that need to be addressed to rapidly respond to new emergencies and improve the efficiency of ongoing reporting and surveillance processes. Micky Tripathi, PhD, ONC's National Coordinator also indicated the need for essential updates to the public health infrastructure.

Key areas to focus on are:

- Streamlined and focused notifications for reportable conditions and tests
- Expansion of bi-directional immunization reporting and querying capabilities
- Expansion of case reporting adoption to capture data beyond the notifications
- Maintaining the minimum necessary principle
- Introduction of computable measures enabling
  - Operational data reporting
  - Real-world data research using federated query approaches
- Enabling provider, community, and individual access to public health data and dashboards
- Emergency preparedness validation

HL7 FHIR will play an important role in enabling and expanding on these capabilities, as well requiring policy and regulatory focus to fund and drive adoption by all stakeholders in concert. HELIOS, an HL7 FHIR Accelerator, was established as a collaboration between CDC, ONC, STLTs (State, Tribal, Local, or Territorial public health departments), and the industry to support these efforts identifying and developing FHIR based implementation guides.

7.4.8 Measuring Impact

In 2016 ONC funded the National Quality Forum (NQF) to establish an Interoperability Measurement Framework. The framework identified the following (sub-)categories to consider measuring interoperability[57]:

Domain	Subdomain
Exchange of electronic health information	• Availability of electronic health information • Quality of data content • Method of exchange
Usability of exchanged electronic health information	• Relevance • Accessibility • Comprehensibility
Application of exchange electronic health information	• Human use • Computable
Impact of interoperability	• Patient safety • Cost savings • Productivity • Care coordination • Improved healthcare processes and health outcomes • Patient/caregiver engagement • Patient/caregiver experience

Source: National Quality Forum—A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy—September 1, 2017

Some measures, such as transaction volume are easily obtainable from systems, but others, such as how well data is integrated upon receipt with the least amount of effort and highest level of accuracy (e.g., patient matching, de-duplication of external/internal data, or reconciliation), are more challenging.

There are many success stories where access to external data demonstrably improved on the clinical decision making,[58] as there are many stories where lack of interoperability has demonstrated negative impacts on patient care: missing records, repeat information gathering, duplicate services/procedure, delayed access, reduced patient and clinician satisfaction. While it may be a challenge to measure more accurately the impact of interoperability, it should be clear that having access to a patient's full medical record, whether for the provider or patient, is essential to have the ability to provide optimum care and manage one's health.

[57] https://www.qualityforum.org/Publications/2017/09/Interoperability_2016-2017_Final_Report.aspx.

[58] Sample success stories: https://www.ehra.org/sites/ehra.org/files/docs/Value%20of%20Interoperability%20Success%20Stories%20-%20Updated%20August%202017.pdf.

Question and Answer

1. Name different levels of interoperability.
   a. According to health level seven: technical, semantic and process. According to HIMSS: foundational (level 1), structural (level 2), semantic (level 3), organizational (level 4). See "Definitions" for a detailed explanation and distinctions.

Health Information Exchange

8

David Horrocks, Lindsey Ferris, and Hadi Kharrazi

Abstract

Clinicians, care coordinators, and epidemiologist need timely access to patient data from the healthcare organizations which hold it. However, many barriers exist to requesting and receiving data. Technical standards must be decided and implemented consistently. Privacy protections must be maintained, including audit logs of transactions and methods for patients to express consent. Data use policy must be agreed between the parties exchanging records. Legal protections and recourse for misbehavior must be established. A Health Information Exchange (HIE) is an organization established as a trusted intermediary between the parties, able to address the varies obstacles to exchange, usually through a collaborative governance process. The specific roles and scope of HIEs vary greatly, generally shaped by the purposes for which they were first established. These purposes continue to evolve to meet the needs of the healthcare industry.

D. Horrocks (✉)
New York eHealth Collaborative, New York, NY, USA
e-mail: dhorrocks@nyehealth.org

L. Ferris
Chesapeake Region Information System for Our Patients (CRISP), Columbia, MD, USA
e-mail: lindsey.ferris@crisphealth.org

H. Kharrazi
Johns Hopkins School of Public Health, Baltimore, MD, USA

Keywords

HIE · Use case · Interoperability · MPI
Health record bank · National networks
Health data utility · Query · Notifications
CRISP · SDOH

Learning objectives:

- Define and describe the purpose of Health Information Exchange
- List and describe approaches to achieving Health Information Exchange
- Summarize and describe progress of health information exchange in the United States

8.1 Intro: Why Health Information Should Be Exchanged

To provide the best clinical care, practitioners need timely access to patient data that is correct, current, and complete. Since much of a person's data is generated and stored across multiple, non-affiliated organizations, the aim of Health Information Exchange is to connect these disparate data sources, to deliver the right information, about the right patient, at the right time [1].

A Health Information Exchange is the organization which serves as an intermediary or facilitator of the electronic transactions through

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which health data is shared by other entities. The term "Health Information Exchange" is also used to describe the act of exchanging health data—i.e. it serves as a verb. As described by the HIMSS Interoperability in Healthcare Guide.

> Health information exchange, or HIE, provides the capability to electronically move clinical information among disparate healthcare information systems and maintain the meaning of the information being exchanged. The goal of health information exchange is to facilitate access to and retrieval of clinical data to provide safe, timely, efficient, effective and equitable patient-centered care. HIE can also be used by public health authorities to assist in the analysis of the health of populations [2].

The underlying transactions of HIEs fall into one of two general categories: push or pull. A **push transaction**, or ***Directed Exchange***, sends information to another organization after a trigger event. For instance, a lab might *push* a result to an ordering clinician upon completion of analysis. A **pull transaction**, or ***Query-Based Exchange***, is initiated by the organization in need of relevant information. For instance, a physician in an emergency department might *pull* medical history records from an HIE. A subtype of pull transactions is a ***Consumer Mediated Exchange***, in which a patient directly controls access to his or record [3]. Both push and pull transactions can be manually initiated or automated to occur based on a trigger.

8.2 Common HIE Services

HIE services are typically described as "use cases". Five common categories are: to provide data at the point of care, to deliver data for care coordination, to support public health, to combine disparate data sets, and to produce quality measures. Beyond these clinical use cases, HIEs can also serve as a neutral party for data governance, pulling together different groups for collaboration that may not otherwise typically exchange data. This function occurs within healthcare communities, among entities such as public health agencies, social services and healthcare providers.

8.2.1 Data at the Point of Care

The use case which precipitated development of most HIEs is to provide data collected previously from other providers to a clinician treating a patient, at the point of care. The need is greatest when a patient is new to a clinician and/or has an acute condition. Thus, most general-purpose HIEs focus on providing patient data to clinicians in hospital emergency departments.

In its most basic form, an HIE offers a portal through which an authenticated clinician can search for a patient's record (a pull or query transaction). The clinician may access relevant clinical documents such as lab results, discharge summaries, or procedure notes. An unsophisticated HIE may display these documents without delivering them as structured data. Such documents are viewed through the portal by the clinician but cannot be downloaded and integrated into the local chart.

In a more advanced implementation, an HIE may deliver structured data and automatically integrate it into the local patient chart. Structured data may use standard formats such as the CCD (Continuity of Care Document), which summarizes data about prior medical encounters. Exchanged data may appear directly in the local EHR (depending on EHR vendor capabilities) without the need to navigate to a portal. Other structured or curated data from an HIE available to a point-of-care clinician may include prior imaging studies, claims data, medication lists and/or prior diagnosis codes.

8.2.2 Data for Care Coordination

In contrast to use at the point-of-care, an HIE may deliver patient data to a care manager (not necessarily seeing the patient) for care coordination. Care managers or coordinators use data to help patients navigate appointments and services

over time and medical neighborhoods engage and connect the right patients to the right resources at the right time and location for the right reasons.

8.2.2.1 Notifications

A basic information need of a care coordinator for a patient is data about significant care events. Data from a set of patients may be collected from an HIE as panels on behalf of a care coordinator. As HIEs receive data on care events (such as hospital admission and/or discharge), these may be checked against panels for coordinators to be notified in near-real time (e.g., a push or directed-exchange transaction). This allows the care coordinator to engage the patient at the right time. Such notifications are especially helpful to managed care organizations (MCOs), such as for Medicaid beneficiaries, to optimize care and reduce costs.

8.2.2.2 Delivery System Coordination

For clinicians at the point of care, information in a panel may allow timely engagement of resources during care encounters. For instance, if an ED physician knows that a patient's PCP has a care manager and can assure a next-day appointment or home visits, there may be no need to hospitalize the patient, thus, reducing risks to the patient and reducing costs. Likewise, if a healthcare provider is considering enrolling a patient in a care management program, it is helpful to know what services the patient is already receiving from different organizations.

8.2.2.3 Analysis

HIE push notifications can help healthcare organizations to target care coordination resources where they may be most helpful. For instance, a hospital may decide to provide follow up home visits to patients who have experienced multiple hospitalizations in a defined period. An HIE can provide information about prior hospitalizations over a region, which might flag the patient for a home visit. Push information from HIEs on patient comorbidities or healthcare proxies, can inform clinicians and coordinators when a patient may be unsure or unable to provide the information. Panels of patients can also be built for population health programs. For instance, in a regional program for improving pediatric asthma care, an ED admission for a minor with an uncontrolled childhood asthma exacerbation may trigger an HIE alert for informing program outreach and monitoring.

8.2.3 Public Health Support

Public health infrastructure is built on data collection, sometimes using methods which are decades old. With an electronic network connecting regional healthcare providers and EHRs, an HIE can provide an infrastructure for improving public health through improved surveillance, better case management and point-of-care/patient-specific feedback.

8.2.3.1 Surveillance

Public health departments are legislated to collect data, both identifiable and in aggregate form, from the healthcare community. For instance, epidemiologists, to understand and control infectious disease outbreaks, need access to timely mandated reporting from primary care practices and laboratories. In other instances, health departments require hospitals to report patient-level (largely de-identified) syndromic data from ED visits and aggregate data, such as the number of patients presenting with respiratory symptoms each day. Such reporting is gradually being automated.

HIEs which are already receiving relevant electronic data from healthcare providers can automate health department case reporting, thus reducing the burden of reporting and increasing regulatory compliance with reporting. HIEs can also aggregate de-identified data for graphing disease progression and for prediction. In some cases, without an HIE such reports which would only be possible through greatly expanded and burdensome reporting requirements.

8.2.3.2 Case Management

HIEs can support public health case management in different ways. First, epidemiologists can use the historical medical information available

through an HIE to understand the contexts of individuals with a reportable condition and to extend data collection relevant to an investigation. Second, contact tracers can look up address information through an HIE to reach out to individuals during an infectious disease outbreak and to co-located exposures. Third, public health programs can use transaction messages received through an HIE to find individuals in ongoing care programs who become unreachable, or "lost to care". For instance, an HIE may be configured to send a hospital/ED admission messages to a public health case manager for patients on Directly Observed Therapy (DOT) program for HIV. Such capabilities are particularly useful for managing persons with significant health needs who are homeless.

8.2.3.3 Sending Data Back to Clinicians

HIEs facilitate interoperability adoption and can be a useful infrastructure for public health interventions involving information flows between different parts of the healthcare ecosystem and clinicians at the point-of-care. For instance, as part of a mandated Prescription Drug Monitoring Program (PDMP), an HIE may collect prescription drug data from pharmacies, making the information available within the workflow of prescribing clinicians with whom it has connectivity. Likewise, as part of a state-mandated immunization information system, an HIE can send collected data on previously administered vaccines to clinicians trying to determine what vaccinations are appropriate to administer to a patient at a point-of-care. Yet another scenario is an HIE that can send alerts to hospitalists about new inpatients with known drug-resistant infections for isolation.

8.2.4 Data Combination, Mastering, and Normalization

A core function of an HIE is to match records from different organizations to a single patient—"patient matching". For instance, claims data, social services data, and hospital admission data might be consolidated, often as a limited data set without patient names. Such data may be limited to a panel of patients under care, preserving the ability of care managers to drill down within the report to specific identities. Once identities are combined across multiple datasets, HIE can assist with mastering and normalizing similar data elements across multiple sources with the goal of obtaining a cleaner, more complete and usable representation of the data. For example, race and ethnicity data, which is instrumental to ensuring health disparities are addressed by public health programs and interventions, may be reported in claims, hospital encounter, and lab data. An HIE can assist with organizing the data such that the most accurate data are captured across multiple sources in support of public health response efforts.

8.2.4.1 Operational Reporting

HIEs can facilitate the application of clinical and business analytics functions on patient data. Examples include measurement of healthcare performance for different patient populations, demonstration of the effect of community interventions on hospitalizations, or illustration of how shared savings programs impact specialty utilization. HIEs also provide good platforms for sharing and presenting privileged information to a variety of stakeholders. Because they authenticate and authorize many community stakeholders for access and because their governance is often shared among many, HIE organizations are neutral and form a natural platform to manage analytics for sharing reports among diverse stakeholders. These cross-stakeholder data combinations, analysis, and reports can be key for measuring the performance of the healthcare system and the outcomes for patients on a population level [4].

8.2.4.2 Research Analysis

For healthcare researchers, the aggregated data in an HIE is a unique resource and opportunity to study population and individual health. In deidentified form, it can afford broad analysis of trends and outcomes. Structurally, the data in an HIE may function like an all-payer claims database, but with clinical data instead of or in addi-

tion to claims. With patient consent and institutional board review board permissions obtained, an HIE can also be used to provide data for human subjects research.

8.2.5 Quality Measurement

Some HIEs support electronic clinical quality measurement (eCQM) for care providers and claims-based quality measurement for payers. HIE involvement with eCQM has evolved as reporting requirements have evolved, with most changes evoked by the Promoting Interoperability EHR incentive program. HIE involvement in claims-based quality measurement has been supportive of reporting common clinical quality measures [5]. However, prior to HIE involvement, many tools for data collection and measure calculation were already in use. HIEs occupy an "intermediary space", with some HIEs employed to ingest the clinical data, map it to the measures, and calculate the results for regulatory CQM reporting [6]. Evolving HIE functions in QM include facilitating data exchange to supplement and strengthen reporting databases and serving as the centralized reporting mechanism by which providers report eCQM results to state programs [6].

8.3 Technical Approaches

Two core technical functions of an HIE are: (1) to match health records from various places to a single patient and (2) to move health records where needed. In different technical models, "matching" and "moving" occur on-the-fly, in advance, or through some combination of the two. Each approach has advantages, and the architecture directly impacts the ability of the HIE to provide more advanced capabilities beyond matching and moving.

8.3.1 Distributed Architecture

At the time of the HITECH Act in 2009, when many state HIEs were initially funded, a popular design for information exchange placed records at the "edge" of a network waiting to be queried, rather than moving them to a central repository in advance of being accessed. This approach has the benefits of moving the minimum necessary amount of data and ensuring that health information would not be aggregated in ways unintended by participating healthcare organizations. In this period when many HIEs were just forming, participating organizations often preferred a model in which data was not fully aggregated.

When data remain distributed, the HIE retrieves it on demand, on behalf of a clinician or care manager who requests it (Fig. 8.1). In the classic design, the HIE tracks the location of a patient's data, so it knows where to look when asked to do so, minimizing the volume of transactions taxing the edge device storing the data (and improving response times). The Record Locator Service (RLS) that performs this function is populated by healthcare providers who push basic encounter facts to the HIE as they occur.

National networks such as **eHealth Exchange** and **CommonWell** use a distributed architecture, keeping minimum information locally [7]. Whereas **CommonWell** uses an RLS to find records [8], **eHealth Exchange** has no built-in RLS, although the Surescripts RLS can be used for an additional charge [7]. Organizations querying **eHealth Exchange** will send a user-directed query to a destination known or suspected to have data on a given patient [7]. Only the Veteran's Health Affairs and Department of Defense has the ability to conduct a "fan-out" query that will search all nearby network participants for patient data to minimize unnecessary taxation on the system [7].

In a distributed architecture, advanced functions such as data normalization must be done dynamically. In this architecture, it is challenging to perform functions such as data aggregation, reporting, and research on deidentified data because of the sheer volume of data that needs to be retrieved initially from many stakeholders.

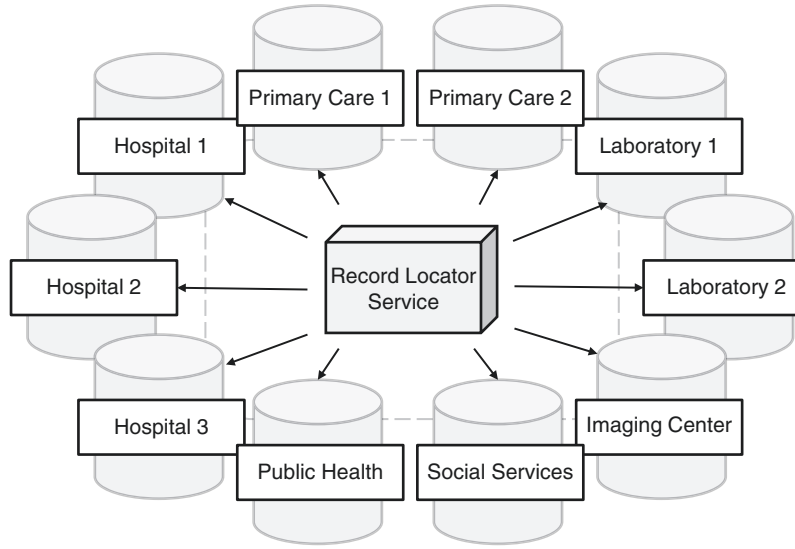

Fig. 8.1 Distributed HIE architecture

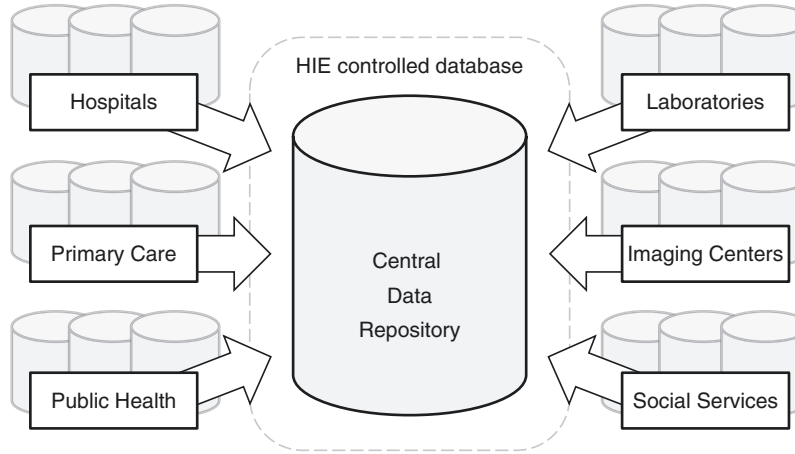

Fig. 8.2 Centralized HIE architecture

8.3.2 Centralized Architecture

Most state and regional HIEs have adopted an architecture with at least some degree of data centralization. While data provenance (i.e. the source of a given datum) is always maintained, some HIEs co-mingle health records of all patients in a common data store (Fig. 8.2). By preprocessing some information, data normalization is easier, and queries can be processed swiftly. Other advanced use cases, such as temporal analysis (Ex. graphing lab values over time) or population-level measure assessment (Ex. prevalence of Type 2 Diabetes in a region) become tractable in a centralized HIE design.

While centralized architecture affords speed, advanced capabilities and data aggregation, the approach creates privacy risks for patients and requires a high level of trust by participants. Furthermore, centralized models are more difficult to scale up.

8.3.3 Health Record Banks

Increasingly, various healthcare stakeholders have preferred patient-centric over provider-centric health IT solutions (Fig. 8.3). However, most HIE approaches to interoperability are provider-centric, with transactions moving data between

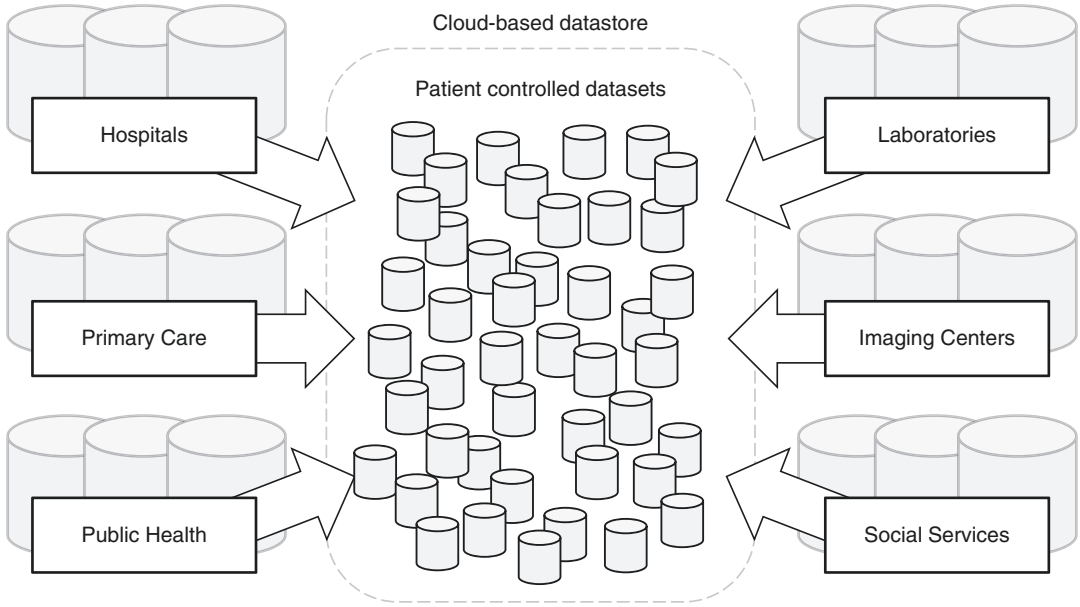

Fig. 8.3 Health record banks

healthcare organizations. Health Record Banking has been an effort to put patients back in the center of transactions involving their health data.

A Health Record Bank (HRB) architecture seeks to centralize all records for a person into one cloud-based data store. During a care encounter, a clinician, with a patient's consent, is granted access to the patient's relevant data from the HRB. At the conclusion, summary information and documents from the encounter are uploaded from the local EHR to the HRB (as designated by the patient). This model is functionally similar to a paper record which a patient (or parent) carries (such as an immunization passport) and which providers at each encounter update and annotate.

According to advocates, "Storing health records for each person in one place (but not everyone's health records in the same place) and letting patients control access allows the complex, interrelated problems of privacy, stakeholder cooperation, incomplete information, and financial sustainability to all be successfully addressed" [9]. In the United States only a few successful HRB models exist and are of limited scope. Attempts by Microsoft (HealthVault) [10] and Google (Google Health PHR) [11] have demonstrated the difficulty of reordering the marketplace. The most prominent current example of an HRB is Apple Health, which aggregates records from many health systems, allowing patients to view them on an iOS device (iPhone, iPad). Advocates of HRBs suggest this model is better suited for capturing and managing patient generated data than for collecting clinical information from healthcare providers (e.g., EHR data) [12].

8.4 Organization

8.4.1 Non-profit HIEs or RHIOs

Until 2009, non-profit HIEs were operating in just a handful of locations. A few were statewide and others were affiliated with smaller medical trading areas. ONC funding through the HITECH Act and state cooperative agreements spawned non-profit HIEs in nearly all states. These efforts have been characterized in a variety of ways, including by ONC [13]. Many were founded as public-private partnerships, receiving some funding from public sources, including public appointees on theirs boards of directors. Efforts have evolved, and states can now be described as having:

- A single designated HIE: Maryland, Arizona, Delaware, Nebraska
- Multiple designated regional HIEs with a coordinating entity: Pennsylvania, New York
- Competing HIEs with minimal state involvement: California, Texas, Georgia

About 70 non-profit HIEs participate in a national trade association called **Strategic Health Information Exchange Collaborative (SHIEC)**. The level of maturity varies significantly between states. In a few and growing number of instances, non-profit HIEs in different states are affiliated to share a single technology stack, e.g. Maryland, West Virginia, and the District of Columbia.

8.4.2 Vendor Driven

Some EHR vendors have invested in interoperability solutions, for exchanging data among customers of their own products and for connecting their customers to other healthcare providers. These solutions, while not as broadly-based or governed as community HIEs, are often workflow-friendly for the clinicians who use them. Epic's Care Everywhere is perhaps the most widely recognized example of such an interoperability solution developed by an EHR vendor, reporting over 1700 participating hospitals by 2017 [14].

8.4.3 National Networks

Several non-profit networks have been established with the goal of enabling basic exchange transactions anywhere in the United States. The **eHealth Exchange** claims the title of the nation's largest query-based network, with participation of 75% of all U.S. hospitals [15]. It is well known as a means of exchanging data with federal agencies such as the Social Security Administration, Department of Defense, and Veteran's Affairs. The **eHealth Exchange** grew out of an initiative by the U.S. Office of National Coordinator for Health IT (ONC) originally called the **Nationwide Health Information Network (NHIN)** or **(NwHIN),** which established a "common set of web services and data content" [16]. Started in 2004, the project transitioned to private control under **The Sequoia Project** in 2012. The **eHealth Exchange** is a lightweight network, its only centralized functions being to establish a Data Use and Reciprocal Support Agreement (DURSA), to test for compliance, and to maintain a directory of participants. It does not include a Master Patient Index (MPI) or Record Locator Services (RLS). To query, one can directly contact one participant node without sending data through a central network. Recently, the **eHealth Exchange** added a hub service which will accept and automatically send a single query to all endpoints.

The **CommonWell Health Alliance**, or simply **CommonWell**, was founded in 2013 by seven EHR vendors to promote interoperability in the industry. The network has grown, but notably does not include some of the leading hospital EHR vendors. In addition to basic services similar to the **eHealth Exchange**, **CommonWell** maintains a Records Location Services (RLS) so that queries can better locate information from among the more than 14,000 provider sites. Its most used function is "the exchange of structured chart and encounter data, formatted as Consolidated-Clinical Document Architecture (CCDA) documents" [17]. The alliance aims to support push transactions in the future. Some EHR vendors have facilitated workflow for ambulatory practices to participate in **CommonWell**.

Carequality describes itself as a framework that "enable data to flow between and among networks, platforms, and geographies" [18]. As a network-of-networks, it aims to make existing HIEs interoperate rather than supersede them. Both the **eHealth Exchange** and **CommonWell** participate in **Carequality**, giving it a national reach. Individual provider organizations are most likely to take advantage of **Carequality** when their HIE partner (be that a local HIE, the **eHealth Exchange**, or **CommonWell**) sends queries, to

determine if other networks have information that it does not.

While the other national networks have centered on query transactions, **Patient Centered Data Home** (**PCDH**) seeks to build a national network of push transactions. Its primary use case is to send encounter notifications from a hospitalization in one state to the HIE in a patient's home state. Run by SHIEC, PCDH currently connects 26 regional HIEs [19].

8.4.4 For-profit Networks

A handful of investor-backed companies have started to build health information networks. These networks address a narrower customer base than state-affiliated, non-profit HIEs and seek to build sustainability from value-added services. **SureScripts**, started in 2001 to promote electronic prescribing, bills itself as the nation's largest HIE, specializing in electronic prescription data [20]. With connectivity to a large portion of retail pharmacies and pharmacy benefit managers, it is best known for aggregating prescription drug data to improve decision making at the point of care. The company is leveraging this connectivity to branch into new services, including a record locator capability for organizations using national networks to retrieve records.

Another group of companies is building networks for push transactions, focusing on sending encounter notifications to care managers and payers. Several have raised venture capital to build their networks and associated services [21–23], also providing infrastructure technology to state-based HIEs.

8.4.5 Case Study: CRISP Maryland's HIE

CRISP (Chesapeake Regional Information System for our Patients) is a non-profit HIE chartered to serves the state of Maryland. It is a public-private partnership, designated as the statewide HIE by the Maryland Health Care Commission in 2009. Founded by the state's three largest health systems and by Erickson Living, a senior living operator headquartered in Maryland, CRISP's board is now comprised of 17 people from health systems, payers, small provider organizations, two consumer representatives and two appointees of the state Secretary of Health. Data contributors to CRISP include every Maryland acute care hospital, most large laboratories, two-thirds of skilled nursing facilities and most outpatient radiology facilities.

In addition to Maryland, CRISP operates the HIE technology stack used by HIEs in Washington DC, West Virginia and recently Connecticut. Its services have grown beyond basic movement of medical records to include five lines of service [24]:

1. **Point of Care: clinical query portal and in-context information**
   - Search for your patients' prior hospital records (e.g. labs, radiology reports, etc.)
   - Determine other members of your patient's care team
   - Be alerted to important conditions or treatment information
2. **Care Coordination: encounter notification service (ENS)**
   - Be notified when your patient is hospitalized in any regional hospital
   - Receive special notification about ED visits that are potential readmissions
   - Know when your Medicaid MCO member is in the ED
3. **Population Health: CRISP reporting services (CRS)**
   - Use all payer claims data and Medicare claims data to: identify patients who could benefit from services, measure performance of initiatives for QI and program reporting, coordinate with peers on behalf of patients who see multiple providers
   - Public statewide health indicators, including extensive COVID reports and interactive analysis

4. **Public health support**
   - Deploying services in partnership with Maryland Department of Health, such as to improve public health surveillance, support disease investigations, and assist public health case managers
   - Enabling researchers to appropriately access aggregated data and manage cohort studies
   - Housing the Prescription Drug Monitoring Program (PDMP) which is especially important for clinicians to know about previously dispensed opioids
5. **Program administration**
   - Making policy discussions more transparent and informed
   - Supporting Care Redesign Programs

Nearly all practicing Maryland physicians are credentialed to access CRISP. Maryland clinicians launch manual queries 25,000 times a day, about 60% of which come through a standalone portal. The remaining 40% of queries originate from hospitals, which have integrated CRISP tools with their institutional EHR (Epic or Cerner). CRISP automatically pushes prescription drug data into hospital EHRs, with more than 100,000 of these transactions occurring each day.

CRISP's partnership with public health agencies has gradually expanded, and a significant portion of the data it delivers to clinicians comes through partnership with the state. Information available through partnership with state agencies includes: dispensed opioid prescriptions, reportable diseases (such as COVID-19), health events (such as overdoses), Medicare and Medicaid claims data. In some instances, participation in CRISP is required as a condition of participation by providers in certain shared savings programs.

The CRISP team has grown to 100 FTEs and fiscal year 2020 revenue exceeded $40M, of which half was investment in new projects and capabilities. Hospitals and health plans pay fees to participate in CRISP, but services are free to ambulatory practices. Maryland's state agencies, including Medicaid, have directed significant grants to fund ongoing operations and nearly all new projects are grant funded, often with matching federal components. CRISP continues to drive down per capita costs by adding additional partner states which will share the same HIE technology stack.

8.5 Current Developments

8.5.1 FHIR Specifications for Healthcare Data Exchange

FHIR (Fast Healthcare Interoperability Resources) is a specification for exchanging healthcare information electronically, developed by HL7, which also developed the health data exchange specifications HL7v2 and HL7v3 [25]. HIEs are monitoring but have not broadly implemented FHIR for inter-organization exchange. When FHIR is combined with software APIs (application programming interface) to call structured healthcare data from other systems at a granular level, it is called SMART on FHIR [26]. ONC is promoting the FHIR approach to interoperability through various rulemaking, especially its EHR certification program [27]. Many observers are optimistic that FHIR implementation will ultimately empower consumer facing applications to access data on a patient's behalf. It remains to be seen whether FHIR will allow more exchange to happen without an HIE serving as an intermediary to enforce data use rules, curate data, and match patients to their records.

8.5.2 Information Blocking Regulations

In 2016, the 21st Century Cures Act [28] was signed into law, and among other things gave ONC the authority to create regulations which promote interoperability among organizations

which hold healthcare records and between those organizations and patients. ONC's Cures Act Final Rule [29, 30] prohibits organizations from information blocking—activity that will "interfere with access, exchange, or use of electronic health information (EHI)" [31]. The regulations are due to come into force in 2021 [32]. Because it can be difficult to define activities that violate the new rules, HIEs are anxious to see how the regulation shapes the interoperability space. In theory, more health information should be available for HIEs to curate and deliver.

8.5.3 Need for Public Health Infrastructure: Health Data Utilities

The National Academy of Medicine, in its recent evaluation of health data interoperability, notes: "Advances in the collection and use of health data offer tremendous opportunities to improve patient health outcomes, improve evidence-based decision making, and transform the nation's health care system" [33]. Examples from states in which the HIE is closely partnered with public health officials demonstrate the potential for additional population health services [34]. During the COVID-19 pandemic, HIEs have linked reportable conditions data such as lab test results, deaths, and immunization administration with demographic data, such as race, ethnicity, and geography, to help evaluate impacts of the disease and of interventions, which is important for directing resources.

Some HIEs have begun to adopt the term "Health Data Utility" to describe their role as a partner to public health [35]. A Health Data Utility will be a public-private partnership, designated by state government. Some of the data it exchanges will be received by state mandate on providers and payers, creating statewide data with fewer gaps. As states support their health data utilities, they will also regulate the organizations, ensuring that their activities are consistent with the intended public good.

8.5.4 Social Determinants of Health

Social determinants of health (SDOH), broadly defined as the physical environmental factors that impact health [36], are increasingly being recognized and addressed within the healthcare industry. SDOH data are often captured incompletely in EHRs at the point of care [37], so HIEs are beginning to play a role in the intersection between health and social services, facilitating data exchange aimed at improving care coordination to address identified social needs [38]. Some HIEs have integrated SDOH data within their existing platforms, while others have created separate exchange environments specifically aimed at community care planning [39]. The ability to exchange SDOH data is not as mature as for healthcare data, and data standards for the SDOH domain are in early stages of formation. The **Gravity Project** (hl7.org/gravity/) was initiated to accelerate the interoperability of core SDOH data, focused specifically on coding data captured within the EHR for screening, diagnosis, planning, and interventions activities across three domains: food insecurity, housing instability and quality, and transportation access [40].

In the meantime, HIEs are facilitating non-standards-based data exchange and serving as a translation layer for value set nomenclature as national SDOH data standards are developed. Core components of SDOH data technology commonly supported by HIEs include:

SDOH component	Description
Social service screening and assessment tools and results	HIEs that collect social service screenings can display the results at the point of care, assisting providers in understanding the broader context of a patient and connecting to care coordinators to facilitate addressing the social need(s)
Resource directories	Well-maintained and current resource directories are critical to connect patients to the right service organizations. HIEs can make the resource directory available to its users for easy access alongside other EHR tools centered on SDOH

SDOH component	Description
Closed-loop referrals and communication	Referring patients to receive services is common, however, assuring feedback on the status of the referral to meet the patient need remains difficult. HIEs can support closed-loop communications between healthcare and social service providers and feedback on the status of referrals
Evaluation of the impact of social needs and referrals on cost, utilization, and outcomes	The Accountable Health Communities Model initiative from CMS [41] requires substantial reporting and analytics capabilities to measure the impacts of new programs on multiple aspects of health. HIEs can capture a robust analytic dataset from collected, stored SDOH data and metadata

8.6 Closing

HIEs facilitate the exchange and aggregation of health data as intermediaries. As developing standards and national networks make the basic movement of data easier, HIEs are moving upmarket to offer more sophisticated services. The business model and core audience for such services continue to evolve, with many different approaches among the states. Information blocking regulations and the innovation of commercial offerings will continue to force change in the HIE field.

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Part II

Innovations and Trends

Progress in computing technologies and expansion of healthcare connectivity have created stable and novel platforms on which innovations can be piloted, tested, implemented, and widely deployed in a relatively short time. The maturation of service-oriented architectures (SOA) and widespread adoption of secure smartphone/client app-based technologies has led to rapid development of healthcare-industry-grade mobile/point-of-care solutions for improving the quality and measurement of healthcare processes and outcomes.

An additional wrinkle uncovered during the creation of this edition has been the challenges and opportunities posed by the COVID-19 pandemic, which continues to make demands on healthcare delivery and its measurement. One area that has benefited has been the field of remote care and telehealth, which is overcoming traditional barriers that have impeded its widespread adoption. Clearly, the pandemic has boosted opportunities for innovation to address traditional and new problems in healthcare delivery.

Topics covered in this Section include:

- An overview of telemedicine/telehealth
  - A history, present assessment and look at its future by Richard Bakalar
  - A look at how it is meeting emergent healthcare delivery needs during the COVID-19 pandemic by Anne Hewitt and Joan Kiel
- Views of how HIT and electronic health data are being leveraged in different domains:
  - Emergency Preparedness and Response by Stephen L. Wagner
  - Public Health by Musa Kana and colleagues
  - Patient Safety by Yushi Yang and associates from Johns Hopkins and the Armstrong Institute for Patient Safety and Quality
  - Chronic Care and Self-Management by Malinda Peeples and Disha Maity
  - Addressing Justice and Health Equity by Yoonyoung Park and associates from IBM
  - Neurocritical Care by Peter Dziedzic and Jose Suarez from Johns Hopkins
  - Modeling Disease Progression by Kenney Ng and associates from IBM

- Patient Care and Clinical Research by Tianna M Umann and associates from Microsoft
- Long-Term Care and Rehabilitation by Prof. Mohamed-Amine Choukou and associates
- Interprofessional education in a Smart Home by Gabriela Mustata Wilson and Ruth Metzger from the University of Southern Indiana
- Preventive Care Utilization in Direct Primary Care by Sugato Bagchi and associates from IBM and R-Health

Telemedicine: Its Past, Present and Future

9

Richard S. Bakalar

Abstract

The concept of Telemedicine is nearly 100 years old as demonstrated in an early US magazine depiction of the "Radio Doctor" in 1924. Later in the 1960s, innovative physicians leveraged available emerging telecommunications technology and adapted clinical protocols to pilot medical applications that addressed real-world challenges in patient access for remote populations. Health Plan investments and advancements in mobile and network technology enabled limited scale telehealth services direct to consumers in the early twenty-first century. Prior to 2020, adoption was low and targeted. It was restricted by payer payment policy, state and federal medical/health privacy regulations and provider limited acceptance. That all changed with the global emergency declarations resulting from COVID19 pandemic starting in early 2020 when health safety concerns by consumers, first responders and healthcare workers created transformational telehealth adoption. Restrictive regulations and payment barriers were waived, and telehealth demand exploded. Now that patient, provider and payer telehealth benefits have been exposed and partially realized, multispecialty, scalable telehealth services have reached the tipping point for increased enterprise investment, innovation and broadscale adoption going forward.

Looking beyond 2021 there will be greater emphasis on optimized consumer health, wellness and seamless, local and remote, patient-centered *integrated* care for the sick and injured. Telemedicine, telehealth, digital health analytics, standards-based medical sensors and system automation technology advancements will enable improved, timely, scalable patient self-care and augmented, specialist to remote primary care and/or care giver *capabilities* and *capacity*.

Keywords

Telehealth · Telemedicine · Virtual care Virtual visit · Digital health · Machine learning · Autonomous systems and COVID19

R. S. Bakalar (✉)
ViTel Net, McLean, VA, USA
e-mail: rsbakalar@comcast.net

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Learning objective:

- Differentiate telemedicine use before and after the pandemic.
- List some common successful specialties for telemedicine.
- Analyze the clinical practice guidelines for telemedicine from the American Telemedicine Association.

9.1 Introduction

9.1.1 Brief History of Telemedicine

The concept of Telemedicine may have originated in the April 1924 issue of **Radio News**, Fig. 9.1 which depicted a REMOTE doctor interactively evaluating a child's throat with family members looking on from a **video "radio"** screen with a large speaker, multiple adjustment dials and a paper recorder. This was decades ahead of its time and before the enabling network and technology was feasible.

Early audio/video point-to-point telecommunication links became possible in the 1960s. NASA, as well other early telemedicine pioneers from academic medical centers demonstrated early clinical pilots with their "advanced" telecommunications technology and adapted clinical protocols as depicted in Figs. 9.2 and 9.3.

In Fig. 9.3, innovative physicians led early proof-of-concept demonstrations using available off-the-shelf television camera technology to address their current medical challenges in projecting their medical expertise and clinical assessment over time and distance. This original MGH telemedicine project avoided lost travel time in traffic for hospital physicians evaluating and treating patients from the Boston Logan Airport medical clinic.

As desktop computing, telecommunication networks and compact digital audio/video camera technology matured, clinical champions developed more advanced telemedicine pilots. In the mid-1990s this first wave of practical, provider-to-provider telemedicine services supported **remote, underserved patient populations on a limited scale** (*high value, but low volume*). This exploration was expanded by significant investments by the federal government (VA, DoD, and HHS with HRSA grants) over the next two decades.

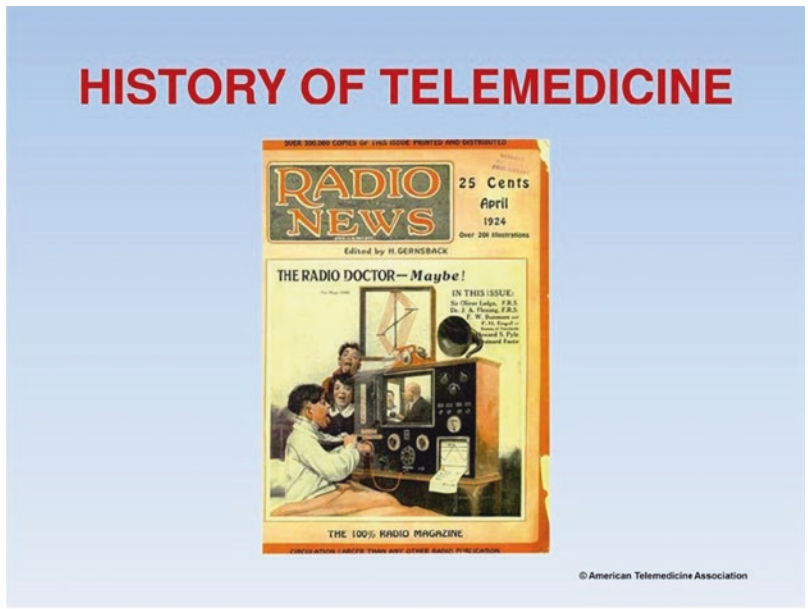


Fig. 9.1 Radio news cover

Courtesy of Jonathan D. Linkous, CEO American Telemedicine Association

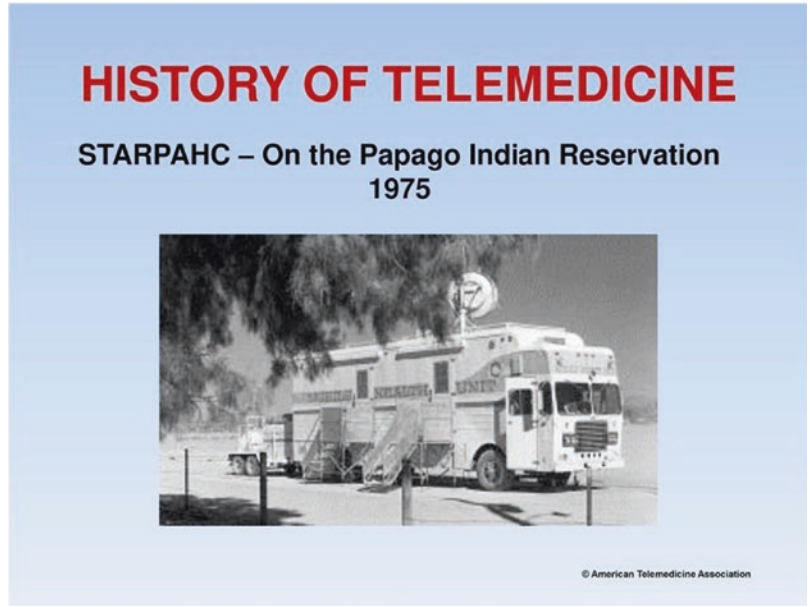


Fig. 9.2 NASA mobile health unit circa 1960s

Courtesy of Jonathan D. Linkous, CEO American Telemedicine Association

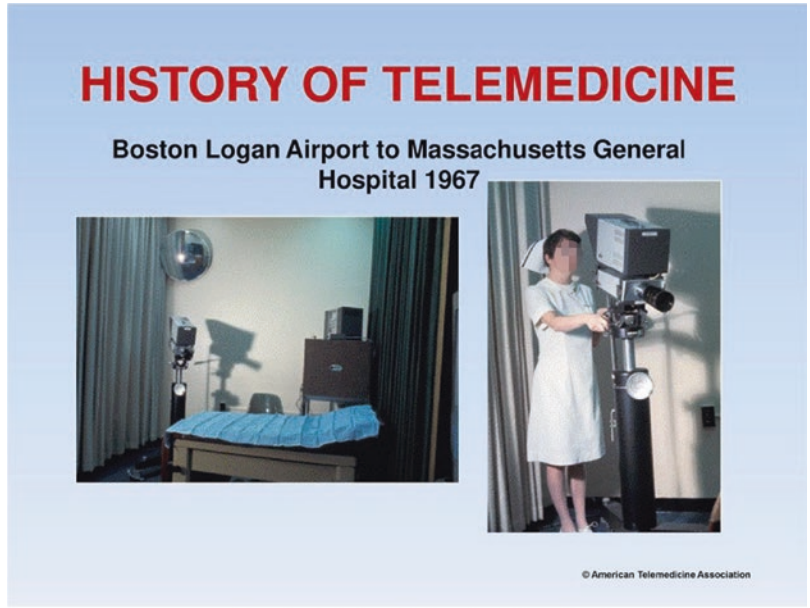


Fig. 9.3 Telemedicine in 1967 at Boston Logan Airport

Courtesy of Jonathan D. Linkous, CEO American Telemedicine Association

As the more affordable Internet, mobile devices and more advanced compact digital imaging tools emerged, direct-to-consumer telehealth services emerged, supported by funding from healthcare payers for selected patients with defined minor acute and chronic medical conditions. This second wave of telehealth innovation was motivated by **reducing managed care costs and improving patient access to timely primary care and specialty healthcare services** thereby avoiding more costly acute emergency department, urgent care, or inpatient healthcare alternative expenses.

Prior to February 2020, telemedicine and telehealth services slowly, but incrementally increased by single digit adoption based increasingly on consumer awareness, demand and trust; a small number of targeted grant-funded **projects** which were clinical champion led with limited support staffing or institutional financial investment; poorly aligned payer financial incentives; and significant state and federal regulatory barriers that impeded mainstream expansion of these proven telemedicine and telehealth delivery models.

During this 25-year exploratory period (1995–2020) of the first and second wave of telemedicine and telehealth there were important foundational lessons learned which will fuel the rapid growth and advancement in 2021 and beyond.

1. **Telemedicine and Telehealth works**—many pilots have shown that with adequate advanced planning, training, communication, multi-disciplinary support and thoughtful execution—patients, providers, and payers all benefit from improved timely access, quality and affordable healthcare.
2. **There must be a medical need identified**—successful projects require a pre-existing health or medical benefit identified up front which is supported by a documented clinical, operational, and sustainable financial business case in advance of execution
3. **Enterprise Governance is key**—telemedicine and telehealth **PROGRAMS** require central, top down strategic leadership, defined measures of effectiveness, programmatic ongoing reporting and oversight, and adequate staff and financial resources
4. **Projects require Program tactical support to scale—**consistent, central multi-disciplinary staffing support and standardization across service lines enable sustainable growth
5. **Measurement and reporting are critical to quality assurance**—each project business case must include pre-defined goals, objectives, and key performance indicators
6. **Standardization leads to increase productivity, efficiency, and lower cost**—clinical protocols, training, technical support, regulatory compliance, communication/marketing, technology/network infrastructure, data sharing and seamless workflows should be centrally coordinated
7. **Innovation originates from the operators**—advancements in new use cases, projects and improved workflows come from providers and patients near the point of service
8. **Patient trust and provider professional bonding drive adoption**—transparency for accountability for patient privacy and evidence of professional credibility are important for program growth
9. **Clinical and operational documentation is foundational**—accurate, timely and structured medical documentation and coding are critical for optimal reimbursement and accountability
10. **Alignment of incentives leads to sustainable growth**—financial, operational, and professional alignment of incentives enhances adoption and program expansion (new service lines)

9.2 Telemedicine and Telehealth Before the 2020 COVID-19 Pandemic

9.2.1 Provider-to-Provider Telemedicine Services

Hub (remote limited number of medical specialists) and **spoke** (many local primary care practitioners/first responders) networks, provider-to-provider telemedicine clinical services have incrementally developed over the past two decades improving access to specialty care for undeserved patient populations from distant, remote locations (e.g. ships at sea, space, south pole), in remote rural communities from critical access hospitals/clinics and in dense urban centers with limited and time-sensitive requirements for augmented sub-specialty care.

The rate of adoption has been hampered by dated state and federal regulatory barriers, payer reimbursement policy mis-aligned for positive telehealth incentives, overworked providers with current in-person care (limited capacity for telehealth), variable provider trust/quality concerns, inefficient workflows and resistance to change from existing provider-centered convenient delivery models.

Some of the most common successful specialties for telemedicine services prior to 2020:

- Tele-radiology—one of the first specialties in telemedicine, starting in 1960s.
- Tele-stroke (neurology)—expedited treatment for patients with acute stroke
- Tele-critical care—from the ICU, NICU and Emergency Department
- Tele-behavioral health—psychiatry, psychology, and social services
- Tele-dermatology—at home and remote inpatient consultation
- Tele-ophthalmology and optometry—screening patients with possible diabetic retinopathy
- Tele-orthopedics—at home follow-up and remote inpatient consultation
- Tele-burn—remote assessment and treatment follow-up
- Tele-ENT—clinic or inpatient remote endoscopy
- Tele-nephrology—remote monitoring patients with renal failure and on dialysis
- Tele-obstetrics—at home and remote inpatient consultation
- Tele-oncology—at home follow-up, remote inpatient consultation, tumor boards, 2nd opinions
- Tele-pathology—remote interpretation of the digital slide or remote microscopy
- Tele-rehabilitation—post-op or medical follow up treatment at home and remote consultation

The **American Telemedicine Association** has published clinical practice guidelines available from their website for many of these adopted telemedicine and telehealth medical applications (https://www.americantelemed.org/resource_categories/practice-guidelines/).

In addition to these medical specialties or clinical condition-based applications, there are examples of proven educational and clinical support use cases such as:

- Tele-medical grand rounds
- Tele-tumor boards
- Tele-second opinion clinical conferences
- Tele-morbidity and mortality conferences
- Tele-mentoring/supervision for surgical subspecialists in the OR for cost-effective training

Finally, there have been innovative telemedicine special case delivery models which have enhanced timely patient access

- **Reverse Telemedicine** where a circuit rider specialist travels to a remote location to perform clinical procedures and continues to follow his primary site patient's remotely online when his/her schedule permits.
- **Spoke (distributed Primary Care) and Hub (Online Specialists) network** of community-based health system hospitals and clinics that contract for online clinical services only (without their technology—hardware and software) from professional service organizations (PSO's). The spoke network leverages their modular platform primary care telemedicine infrastructure to contract for multi-specialty clinical services with the incremental and duplicative cost of additional single service line technology. This more efficient upfront technology investment strategy by the spoke network reduces cost of training, maintenance, health information technology system interfaces and support over time. It also incentivizes the spoke sites to incrementally employ specialists to support their distributed network at a lower cost and transition from contracted PSO clinical contracted services to workload balanced services internally.
- **Infectious Disease isolation room telemedicine**—increase local health provider safety,

improve timely access to remote specialists and reduce need for costly PPE.
- **Strategic value of Tele-education** application such as Grand Rounds as a tool to increase provider adoption and build relationships and trust by enhancing professional bonding of local and remote medical professionals. It also improves and maintains user familiarity with the technology during pre-go live or periods of low utilization.

9.2.2 Direct-to-Consumer Telehealth Services

Recent technology advancements of mobile devices, smart phones and tablets; with their respective applications stores; affordable network bandwidth; increasing targeted reimbursement by payers to avoid more costly in-person care and growing consumer trust has spurred the growth of consumer telehealth over the past decade. Despite the increasing body of evidence supporting the value and safety of this virtual delivery model the incremental adoption has only represented single digit percent volume of ambulatory patient visits during this near term pre-2020 period.

According to 2000 primary care physicians surveyed before the 2020 COVID-19 pandemic the top ten applications for direct to consumer telemedicine services included a range of bundle concierge online services for fee paying patients for convenient access, patients with acute minor conditions, others with chronic conditions requiring follow up or medication renewals, enhanced pediatric after-hours access and post-acute follow up for medical and surgical patients. This category also includes standalone remote patient monitoring nursing services supported by federal, state, and private payers to avoid emergency room and inpatient readmissions after an acute exacerbation for patients with chronic conditions or a new medical diagnosis.

This national survey further concluded that 57% of physicians were willing to conduct video visits with their patients. Just 12% of physicians were unwilling to see a patient over video, while 31% remained uncertain.

The top 10 uses physicians indicated telemedicine can provide. Respondents could choose more than one response.

1. **Concierge services for fee paying patients**: 91%
2. **Medication management/prescription renewal**: 86%
3. **Minor urgent care (i.e. pink eye, fevers)**: 85%
4. **Birth control counseling**: 83%
5. **Home health care**: 82%
6. **Chronic condition management**: 80%
7. **Pediatric after-hours needs**: 79%
8. **Behavioral health**: 77%
9. **Post-hospital discharge**: 73%
10. **Post-surgical follow-up**: 59%

This was a 2016 survey conducted in collaboration with QuantiaMD. Source: Becker's Health IT: https://www.beckershospitalreview.com/healthcare-information-technology/10-top-uses-for-telemedicine-according-to-physicians.html

9.3 Telemedicine and Telehealth During the 2020 COVID-19 Pandemic

9.3.1 The Challenge to Adopt and Scale Telehealth During "Fog of War"

The 2020 COVID-19 pandemic was transformational for many hospitals and healthcare systems. The scale and scope of temporary regulatory and reimbursement waivers made under the national and state Emergency Declarations were unprecedented. Elective medical procedures were cancelled or delayed. Medical staff were furloughed due to lost reimbursement of elective procedures. Online telehealth visits replaced clinic and emergency room visits when possible. But the sudden transition from 11% virtual visits to over 60% in less than a month was challenging for the entire healthcare leadership and workforce. This sud-

den and unexpected medical crisis exposed a lack of enterprise governance, planning, training, and infrastructure to accommodate this rapid change in delivery models.

Prior to March 2020, most telemedicine and telehealth initiatives were project based, led by a departmental champion, funded by grants, or limited targeted payer reimbursement requiring special clinical coding modifiers and supporting EHR documentation to limit overuse of telehealth services. Workflows and clinical data were often siloed and not integrated in the daily clinician workflows. State medical licensure, local definitions of telemedicine services, federal dated regulations and reimbursement policy had been a barrier to innovation and growth of widespread telehealth services in the United States.

Announcements of federal and state regulatory and payer reimbursement copay waivers created initial confusion and poor alignment of policy needed to incentivize early adoption of telehealth services directly to consumers. This crisis exposed the lack of contingency readiness to implement the necessary changes. However, legitimate concerns for patient timely access to critical health services, the viral infection transmission risk for patients, first responders and health workers from COVID-19 and the limited access to the required personal protective equipment by first responders and health workers was a major driver for rapid adoption of telehealth delivery models over the following months. Consumers were forced to socially distance and transition to online video services for work when possible, education and entertainment as the US economy was shut down. The telecommunication providers had to scramble to rapidly expand capacity orders of magnitude to accommodate this sudden transition to online commerce and communication. Healthcare was competing for bandwidth, infrastructure, and technology to scale these mission critical services. The lack of enterprise program governance in hospitals and health systems made this transition to online healthcare difficult, costly and in some cases limited in quality. Many providers had to resort to telephone online services because of their lack of readiness with video technology and user training at the scale needed, adding thousands of users from a baseline of less than 20 in some cases.

A few advanced health systems were able to successfully scale their pre-pandemic telemedicine and telehealth services having a pre-existing enterprise program office with dedicated multidisciplinary stakeholders for planning, training, and executing these remote clinical services. Organizational governance; standardized and integrated technology and reporting metrics; dedicated support staff; well-defined clinical protocols; and a scalable, sustainable business case were all critical success factors in making this unplanned transformation over a few weeks rather than several months.

9.4 Telehealth After the 2020 COVID-19 Pandemic

9.4.1 Emergence of Telehealth Programs: Convergence of Telehealth Projects

As providers, clinics, hospitals, health systems, payers and patients recover from the financial and operational disruptions created by the pandemic healthcare crisis over the next year or two, telehealth providers and administrators will now have a seat at the table with a new mission critical role in planning for the future new normal. Based on lessons learned, prior pre-pandemic projects will converge into enterprise programs with the clinical oversight, administrative support and business discipline required for sustainable growth and quality assurance. These institutional cross-departmental healthcare services could benefit from organizational models adopted by other healthcare ancillary services (such as medical imaging, laboratory, or pharmacy).

As illustrated in the KPMG, LLP diagram below in Fig. 9.4 there are proven critical success factors than enable hospitals and health systems to incremental scale, extend and sustain telemedicine and telehealth service lines leveraging common governance, staff, technology, and infrastructure. This enterprise programmatic approach to leverage shared resources and stan-

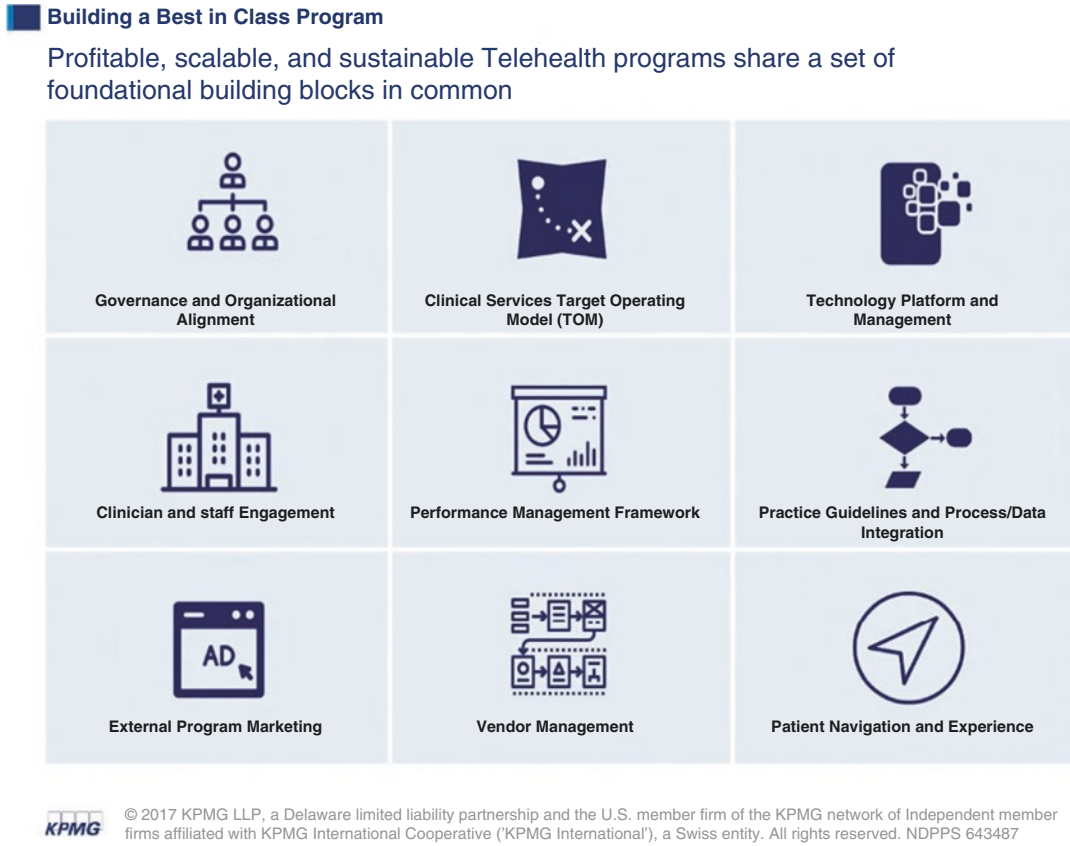


Fig. 9.4 Telemedicine program critical success factors

dardize operational and clinical protocols, share data, interoperable technology and reliable and timely support is key to affordable and scalable growth of virtual care services.

Of the nine critical success factors, the top three most important are the enterprise governance and organizational strategic alignment; clinical protocols and workflows; and integrated technology platform management. The ViTel Net telehealth modular platform design shown in Fig. 9.5 is an example of how existing investments in health information technology (HIT) can be incorporated into an integrated telehealth service delivery model with share data and workflows. Maturity of these three foundational components represent the key difference between temporary and siloed telehealth projects and a sustainable and extensible telehealth innovation program. To achieve the full potential of scalable, broad adoption of telemedicine and telehealth services going forward healthcare providers and payers will make investments in governance (see Fig. 9.6), clinical leadership, and shared and integrated modular platform technology. In Fig. 9.7, there is an example of workflow standardization based on service line clinical guidelines.

9.4.2 Critical Components in Telehealth Program Design

The KPMG information contained above in Figs. 9.4, 9.6 and 9.7 is of a general nature and is not intended to address the specific circumstances of any particular individual or entity. For additional news and information, please visit KPMG at https://home.kpmg/us/en/home.html.

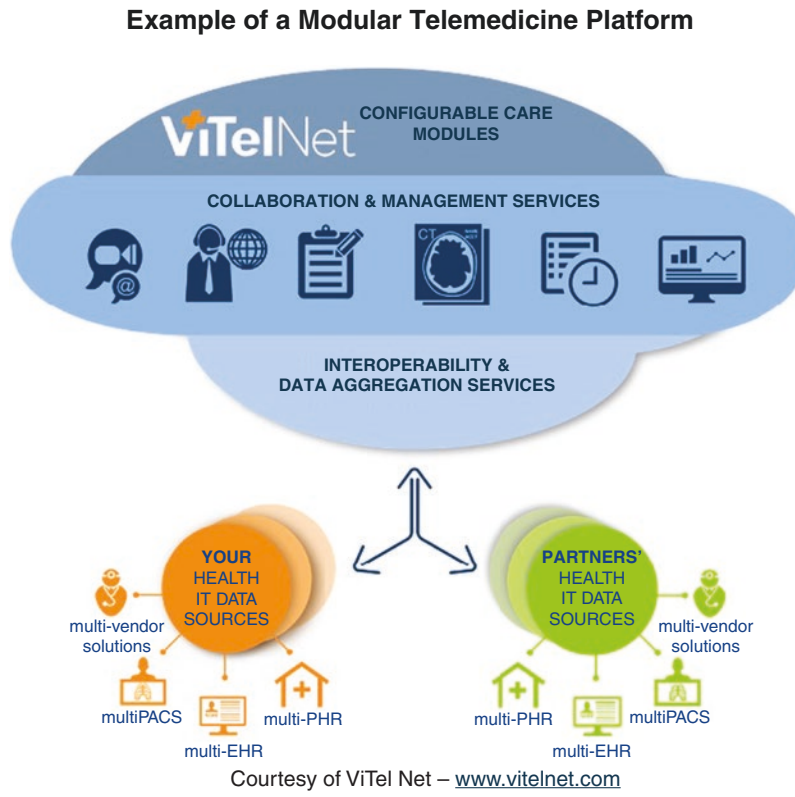


Fig. 9.5 Example of a telemedicine platform design

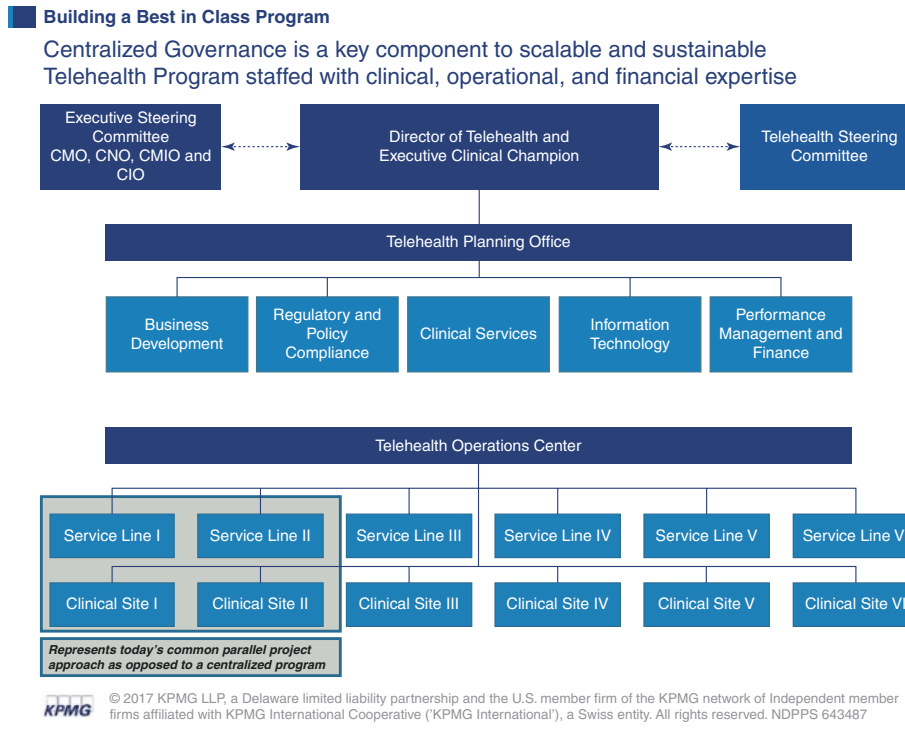


Fig. 9.6 Example of a telemedicine program governance structure

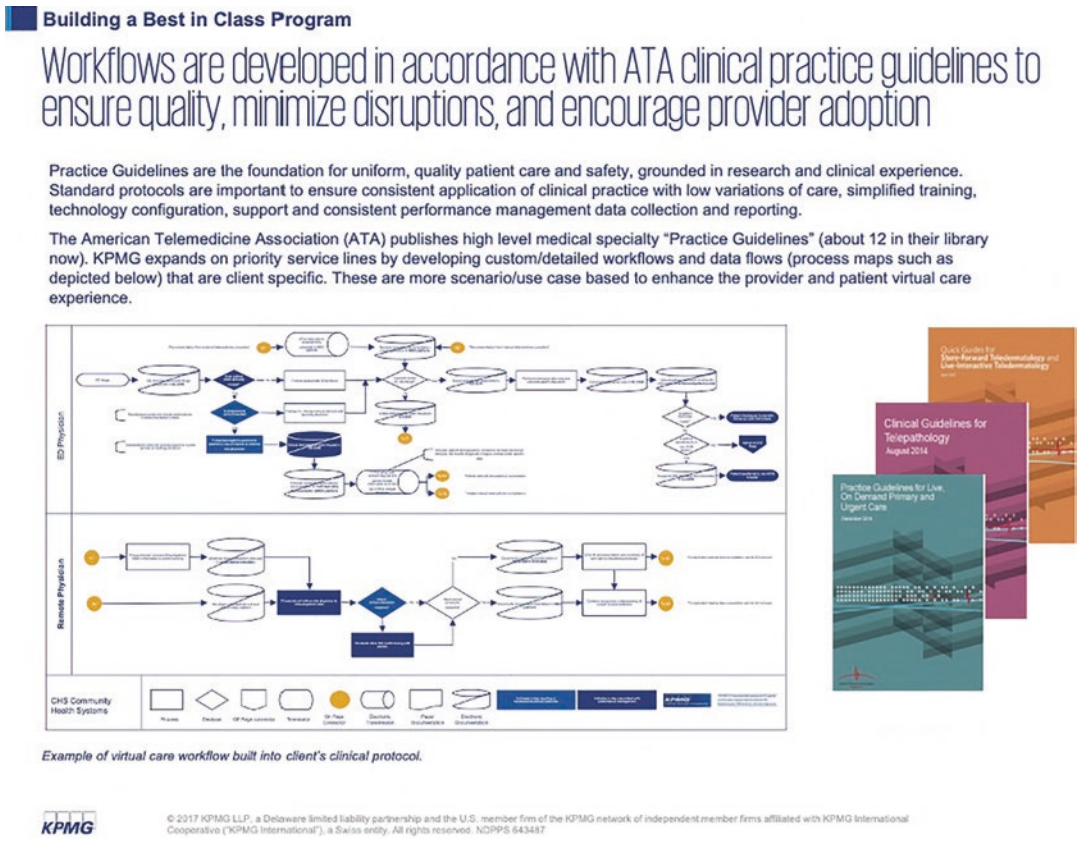
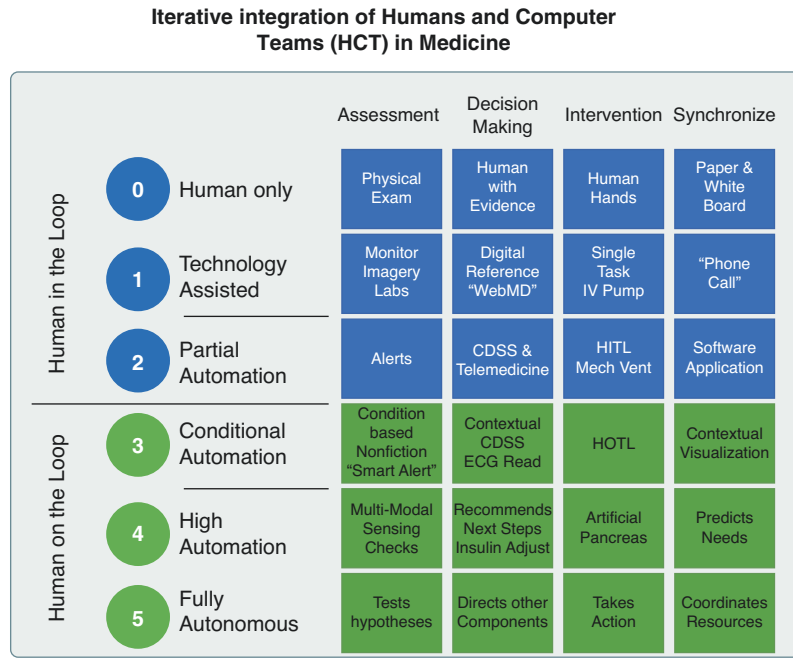


Fig. 9.7 Example of a Telemedicine Process Map and Guidelines

Fig. 9.9 Example of envisioned medical automation levels



Courtesy of COL Jermy C. Pamplin, US Army, Director, TATRC, (http://www.tatrc.org)

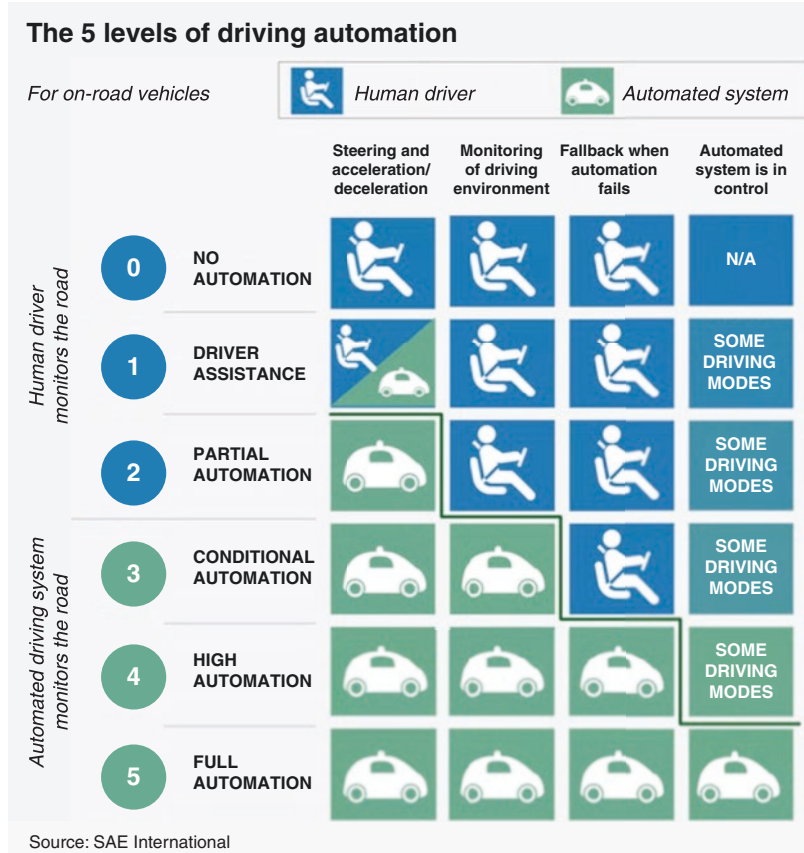


Fig. 9.8 Automotive industry levels of automation

9.5 Future Directions and Innovation in Telehealth in the Future

As healthcare providers invest, standardize, and leverage existing advanced HIT and digital technology in telehealth, governments and industry are investing in the next generation of telehealth and telemedicine capabilities for the future. This next wave of virtual care innovation will focus on interoperability of medical devices and sensors; automation and autonomous systems; and artificial intelligence, machine learning and predictive analytics. As shown in Fig. 9.8, the automotive model for incremental automation to advance from manual, human drivers to autonomous computer system driven cars can be a guide for future healthcare or medical incremental transformation toward autonomous closed loop clinical systems as shown in Fig. 9.9. The US Army Telemedicine and Advanced Technology Research Center (TATRC, https://www.tatrc.org/www/about/) has sponsored this advanced research in making this aspirational vision a reality.

In summary prior to 2020 Telemedicine project objectives were focused on improving patient clinical access, projecting medical specialist expertise to providers of remote underserved populations, reducing healthcare avoidable costs just as unnecessary early readmissions or emergency room visits and treating patients where they are, thereby enhancing timely patient access, clinical quality and payer value.

Looking forward to 2021 and beyond there will be greater emphasis on consumer health optimization and seamless, local and remote, patient-centered *integrated* care for the sick and injured. Telemedicine, telehealth and digital health information automation technology advancements in the future will enable enhanced patient self-care and augmented remote care giver ***capabilities*** **and** ***capacity*** using existing

medical devices and sensors with software adapters and increased adoption of existing interoperability software standards such as **ICE** (*integrated clinical environment*, http://www.mdpnp.org/mdice.html) and the complementary **MDIRA** (*medical device interoperability reference architecture*, https://secwww.jhuapl.edu/mdira).

Future telemedicine scenarios will drive investment in new medical devices and sensors which will be compliant "out of the box" with these interoperability standards leading to efficient, affordable, contextual and incremental deployment of advanced closed loop autonomous systems, use of big data and artificial intelligence which will transform our national and global health systems expanding their scale, scope, and capacity of our current day limitations of healthcare delivery.

The Telehealth Challenge During COVID-19 Emergency Preparedness and Response

10

Anne M. Hewitt and Joan M. Kiel

Abstract

The pandemic has presented itself unique challenges for healthcare information technology administrators. With time not on their side, many adjustments had to be made in a moment's notice. Previously written disaster manuals and contingency plans were adequate, but not fully functional for something as unprecedented as the pandemic. Face to face physician office visits were replaced by telehealth thus creating a cadre of challenges from information technology security to HIPAA to staff training to infrastructure. Using a step-by-step telehealth development process rooted in emergency preparedness, rapid pivoting to telehealth resulted in overall positive outcomes and lessons learned for mainstream use of telehealth in the future.

Keywords

Telehealth · Telemedicine · HIPAA Emergency preparedness · Emergency response · Digital interaction

A. M. Hewitt
Seton Hall University, Nutley, NJ, USA
e-mail: Anne.Hewitt@shu.edu

J. M. Kiel (✉)
Duquesne University, Pittsburgh, PA, USA
e-mail: kiel@duq.edu

10.1 The Unique COVID-19 Challenges for Health IT

The devastating economic and personal tolls from the COVID-19 pandemic continue to impact the international community, the entire nation and especially the health sector [1]. The enormity of the initial challenges met and overcome, by the nation's Heath Heroes demonstrates the success of collaboration and commitment. Previously, unimaginable initiatives, such as operation warp speed, facilitated the development of a novel vaccine in less than a year [2]. Across the country, thousands of health information experts and managers completed system transformations and reconfigured their health systems infrastructure [3] without the benefit of a phase-in timeline or strategic telehealth plan.

10.2 The Scope and Vital Role of HIT During COVID-19 Response

Responding to any health crisis or emergency presents disruptions into traditional routines and processes, but the revolutionizing impact of COVID-19 presented unknown and unanticipated problems that health IT managers had never imagined or contemplated. Information remains the lifeblood of any organization, but in a pandemic health crisis—communication, one

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of HIT's primary functions, can be the critical success factor as it is the key to effective mitigation, preparedness, response, and recovery [4]. The COVID-19 challenge required HIT managers to pivot beyond supporting traditional emergency command centers and seek immediate solutions to a system wide communication crisis.

Health IT departments, within a single hospital or multi-system organization, have an essential and critical role to ensure all staff and have the capabilities to manage and care for patients [5]. See HIT core functions, briefly outlined in Fig. 10.1.

Each of the HIT operations presented above changed during the pandemic period either by expansion, revamping, revising, or adopting brand-new platforms and protocols. These examples reflect transitions accomplished under unprecedented pressure for completion.

- HIT departments were challenged to communicate previously uncollected real-time data with multiple external stakeholders, including state health associations, public health departments, and other national health agencies. COVID-19 increased the interface between heath systems and public health especially in the areas of surveillance, disease monitoring, screening, testing, and vaccinations scheduling and follow-up. The role of HIT interoperability in exchanging information and supporting public health activities such as disease monitoring and surveillance can critically impact outcomes [6].
- Clinical interfaces, integration and workflow were impacted throughout the internal system requiring new equipment, databases, platforms, and workflows. Alterations and enhancement of the Electronic Medical Record (EMR) were implemented [7].
- System complexity expanded the need for access to real-time data for decision-support information, data analytics and dashboard reports. Common tasks such as treatment coding and billing systems were immediately impacted by COVID 19 changes.
- Patient Engagement opportunities and workflows were developed and implemented that included routing and triaging of patient phone calls [7].
- A remote workforce required training and support as well as changes in workflows and connectivity options, with additional concerns for HIPAA security issues. Out-of-network utilization also became a HIT risk concern due to the rapid expansion telecommunications infrastructure.
- The pandemic challenged HIT to seriously consider artificial intelligence and other options such as chatbots for interactive triage with patients. Other significant data analytic challenges emerged as well including revisions to risk modeling [3].

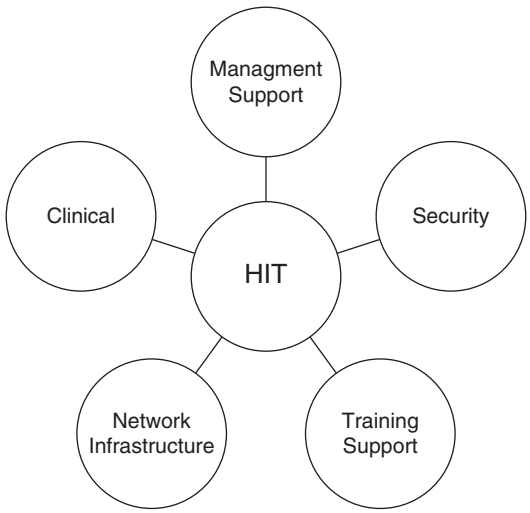

Fig. 10.1 Summary of HIT core functions

10.3 The Telehealth Challenge

Primary among the enormous HIT COVID-19 challenges was the immediate impact of social distancing and the need for off-site remote work capabilities for the entire organization. Even if clinicians and other health professionals were onsite and available within the hospital facility, they often were restricted from face-to-face interactions with patients and other providers. As the health system became overwhelmed with the unprecedented demand for care, the pressure for

telehealth options surged [1]. The necessity for an alternative digital communication option immediately expanded the scope of HIT into providing multiple telehealth and telemonitoring operations.

Whether referring to "telehealth" or "telemedicine", the idea represents a **digital interaction between a health provider and patient.** Although confusion exists between the various terminology for telehealth, telemedicine, telemonitoring, e-health, mobile or virtual health, the **common factor is the ability to interface with health consumers without them physically coming to a healthcare location where health providers are located** [8]. Prior to COVID-19, hospitals and health systems had previously adopted limited telehealth and mostly telemedicine initiatives were single department projects, Telehealth, as described by the CDC [9] in guidance for COVID-19 use, can offered be offered in three modalities as presented in Fig. 10.2.

When a patient with a smartphone, tablet, or computer interfaces from a distance with a health provider, this interaction is considered synchronous. These connections can also include digital medical equipment such as e-stethoscopes or other devices that may be operated by another provider on-site as the consulting health provider assesses from a distance to complete a remote evaluation. Asynchronous telehealth is most often associated with patient portals that allow secure communication between provider and patient through secure messaging that does not have to be real-time.

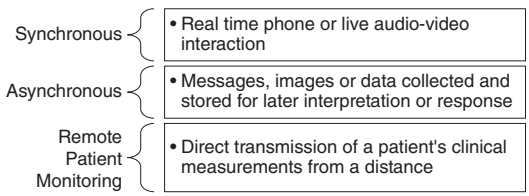

Fig. 10.2 Telehealth modalities for COVID-19

Remote patient monitoring, the third type of telehealth services, may or may not be real-time, but does allow data transmission from a patient to their healthcare provider [10]. The steps in creating a telemedicine presence follow a traditional project development model as presented in Fig. 10.3.

Prior to COVID-19**,** hospitals and health systems had previously adopted limited telehealth as most telemedicine initiatives were single department projects [11]. The two healthcare service areas previously associated with telemedicine services were rural health [12], and behavioral health [13]. Obviously, using digital capabilities to expand and enhance health care options for reaching specialists and emergency care made sense as in the case of rural health. Behavioral health providers, who traditionally conducted face-to-face meetings weekly with their patients and support groups, had also begun to appreciate the importance of virtual care opportunities. But beyond these two applications, most health systems had not yet explored telehealth options for their entire populations.

10.4 COVID-19 as the Catalyst for Rapid Telehealth Adoption and Integration

COVID-19, a pandemic crisis, impacted every aspect of the Continuum of Care as this infectious disease's potential severity and rapid onset resulted in an unprecedented patient surge. Another precipitating crisis factor was the unanticipated lack of personal protective equipment (PPE) which placed almost all health personnel at risk. Table 10.1 illustrates the HIT telehealth response required for COVID-19 using the Continuum of Care framework.

The use of telehealth emerged as an HIT strategy to successfully impact COVID-19 health outcomes across the continuum of care [14].

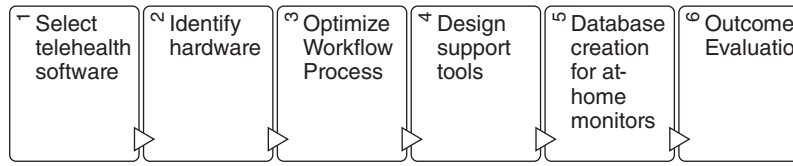

Fig. 10.3 Step-by-step telehealth development process outline (adapted from [7])

Table 10.1 COVID-19 telehealth examples impacting continuum of care

Continuum of care	COVID-19 telehealth example
Preventive care Health promotion Health prevention	• Altered communications through patient portals, targeted patient messaging, annual wellness visits notifications to communicate COVID-19 risks, and prevention action steps, integrated "click and chat" options • Enabled patient screening for COVID-19 symptoms with referral capabilities (triage routing of patient phone calls)
Primary care/ urgi-care	• Screening for symptoms • Scheduling and follow-up capabilities for low-risk COVID-19 assessments
Acute care/ specialty care	• Add internal on-site remote communications between health provider and ICU patient/ health providers to limit COVID-19 exposure • Provide health peer to peer consultation opportunities both on-site and remote
Post-acute/ chronic care Rehabilitation Home Health Palliative Hospice	• Added linkages for support groups and coaching to manage COVID-19 health consequences (medication management) • Added remote monitoring capabilities at home for clinical health status and continued assessment of COVID-19 patients to reduce unnecessary readmissions

Adapted from CDC [10] and Hewitt [8]

10.5 Overall Impact of COVID-19 Telehealth Initiatives

Evidence suggests that virtual care visits increased significantly and, in some cases, doubled during the COVID-19 pandemic [15]. The two service lines with the largest increases were behavioral health and chronic care [16]. Health managers routinely face challenges in managing these two at-risk populations, and the rapid adoption of telehealth proved especially beneficial.

A related consequence of the COVID-19 telehealth success is the Hospital without Walls concept. In 2019, CMS expanded its acute hospital at home program [17] and in March 2020, CMS announced a Hospital Without Walls program [18], which included regulatory flexibility for hospitals to provide services in locations beyond their existing walls. Telehealth and telemedicine remain essential components of this recent healthcare delivery innovation. Recent research suggests that home hospital care can decrease healthcare costs significantly (<30%) compared with usual hospital care and decrease the number of readmissions by more than half [19].

The rapid rise of virtual care via telehealth and telemedicine will serve as a parallel care coordination model for health providers. Consumer surveys suggest that 75% of patients who had never tried telehealth visits expressed an interest in participating, and Industry experts report post-Covid-19 telehealth to be a quarter-trillion-dollar opportunity [20], and predict that, in 2020, 1 billion virtual care visits will occur [21]. Recent telehealth legislation has improved reimbursement rates and/or made access to virtual care easier [22].

One of the lessons learned from the pandemic telehealth response is that disparities did exist in use of the technology. Researchers found that in the early COVID-19 months, older Americans, non-English speaking individuals and Asian people used telemedicine at a lower rate [23]. To meet this challenge HIT will need to focus on health literacy as well as the impact of social determinants of health.

10.6 HIPAA Changes with Telehealth During the Pandemic

Privacy and security of patient health information are paramount at all times. This did not change during the pandemic, but certain aspects of the Health Insurance Portability and Accountability Act (HIPAA) were modified to work within the framework of the pandemic, a national emergency.

Penalties were not enforced for covered entities or business associates if the use and disclosure was for public health and health oversight

activities. It was not blanket statement though, as the covered entity and business associate had to make a good faith attempt to maintain compliance with the HIPAA Privacy Rule. In addition, the business associate had to alert the covered entity of the use or disclosure within ten calendar days [24].

As telehealth use soared during the pandemic with many patients having that as the only option during State lockdowns, modifications were made to HIPAA. Covered entities who provided telehealth services in good faith were not penalized if violations occurred under the Privacy, Security, and Breach Notification HIPAA Rules. The priority was to provide healthcare to individuals in the safest manner possible. As State stay at home mandates scared people to not go out even for healthcare visits, telehealth was a viable option. Providers could reach patients on non-public forums whereby each participant could control access to other users and individual password or controls were employed. For example, the physician and patient could conduct a zoom visit as each individual would be able to verify the other, with the camera and microphone on, and each individual would have a password to the zoom visit. In contrast, a session on TikTok would not provide this protection and thus would not be in good faith [25]. HIPAA recognized that during the pandemic, getting care to people was paramount as was privacy and security, but amendments could be made to satisfy both parameters.

The goal during a pandemic is to control and mitigate the spread. In accordance with HIPAA 45CFR164.512(b)(1)(i), PHI can be collected, within minimum necessary parameters, for the purpose of 'preventing and controlling disease'. HIPAA also allows for the 'conduct of public health surveillance', as well as under HIPAA 45CFR512(j)(1)(i) (A), 'to prevent or lessen a serious and imminent to the health and safety of a person or the public' (Standards, Parts 60 and 164) [26].

Here again, HIPAA does not constrain the public health mandates for disease control, but merely sets standards such that information privacy and disease mitigation can co-exist.

Summary This twenty-first century pandemic not only exposed general weaknesses within the health sector system [22], but provided impetus for Health IT to become a major innovator and collaborator within every health system. HIT systems met the core challenge to pivot to telehealth during COVID-19. Today, we know that COVID-19 accelerated the adoption of technology-enabled strategies. We should expect that virtual care visits should transition from an alternative care delivery option to an integrated component of all health care. More than lessons learned from a health emergency and crisis, HIT departments technology enabled operations now constitute the basis for normal care going forward. Experts suggest that digital health will reshape the health care sector, especially patient engagement, care delivery and payment models [27].

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11 Information Technology and Operational Issues for Emergency Preparedness and Response

Stephen L. Wagner

Abstract

This chapter explores a framework for understanding and moving forward with emergency management and preparedness. Emergency Management (EM), preparedness, and response for the information technology department of any organization has become increasingly important as has been further demonstrated by the current Covid-19 pandemic. IT operations may be affected for long periods of time in emergency situations requiring adaptations such as work from home, bringing new vulnerabilities for this critical infrastructure.

Several key concerns face emergency management efforts of an organization. The unique nature of each organization presents challenges making emergency management more of a mindset than a prescriptive approach to the subject and requires vigilance and the recognition that complacency is the enemy of emergency management and preparedness. A continued need for vulnerability analysis, proactive resource management, and a thorough understanding of the topic is incumbent upon IT professionals.

The EM process includes four primary phases: mitigation, preparedness, response, and recovery. All of these must be addressed to have an effective plan. The principal duties of EM are to safeguard people, property, insurer communications, develop alternative operating plans, and manage the expectation of members of the organization as well as its other stakeholders. It is also incumbent upon the plan to reduce the spread of disease or harmful agents.

Cyber security is of the utmost importance since hackers and other cyber criminals exploit the vulnerabilities created by emergency scenarios. Hypervigilance to these threats is required when changes are made to the operations to accommodate emergency procedures.

Community collaboration is also an important aspect of emergency planning and preparation. Consider how effective IT can be in helping with such activities as vaccine distribution. In a large-scale crisis we all are dependent on one another for support and IT can play a major role in bringing about community connectedness.

Keywords

Preparedness · Emergency management
Alternative operations · Pandemic
Bioterrorism · Framework · Recovery
Response · Mitigation · Community involvement · FEMA · CERT

S. L. Wagner (✉)
Seton Hall University-Interprofessional Health Sciences Campus, Nutley, NJ, USA
e-mail: Stephen.Wagner@shu.edu

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Learning objective:
- Explain some of the key concerns with emergency preparedness.
- Evaluate the four phases of emergency management.
- Define how information technology brings vulnerabilities to an organization.

Those that work in IT have long understood the idea that a system can become "infected," with a computer virus which will wreak havoc on the organization. Now we are learning that it is much the same for human pathogens. Covid-19 has shown us how devastating a pandemic can be to an organization and its people. Much the same as with computer system infections organizations must be prepared for emergencies including pandemics by careful planning and analysis, and by preparing alternative operating plans. Examples such as "working from home," and other remote operating strategies are becoming a standard of operations in pandemic times [1–3].

11.1 IT Operations

In the electronic age, most if not all organizations have become dependent on all manner of electronic systems. As efficient and powerful as they can be, it also brings vulnerabilities to the organization. Planning, policies, procedures, and drills for "downtime"—regardless of the cause—are essential for all organizations so they may meet the expectation of the organization to operate during outages or emergency situations. We are learning from the pandemic that the timeframe for operating in an alternative environment may be for an extended period of time and may actually change operations permanently [4].

The expectations of stakeholders in these unusual circumstances need to be understood by the organization, and the intentions of the organization to meet those expectations must be understood by the stakeholders. Of course, the type of organization has an important bearing on this determination. Organizations that routinely work under pressure and providing vital services may find decision making about alternative channels of service difficult and may be more likely to remain open under difficult circumstances even if it is with a small staff dealing only with the most urgent needs.

11.2 Key Concerns

One dilemma that any organization faces with emergency preparedness and management is whether the organization expends valuable resources to prepare for an event that has a low probability (or infrequent) of occurrence but that, once it occurs, it brings devastation and the failure to prepare is costly and threatening its survival.

An important aspect of this dilemma is the ongoing nature of emergency preparedness. Although some organizations do a good job in the planning process, they often fail to keep those plans current and engage in activities to keep staff aware and prepared. If the staff of an organization is unfamiliar with and poorly trained in emergency preparedness plans, those plans may be of little use in an actual emergency. The onset of an emergency is not the time to dust off the plan and read it [5].

11.3 Key Lessons for Emergency Preparedness Stemming from the Recent Pandemic

The recent Covid-19 pandemic, in addition to the numerous adverse natural and man-made disasters such as the wildfires, hurricanes and other severe weather events have brought what was once a rather stodgy forgotten aspect of management front and center. Some important lessons that these recent disasters have taught us include:

1. Above all else one size does not fit all and emergency preparedness and each organization must consider it special circumstances, stakeholders and unique aspects of their operations when developing emergency plan. The

emergency management mindset requires us to think about the unthinkable and continuously assess the probability of various risks.
2. This requires vigilance in continued planning and revisiting plans on a regular basis to ensure that they are up-to-date and that they are fully executable when necessary. Stakeholders should be involved in this process. We often "don't know what we don't know," so gaining knowledge from all stakeholders may provide insights that can easily be overlooked.
3. Complacency is the enemy of emergency management and preparedness. Once the crisis is over and the emergency has subsided it is typical for people and organizations to slide back into their old ways of operation and thinking. Memories fade, so it is important for leadership to continually keep emergency preparedness in the minds of stakeholders and actively continue planning and preparation for what might occur that could significantly disrupt the operations.
4. The continued need for updating a vulnerability analysis to determine how various events and situations could affect the organization.
5. Other than healthcare and food services, many organizations have little experience with plans for infection control. Covid-19 has demonstrated the need for all organizations to prepare for events which require infection control and prevention. Protection for all stakeholders is paramount. As with Covid-19, it often takes time to understand the full impact of the pandemic and its long-term effects. Caution is warranted.
6. Proactive resource management is essential to ensure financial stability and to safeguard the livelihood of workers. Management of the supply chain takes on a whole new meaning in the context of emergency management. We have learned during the Covid-19 crisis that just-in-time supply chains do not always serve the best interest of the organization and its stakeholders. Consideration should be given to essential supplies and how they might be stockpiled or how supply chains can be bolstered including alternative sourcing. The management of the supply chain takes on a whole new meaning in the context of crisis management.
7. As IT professionals understanding, the critical nature of the information technology infrastructure can hardly be overstated. Building robust systems with redundancy and multichannel capabilities is essential in the emergency planning process.

The need for emergency management of the organization exists at two levels. The first level is management of the organization in emergency situations, dealing with the organization itself and its technical and non-technical staff. The second level is characterized by the need for all personnel to be called on to assist in the broader community emergency situations because so many emergencies, whether arising from natural disasters, terrorist attacks, or pandemics, require everyone's assistance even if that is only compliance with recommendations and mandates from official authoritative sources [6]. Those with technical expertise are often in a good position to provide invaluable service. With this understanding, the importance of emergency management may obviate the need for an organization to decide between two aspects of the cost dilemma, which is risking lost and the cost of operations during the emergency or risk the loss of the business if it discontinues operations on a temporary basis. As with the Covid Pandemic, that decision varies greatly by business where some business has thrived and other have gone out of business [7].

11.4 Emergency Management Process

As mentioned earlier, at a minimum a basic understanding of the principles and scope of emergency management are helpful to the modern organization's management and leadership. Emergency management encompasses several good management practices, such as clear and concise communication and service planning and training.

Fig. 11.1 Education and outreach

Furthermore, although an organization may elect to not be involved in community or regional emergency preparedness and emergency management (EP/EM) efforts, it should be aware of the EP/EM activities and programs where the organization resides. Figure 11.1 illustrates the levels of education outreach that typically exist in communities today. Depending on an organization's scope, size, and resources, it may be asked to play a significant role in EP/EM [8].

11.5 Emergency Management Is Framed by Four Phases [5, 9, 10]

1. Mitigation—those activities an organization undertakes to lessen the severity and impact a potential disaster or emergency may have on its operations.
2. Preparedness—those activities an organization undertakes to build capacity and identify resources that may be used should a disaster or emergency occur. In preparedness planning, community integration is key. Community integration is a process of developing relationship and a mutual commitment to each other and the community they serve, with other providers in the community which can be called upon in an emergency to share resources or staff or accept stakeholders [11].
3. Response—activities that take place at the time of an actual emergency.
4. Recovery—a plan to continue or reestablish business operations that involves
   a. Disaster recovery, either short or long term;
   b. Insurance coverage;
   c. Inventory systems;
   d. Information systems;
   e. Outsourcing of service provision, if necessary;
   f. Security, of both facility and documents;
   g. Potential to provide assistance to staff;
   h. Public relations and communication with stakeholders;
   i. Consider changes and lessons learned.

11.6 Developing an Emergency Preparedness Plan for the Organization

Preparing an emergency plan for the organization is essential for effectively addressing the organization's needs during an emergency or a disaster. The plan must be kept as simply as possible to do the job; it needs to be understandable and usable, not dense with unnecessary detail.

A plan offers a sense of organization, confidence, and awareness for organization members should an emergency arise. Calm demeanor is a key to effectively dealing with emergency situations, and a well-designed and -implemented plan helps instill an atmosphere of calm under stressful situations. Recall the story of Captain Chesley "Sully" Sullenberger, the US Air pilot who guided a damaged aircraft to a controlled crash landing on the Hudson River, saving all aboard. He and his crew exhibited no panic, just a calm, well-organized execution of emergency procedures. Captain Sully had rigorously trained and prepared for this potential event on numerous occasions, and his instincts and skill set were honed by those experiences [12]. Organizations need to be at that same level of readiness to deal with emergencies that arise.

A necessary first step is to consider the requirements of an emergency preparedness plan from the points of view of all stakeholders affected by the emergency.

Often, an emergency preparedness plan is seen as a mandate rather than a living, useful document and is given little additional thought. Organizations must avoid this trap and instead put deliberate effort into thinking about who will use the plan, what components will help them in an emergency, and how usable it will be to deploy in the case of a disaster. Many emergency plans are incredibly detailed and overly complex, and they will never be put in effect in an emergency [8].

For example, think about how individuals learn and follow instructions, and how they may interpret instructions in a variety of ways. There is a simple exercise that one can do to demonstrate this in a vivid way to participants. The "Animal Cracker Exercise," is a simple but interesting activity that allows individuals to see how all of us process and make decisions in different ways. The exercise begins by dividing the group into individual teams the number of teams and the number of members is somewhat immaterial. Give each participant on each team a box of animal crackers and instruct them to divide the animal crackers into groups. What one inevitably finds is that different groups and different team members will interpret those instructions in a variety of ways. They may divide the animal crackers based upon the animal depicted, bears to bears, elephants to elephants, etc. Some may divide them based upon those that are broken and those that are not. They may divide them based upon a more generic nature of the creatures for example large animals versus small, cookies with icing and those without. Or they may divide the cookies in the same way large cookies versus smaller ones. The question really is which one is correct? Of course, the answer is neither. It Is a question of what the situation requires, and this exercise demonstrates clearly that we all have different perspectives and therefore instructions should be clear and specific to achieve the desired result and unified action especially in an emergency. The level of variation needs to be accounted for when devising a plan for an emergency [13].

One recommended method for emergency planning is the all-hazards preparation framework. An organization rarely knows with certainty what type of emergency might beset it, even for those organizations that undertake a service analysis of vulnerabilities. However, common occurrences characterize many needed considerations which include:

- Safeguarding people
- Safeguarding property
- Ensure communications
- Develop alternative operations
- Manage the expectations of each member of the organization
- Reducing the spread of disease or harmful agents

Many free educational courses on emergency planning and management are available from the Federal Emergency Management Agency (FEMA). https://training.fema.gov/.

Figure 11.2 illustrates the planning cycle. Note that the plan requires consideration of the nature of the organization and how to equip organization members to respond to emergencies. Training is critical, including exercises for improving proficiency and evaluation and enhancement of the emergency plan. So often, plans are left untested and untouched, and then, of course, they work at a suboptimal level when implemented.

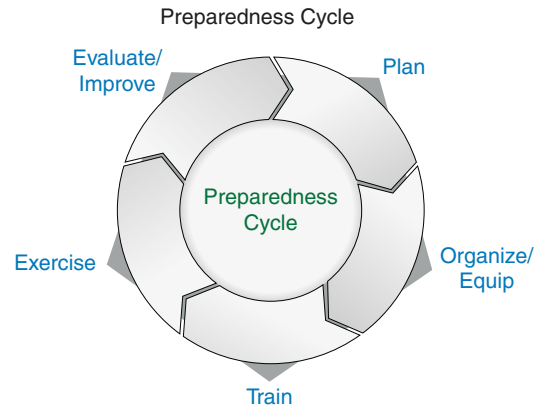

Fig. 11.2 Preparedness cycle

Developing an emergency management plan also requires consideration of the threats and hazards that might be faced by the organization. This process is known as vulnerability analysis (VA). Figure 11.3 illustrates the sequence of events needed to complete this portion of the planning process.

Of particular importance are the following factors:

- Continuity of the facility—Is the facility habitable and safe to be used by staff and stakeholders? Are alternative plans in place for having facilities available to the organization to see stakeholders and conduct the work of the organization?
- Continuity of communications—Are mechanisms in place to communicate with all stakeholders? For example, for your organization, should you reach your constituents using social media, e-mail, telephone trees, emergency communications over television or radio broadcast stations, or some combination of these? Should you deploy a special website or front web page that provide a status report on the organization that can be accessed by stakeholders? In large-scale disasters, electronic services may be severely curtailed or overwhelmed, so multiple communication strategies should be considered. Information technology plays a particularly important role in this process and should carefully evaluate in advance what communication methodologies and vehicles would work best in any situation given the unknown nature of the potential emergency paragraph multiple channels of communication should be developed, and stakeholders need advanced communication on where such information can be found in what communication can be expected when the need arises.
- Essential record-keeping—What records are essential to see you through this situation, and how are the records safeguarded? Stakeholders being treated under emergency situations require documentation of that treatment not only for future service but for liability purposes as well.
- Human resources—What is your organization doing to safeguard staff? To what extent, if any, are they expected to work in an emergency scenario? Are special human resource policies in place regarding pay and other forms of support? If not, should such support be considered? If the organization were unable to operate over an extended period, would any or all staff be laid off, or would they be maintained to help

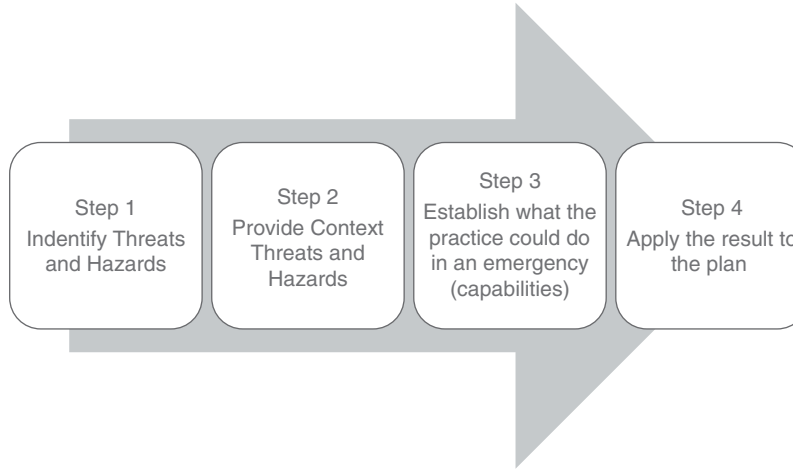

Fig. 11.3 Threat and hazard identification and risk assessment

Table 11.1 Discussion-based exercises

The homeland security exercise and evaluation program (HSEEP) provides a standardized methodology for planning and conducting individual exercises. The process includes four phases • Exercise design and development • Exercise conduct • Exercise evaluation • Improvement planning Do you have preparations for • Determining long-term training and exercise goals and objectives for your practice? • Creating a multiyear training and exercise plan? • Identifying members of a planning team? • Designing and developing training and exercises to achieve your identified goals and objectives? • Conducting the training and exercises developed by your planning team? • Evaluating your training and exercises, including development of after action reflection? • Translating lessons learned into measurable steps for improving your practices response capabilities? • Assigning responsibility and setting timelines for implementing improvements, and tracking their completion? • Sharing with others the lessons learned from training and exercising?

Adapted from https://emilms.fema.gov/is910a/EMPF-summary.htm

in the recovery phase? As we have seen in the recent 2020 code 19 pandemic, government plays an essential role here in provided needed support to organizations.

The organization must consider its exercise methodology and how it will bring about the training needed to effectively respond to an emergency. Some of those considerations are shown in Table 11.1.

Once the exercise plan is developed, organization managers and leaders must determine how the plan will be implemented. Exercises that the organization can undertake are available in numerous formats. Table 11.2 illustrates some commonly used discussion-based and operationally based exercises for improving response skills as well as the understanding of the emergency plan.

Table 11.2 Operations-based exercises

Types of exercises	
Exercises fall within two broad categories	
Discussion-based exercises	
Discussion-based exercises center on participant discussion. They familiarize participants with current plans, policies, agreements, and procedures, or may be used to develop new plans, policies, agreements, and procedures	
Type	Description
Seminar	A seminar is an informal discussion, designed to orient participants to new or updated plans, policies, or procedures (e.g., a seminar to review a new evacuation standard operating procedure)
Workshop	A workshop resembles a seminar, but is employed to build specific products, such as a draft plan or policy (e.g., a training and exercise plan workshop is used to develop a multiyear training and exercise plan)
Tabletop exercise	A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. Tabletops can be used to assess plans, policies, and procedures
Game	A game is a simulation of operations that often involves two or more teams, usually in a competitive environment, using rules, data, and procedures designed to depict an actual or assumed real-life situation
Operations-based exercises	
Operations-based exercises focus on action-oriented activities such as deployment of resources and personnel and are more complex than discussion-based types. They are used to validate plans, policies, agreements, and procedures; clarify roles and responsibilities; and identify resource gaps in an practice environment	
Type	Description
Drill	A drill is a coordinated, supervised activity usually employed to test a single, specific operation or function within the practice

(continued)

Table 11.2 (continued)

Types of exercises	
Functional exercise	A functional exercise examines and/or validates the coordination, command, and control between the practice and other community partners (e.g. hospital, police, fire department or health department). A functional exercise does not involve any "boots on the ground" (e.g., first responders or emergency officials responding to an incident in real time)
Full-scale exercise	A full-scale exercise is a multi-organizational exercise, involving a "boots on the ground" response (e.g., firefighters, ems, police, health department or hospital)
Adapted from https://emilms.fema.gov/is910a/EMPFsummary.htm	

11.7 Who Is an Emergency Manager? Does the Organization Need One?

Depending on the size of the organization, the emergency planner for the organization may be the organization manager or administrator or another staff member with an interest in assuming this role. Although designating an emergency planner is important, disaster preparedness should be everyone's job in the organization. Many organizations offer training and information for emergency managers at all levels of expertise, from novice to expert. Currently, many of these organizations are governmental, as protecting residents is historically a primary function of government. Internet-based documents, templates, and information are often the most useful because emergency preparedness and management is a rapidly evolving field with new information developed on a continuous basis, rendering other media less useful. The following are useful websites for emergency management resources:

- http://emergency.cdc.gov/healthprofessionals.asp
- http://emergency.cdc.gov/planning/
- http://ready.gov
- http://emergency.cdc.gov/
- http://www.aafp.org/afp/2007/0601/p1679.html
- http://emergency.cdc.gov/bioterrorism/training.asp http://emergency.cdc.gov/bioterrorism/
- https://emergency.cdc.gov/planning/
- http://www.redcross.org/get-help/prepare-for-emergencies/workplaces-and-organizations

One of the most important aspects of emergency preparedness management is keeping preparedness at top of mind in all areas of the organization. Often, organizations prepare but then forget about emergency issues, and that learning soon dissipates. The effective emergency manager provides regular updates, training, and information, keeping emergency management on the minds of everyone in the organization.

11.8 Community Emergency Response Teams

The Community Emergency Response Team (CERT) program educates individuals about disaster preparedness for hazards that may affect their area and train them in basic disaster response skills, such as fire safety, light search and rescue, team organization, and disaster medical operations. The training is conducted both in the classroom and using exercises. Becoming familiar with the local CERT can be a proactive way to learn about EP/EM, and it also provides a means to connect with the community that may be beneficial in an emergency or disaster situation [14].

11.9 Special Situations

In this section, we discuss specific disaster and emergency scenarios that have emerged or become increasingly common in recent years.

11.9.1 Terrorism

Just in the past decade or so, the likelihood of terrorism affecting medical organizations in the United States has shifted from improbable to possible and has emerged as an issue that needs to be addressed. Organizations must consider their role in responding terrorism situations. Much of this response depends on the nature of the organization, whether it is part of a larger organization or an independent business or unit, where it is located (e.g., urban or rural), and whether or not the organization is located near other potential targets of terrorist groups [15].

11.9.2 Bioterrorism

Bioterrorism is one clear emergency in which the organization can assist the community. According to the Centers for Disease Control and Prevention, bioterrorism potentially involves three primary agent categories, designated by A, B, and C.

Category A
These high-priority agents include organisms or toxins that pose the highest risk to the public and national security because of the following traits:

- They can be easily spread or transmitted from person to person.
- They result in high death rates and have the potential for major public health impact.
- They might cause public panic and social disruption.
- They require special action for public health preparedness.

Category B
These agents are the second highest priority because they pose the following types of concerns:

- They are moderately easy to spread.
- They result in moderate illness rates and low death rates.
- They require specific enhancements of CDC's laboratory capacity and enhanced disease monitoring.

Category C
These third highest priority agents include emerging pathogens that could be engineered for mass spread in the future. Their common characteristics include the following:

- They are easily available.
- They are easily produced and spread.
- They have potential for high morbidity and mortality rates and major health impact.

When establishing processes for responding to acts of bioterrorism, the organization manager and leader must consider and plan for all these possibilities [16, 17].

11.9.3 Pandemics (as has Become All Too Clear with Covid-19)

Pandemics are widespread occurrences of infectious diseases affecting large populations or regions. What is the role of the organization in addressing potential or actual pandemics? Although the answer varies significantly depending on location and type of organization, at a minimum the organization needs to be prepared to deal with significant numbers of stakeholders who are affected by a pandemic. Protection of the staff and other stakeholders is of utmost concern.

The organization may also cooperate with other local community organizations as part of an overall National Incident Management System (NIMS) [11]. Such partnerships bring government and non-government organizations and agencies together to manage disaster and emergencies. It is intended to bring the whole community together.

11.10 Preparing for a Pandemic

Although Covid-19 is upon us, future thought should be given to "the next time." One way to address a pandemic preparedness and how the organization might respond is to conduct a tabletop exercise. The scenario is the development of a pandemic in the region served by the organization.

First, the facilitator should provide a space that allows the group to work together on the exercise. If the group is too large, multiple groups may be created. Groups should not exceed seven people. The facilitator also provides flipcharts and markers or other means to record the activities of the groups.

Second, the facilitator gives each group a series of progressive events related to the pandemic, described in stages, and asks the groups to discuss and document how the organization would respond in this situation. They are given a 10-min time limit for each phase and are instructed to be prepared to share their conclusions with the facilitator and other groups.

- Stage I: Reports have been received that the number of cases of a novel strain of a pathogen is on the rise.
- Stage II: The organization has begun to see a number of employees with this illness.
- Stage III: The organization is receiving so many phone calls and visits from stakeholders with this novel illness that the organization is incapable of providing service to all the stakeholders. This unmanageable volume is exacerbated by the fact that many members of the organization staff are also ill. This is not unlike what appliance manufacturers and delivery companies have experienced with the Covid 19 pandemic.

Some findings from participating groups might include the following:

- Maintain proficiency in addressing a possible pandemic. Do not start cutting corners in safety or quality to provide service to all the stakeholders of the organization. This can be very chaotic times in the organization and a plan for the surge in stakeholder demand is required. Many organizations get a sense of this with common outbreaks of the seasonal flu and they certainly have with Covid-19.
- Maintaining the health and safe of the staff is also a priority. Exposure to pathogens can more easily occur in a frantic environment, so order and claim needs to be maintained, which can only be achieved by preparedness training.
- If a known threat exists, establish a protocol for screening, such as asking standard questions about travel, contacts, and location of residence as appropriate.
- Remain alert to for unusual clusters or unusual patterns of illness, especially when a threat is known or possible. For example, during the Ebola outbreak of 2014, people with possible Ebola symptoms were asked about their travel history. More recently Covid-19 caused a new series of screening questions and activities to be developed to help identify carrier of the virus.
- Protect the members of the organization by enacting heightened infection control protocols and equipment.
- Assist in the epidemiologic investigation when required. Government health agencies, such as the CDC at Federal and State Health Departments rely on the input from organizations in the community to help assess the nature and extent of disease outbreaks by reporting the number of cases of the illness under surveillance.

In this simplified example of a tabletop exercise, we see that the progression of a pandemic can quickly become a difficult situation for the organization to handle. What do you do as the manager or leaders of the organization? What plans have been made? What resources can you call on to support your stakeholder volume? Solutions to all these questions and more should be contained in the preparedness plan adopted by the organization, thereby allowing the organization to address an escalating event such as the Covid-19 pandemic in a timely and effective way [4, 18, 19].

11.11 Cybersecurity Threats

Although the issue of cyber security is well covered in other chapters of this text, it is important from an IT emergency management perspective to understand that during various widespread emergency situations cybercrime increases dramatically. Employees working from home and the dependency on digital technology increases the opportunity for security breaches. Chaos and the divided focus of organizations dealing with multiple issues adds to the vulnerability.

Security breaches during the Covid 19 outbreak are becoming all too common, and increasingly costly. At a recent conference at the Aspen Institute the FBI reported that cybercrime had quadrupled during the Covid-19 pandemic. Complaints to the FBI's Internet Crime Complaint Center (IC3) increased from approximately 1000 a day to 3 to 4000 a day as the pandemic developed. Research organizations were a heavy target for these potential intrusions [20].

11.12 Collaborative Emergency Management

In any significant emergency or disaster situation, no single entity will likely be able to manage the needs of the entire community. Technology organization small and large, are often called on to assist in these difficult situations. The organization manager and organization leaders must acknowledge its expected level of involvement in community emergencies and to prepared for the possibility of being asked to assist in a crisis [21].

11.13 Examples of Collaboration in Emergency Management

Potential issues that might involve the organization in an emergency or disaster situation include a pandemic. The organization should regularly seek out and incorporate new information about possible health and safety threats as part of the emergency preparedness plan review and revision process.

The aim of these considerations is for the organization to become an integral part of an overall community response to an emergency. How that effort is organized and who oversees it varies from community to community, but the minimum expectation in many cases is that the organization is involved on some level, even if only to be compliant and informing stakeholders, complying with mandates and suggested protocols for safety, such as wearing mass social distancing and handwashing as in the case of Covid-19 and the seasonal flu. Organizations may also encourage vaccinations and other healthy behaviors as well.

11.14 Vaccine Distribution

A challenge which will be significant during this and other pandemics will be the distribution of vaccine to hundreds of millions of people from all walks of life, in all geographic settings, and do so in a reasonable timeframe. Information technology will play significant role in this activity by allowing the rapid distribution of information, connecting organizations, enhancing communication and networking.

One specific example of an IT solution to help in a pandemic environment was the development of an app for contact tracing. The app known as, "SlowCovid," installed on a smart phone provides, available at no cost in the various app stores, provides a notification to the device whenever it comes into contact with the person that is tested positive for Covid-19 and is in the states database. The app does not require personal information beyond the fact that is installed on an individual smart phone and has been customized to each state [22].

Those individuals who receive a notice that they have been exposed are then encouraged to seek out testing and self-quarantine to prevent the further spread of the virus. The widespread use of this information technology was credited for slowing the infection rate in South Korea by improving contact tracing [23]. Success in United States has been less effective due to the lack of widespread adoption of such measures although virtually everyone has a smart phone. Privacy

concern are always an imposing issue in the United States, as well [24]. The potential for such technology is clear and future education and adoption strategies would be useful for future application.

11.15 Other Resources

FEMA, State emergency management agencies and the CDC assist in developing plans for continuity of operations in times of pandemics or disasters. These resources are logical starting points for medical organizations as they prepare their emergency and preparedness plans.

This chapter has provided only a glimpse at some of the important elements of emergency management and preparedness. The organization manager in this new era must continue to seek new information and education and to develop effective plans for the organization and the communities it serves.

The following resources are useful in preparing an emergency plan for the organization:

1. Business Panning Template at www.Ready.gov/business
2. Pandemic Influenza Business Planning Toolkit at www.health.mo.gov/emergencies/panflu/panbusiness.php
3. Pandemic Influenza Continuity of Operations Annex Template at www.fema.gov/about/org/ncp/coop/templates.shtm
4. The Department of Homeland Security Information Technology Strategic Plan 2019–2023 at www.dhs.gov/publication/dhs-information-technology-strategic-plan-2019-2023
5. Emergency management Training Independent Study at www.training.fema.gov/emiweb/is/is235b/is235b.pdf

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Data Use in Public Health

12

Musa A. Kana, Ahmad Khanijahani, Ismail A. Raji, Abdu Adamu, and Faina Linkov

Abstract

Public health is the science of promoting health, preventing diseases, and prolonging life in human populations through society's organized efforts. Worldwide, local, national, and international public health organizations and governments have established data collection systems that vary depending on local needs, available resources, and infrastructure. This chapter introduces the reader to public health data sources and the basics of monitoring disease risk and burden and allocating health resources to implement and evaluate interventions. Advances in information technology and data science have provided innovative tools and data sources for public health. Hence, we will broadly describe the application of big data in public health. Finally, we incorporated a case study to illustrate the public health approach in health outcome disparity assessment among the vulnerable populations in the United States during the Covid-19 pandemic.

Keywords

Data · Public health · Evidence-based public health · Vital statistics · Administrative data Surveillance systems · Public health research Knowledge translation · Big data

M. A. Kana (✉)
National Institute of Environmental Health Sciences, Epidemiology Branch, Durham, NC, USA

A. Khanijahani · F. Linkov
John G. Rangos, Sr. School of Health Sciences, Duquesne University, Pittsburgh, PA, USA
e-mail: khanijahania@duq.edu

I. A. Raji
Department of Community Medicine, Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria

A. Adamu
South African Medical Research Council, Cochrane South Africa, Cape Town, South Africa

Learning Objectives

- This chapter aims to introduce the public health data collection systems that support efficient and effective decisions and responses at various levels of local, national, and international public health organizations. By the end of the chapter, the reader should understand the different sources of public health data and its use in policy formation, advocacy, regulation, decision systems, research, and implementation and evaluation of interventions.

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12.1 Introduction

The use of data has become essential for public health decision-making at the local, national, and global levels (Fig. 12.1) [1]. Hence, evidence-based public health practice in the twenty-first century requires timely, accurate, and authoritative information from a wide variety of sources. The confluence of improved information systems and technologies, new challenges to the public health system, and changes in the medical care system presents a unique opportunity, to fundamentally improve efficiency and effectiveness of public health practices [2].

12.1.1 Types and Sources of Data Used in Public Health

Quantitative and qualitative data are derived from varied sources and used for primary and secondary data analysis in public health (Fig. 12.2). Quantitative data is measurable, often used for

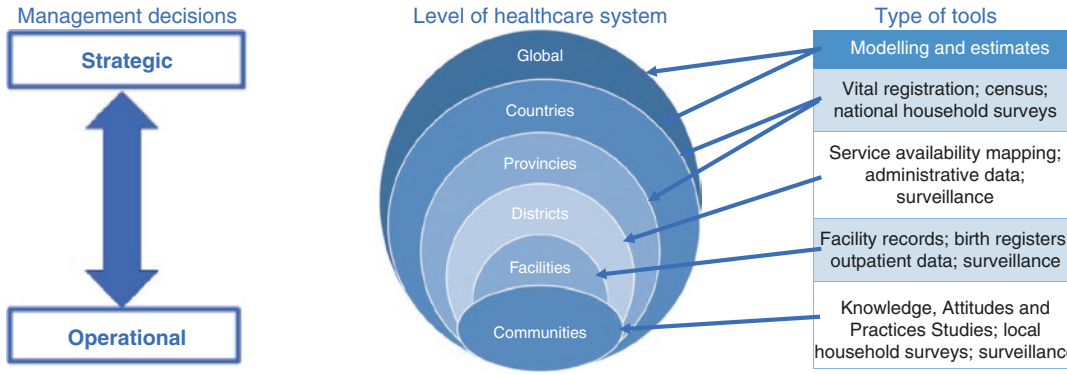

Fig. 12.1 Data needs and data collection tools at different levels of the healthcare system [3]

Vital statistics and administrative data	Surveillance systems	Public health research
• Vital statistics of demographic events • Birth registry • Death registry • Administrative data • Policies and guidelines • Health insurance data • Environmental exposure and monitoring data • Healthcare services and medical records • Census • Population surveys	• Active surveillance □Disease specific □Demographic and Health Surveillance Systems □Cohort studies • Passive surveillance • Disease registries	• Health research, including clinical, health systems and operations research • Community-based and Participatory action research. • Implementation research • Modelling, estimates and projections

Fig. 12.2 Classification of the sources of public health data

comparisons, and involves counting people, behaviours, conditions, or other discrete events. Qualitative data is a broad category of data that can include almost any non-numerical data. Qualitative data uses words to describe a particular health-related event, such as recording a health-related interview with a patient [4].

12.1.1.1 Vital Statistics

Vital statistics is information collected and recorded by the Government of a country about all major life events in the population (e.g., the United States), including birth, marriage, divorce, separations, and death [5]. This information provides valuable insight into the country's birth rate, age stratification, marriage, and death trends. The potential impact of demographic changes and morbidity and mortality prevention activities and policies can also be studied at the national level using these data sources. Moreover, public health threats and disasters such as disease outbreaks (e.g., Covid-19 pandemics) can impact the population dynamics and can be monitored by morbidity and mortality tracking to inform future in-depth studies.

12.1.1.2 Administrative Data

Administrative data refers to records of policies, guidelines, and other valuable information about a nation's public health system, derived from the local, state, national, or global entities involved directly in healthcare or agencies whose policies impact population health. For example, reviewing historical data on lobbying activities and the laws passed by a legislative assembly indirectly assesses a political system's priorities and preferences that impact citizens' health. Administrative records at the organizational level, such as the number of patients receiving services from hospital and healthcare settings, provides information about the organization's policies and interventions that impact patient health outcomes. Medical records documented by paper-based or electronic health record systems and insurance claim data can guide understanding of the organizational level health-related decisions and their impact on healthcare providers or healthcare institutions.

Across the world, government agencies collect and disseminate policies or guidelines under administrative records. At the broader national or the federal level, for example, policy documents and administrative data can be publicly available from agencies such as the National Institutes of Health (NIH) [6], the Centers for Disease Control and Prevention (CDC) [5], Food and Drug Administration (FDA) [7], the National Aeronautics and Space Administration (NASA) [8], and Environmental Protection Agency (EPA) for regularly updated records of air quality, weather changes, precipitation, and temperature) [9].

12.1.1.3 Census

Census is a population-wide decennial data collection that provides household information and demographic characteristics such as age, gender, and race of citizens and residents of a country. Identifying the characteristics of individuals residing in different parts of the country and obtaining an accurate estimation of the population density helps policymakers and planners allocate resources adequately based on objective measurement of the community needs. The process of census data collection can be cumbersome, costly, and time-consuming. Hence, data collection is shifting from paper and in-person interviews to electronic data collection, such as sending survey links to individuals and collecting data remotely.

12.1.1.4 Surveys

Design and data collection approaches for surveys consider the population's characteristics to estimate population health status and healthcare needs. Public health and healthcare research, planning, and policymaking are the primary purposes of surveys. Analysis of survey data yield information about the current state of the population distribution of diseases, availability, and geographical distribution of public health resources, including access and utilization of health services and healthcare professionals' distribution.

In the United States, several types of health-related surveys are conducted and reported to

provide nationally representative estimates of the public health indices of interest. Surveys focusing on population subgroup, such as children, the National Survey of Children's Health (NSCH) provide vast information about children, including data about their health status, family, access, and utilization of healthcare services [10]. The Behavioral Risk Factor Surveillance System (BRFSS) focuses on health behaviors [11]. Surveys such as the National Health Interview Survey (NHIS) provide an opportunity to understand health and healthcare status in different populations and data to perform additional health-related research studies [12]. Secondary data analyses based on the existing survey data address policy-related questions such as the impact of a public health policy or intervention on the intended population and health outcomes. Additionally, merging survey data with data from other sources helps identify individual, neighborhood, societal, local, and other population characteristics and their impact on population-level health outcomes.

12.1.1.5 Surveillance Systems

Public health surveillance is the ongoing systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The purpose of public health surveillance is to equip decision-makers with information to take timely and effective public health actions. These actions aim to improve the population's health and prevent disease.

The public health system's objectives and the actions needed to achieve a positive health impact determine a surveillance system's structure, function, data collection, and data dissemination techniques. For example, suppose a surveillance system aims to prevent the outbreak of infectious diseases. In that case, health authorities need to be able to rapidly access these data in a timely fashion and have the tools available to halt its spread. In contrast, a surveillance system that measures an intervention's impact on chronic diseases such as hypertension would have a timely data collection process. However, rapid access and dissemination might not be necessary. Therefore, different public health objectives require different surveillance system setups. The type and frequency of actions required and what information is needed to monitor specific intervention's effect should determine the kind of surveillance system setup [13]. The surveillance system could be active or passive:

Active Surveillance

This type of surveillance gathers information about diseases or health events by employing technology and staffing specifically to search and collect data by regularly keeping in touch with the health care providers. This form of surveillance usually provides complete and timely information for public health action; however, it is expensive. Active surveillance includes disease-specific surveillance, demographic and health surveillance, and cohort studies capabilities.

Disease-Specific Surveillance

Disease-specific surveillance is a form of active surveillance directed towards specific pathogens, diseases, risk factors, or syndromes in a specified group of people [14]. This form of active surveillance has the advantage of allowing surveillance of a broad spectrum of disease-causing agents or health outcomes. Disease-specific surveillance enables surveillance units to follow the global trend of specific pathogen or disease under surveillance. The health departments can also use disease-specific surveillance to evaluate public health measures instituted as a response that they have employed to fight a particular disease. However, for this type of surveillance to function well, identifying targeted pathogens or disease conditions must precede data standardization and the surveillance system's commencement [14]. The United States Surveillance, Epidemiology, and End Results (SEER) Program for comprehensive cancer statistics is an example of a disease-specific surveillance system [15]. Another is the Acute Flaccid Paralysis surveillance system, which the World Health Assembly implemented in 1988 with the goal of global eradication of poliomyelitis by 2000 [16].

Demographic and Health Surveillance System

Demographic and Health Surveys (DHS) are nationally-representative household surveys, providing data for a wide range of monitoring and impact evaluation activities. DHS data are especially a reliable source of surveillance data in developing countries where routine health records, vital registration, and civil registration are moribund [17]. The DHS data are uniform across countries and regions, making them useful for comparison within and between countries. The DHS is a valuable and valid source of national policymaking data because they represent all demographic groups [17].

DHS data provides indicators used to monitor different demographic groups, which could reveal health and social inequalities that enable health managers to intervene appropriately and promptly. Due to its extensive nature, DHS data enables health authorities to link the respondents' outcomes to their geographic location and sociodemographic characteristics, allowing for identifying the determinants of various health outcomes. DHS is especially valuable in providing unique population-based information for monitoring population health changes. DHS data are generally of high quality [17] and valuable for generating morbidity and mortality measures that can help health managers corroborate data from routine sources such as vital statistics. The drawback with DHS is that it is expensive and labour intensive. As with any survey, the DHS is prone to sampling errors, and its conduct once every five years limits its usefulness as a good data source for routine monitoring of health indicators.

Cohort Studies

A cohort study is a form of observational study in which the recruited participants are followed-up to determine the incidence of a specific outcome of interest in the exposed and non-exposed groups. The design can be prospective or retrospective. The retrospective cohort study is less costly and time-consuming, but the information is usually incomplete and inaccurate compared to the prospective approach [18]. A significant proportion of cohort studies utilize already established routine surveillance systems such as vital statistics and cancer registry to obtain data on the outcomes of interest. Although routine surveillance systems are cost-effective, they might not exist in some settings (such as the developing countriess). It is necessary to put in place a method of documenting the outcome of interest.

Results from cohort studies have helped decision-makers in clinical and public health practice identify the determinants and natural history of diseases. For example, developed countries have reduced the risk of cardiovascular death mainly due to a reduction in the exposure to risk factors identified in the Framingham heart study, a cohort study launched in 1948 [19, 20], which provided the evidence for decision-makers to provide prevention guidelines [21]. Other familiar examples of using the cohort study approach for surveillance include the Atherosclerosis Risk in Communities Study [22], Coronary Artery Risk Development in Young Adults Study [23].

Passive Surveillance

In passive surveillance, the health department receives reports of a disease condition or any event of public health importance from all institutions through routine surveillance activities. Passive surveillance can be in the form of disease notification or disease registries.

Disease Notification

This form of passive surveillance requires reporting specific diseases or events of public health importance by designated health workers, as specified by law, regulation, or agreement. The disease or public health events are known as notifiable or reportable diseases when the law requires reporting of such cases to public health authorities, such as cancer in the US. The gathering of information via a disease notification system provides early warning signs for health authorities to take early actions to prevent disease outbreaks. The notification also allows the health department to monitor the trend of specified diseases. This information gathered over time can

help authorities arrive at policies that will prevent such diseases from escalating into an outbreak. For example, the international health regulation requires the reporting of plague, yellow fever, and cholera.

Disease Registries

A Disease registry uses observational study methods to collect uniform data (clinical and others) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, which serves one or more predetermined scientific, clinical, or policy purposes [24]. A disease registry can help describe a disease's natural history, observe disease trends over time, determine the effectiveness of health interventions, monitor health care products' safety, and assess the quality of care [24]. It is a powerful tool for documenting chronic diseases [18].

Disease registries have the advantage of prospectively gathering the exact surveillance data that meet specific objectives. Registries allow for calculating incidence, prevalence, and survival rates, giving health managers and policymakers insight into the magnitude of the particular disease under surveillance. Health departments use registries to gather information on risk factors, prevention, disease management, and mortality, hence its usefulness in chronic disease control. Registry data usually account for wide variations in patients, disease presentations, treatment protocols, and environmental exposures. Registries can therefore be a vital source of data regarding disease causality, treatment efficacy, and safety [18].

The use of registries for surveillance at the national level can enhance health care quality by pooling administrative data sets. Such information can come in various forms of health reporting measures that health administrators and policymakers can use to enhance the patients' clinical management to improve outcomes [18]. For example, in Portugal, Sweden, and United Kingdom, the collection data on performance indicators, based on clinical and administrative data, has been used to change policy that led to improved health care quality [25, 26].

12.1.1.6 Public Health Research

Researchers rely on public health practitioners and institutions to translate their findings into ongoing health services or population-level intervention programs [27]. Typically, observational and experimental studies conceived and reported as numbers might not meet critical public health evidence needs. Therefore, strengthening the knowledge base by including multiple factors, shared practical experiences, and observations that promote program effectiveness is essential for the following research methods.

Community-Based Research Community-based research in public health focuses on social, structural, and physical environmental inequities through the active involvement of community members, organizational representatives, and researchers in all aspects of the research process [28]. Participatory Health Research (PHR) is a form of community-based research that has become increasingly important as a means for finding solutions in communities where the occurrence and severity of health problems are most significant.

Multilevel Analysis in Public Health Research Multilevel analysis is an analytical strategy that allows the simultaneous examination of group-level and individual-level factors [29].

Modeling Statistical models are increasingly used to attribute health outcomes to multiple risk factors.

Linked Databases Linking databases of health outcomes and health determinants can help increase understanding of causal pathways in both directions. Record linkage promotes policy applications, when databases allow researchers to (a) study interventions longitudinally; (b) compare regions, areas, and hospitals; (c) combine information on patients and physicians; (d) add up expenditures for different services within the

healthcare system; and (e) examine the determinants of health using education and family services data in conjunction with health-related information [30]. It has been recognized that no one dataset will contain information on all the health determinants, which calls for linking multiple databases [31].

Health Systems and Operations Research The focus of these research techniques is to constantly guide the programme implementation to achieve best results. It modulates inputs and processes involved in the programme cycle and strive to produce optimal gains in achieving targets and goals.

Implementation Research Public health practice involves implementing or adapting evidence-based interventions into new settings to improve health for individuals and populations. Such interventions typically include one or more of the 7 Ps (programs, practices, principles, procedures, products, pills, and policies) [32, 33].

12.1.2 Translating and Linking Public Health Data and Evidence to Public Health Action

Public Health Approach (Fig. 12.3) [34], demonstrates how the conceptual framework of Evidence-Based Public Health (EBPH) systematically links data collection with decision systems and appropriate public health action, which impacts disease control and prevention in human populations [3].

Historically, crises, political concerns, and public opinion have frequently driven public health decisions and policies. Therefore, evidence-based public health (EBPH) is promoted increasingly as a practice model because of the successes of evidence-based medicine (EBM) and specific public health interventions [35]. Globally, life expectancy doubled during the twentieth century [36], mainly because of reductions in child mortality attributable to expanded immunization coverage, clean water, sanitation, and other public health programs focusing on infants and children implemented based on scientific evidence [37]. Accordingly, public health data and scientific evidence analyzed using the following analytical tools and processes (Table 12.1) could direct the prescription of appropriate policy formation, advocacy, regulation, design, implementation, and evaluation of interventions [38].

The effective implementation of evidence-based public health policy requires population health indicators utilized as quantitative measures to improve populations' health and reduce health inequalities. Health indicators support this goal through the following key applications: advocacy, accountability, system management, quality improvement, and research [40]. Public health indicators are used to report all the domains of population health in modern times, which are multiple health determinants that interact, including early life experience, with an international

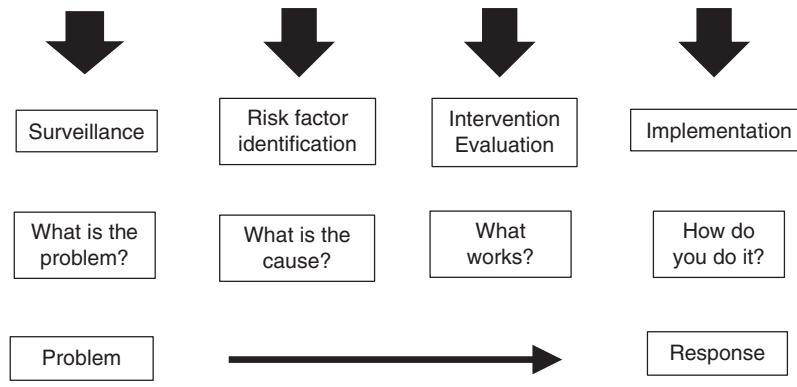

Fig. 12.3 Public health approach adapted from United States CDC public health 101 series [34]

Table 12.1 Analytical tools and processes for evaluating public health data and scientific evidence

Analytical tool and process	Description	Prescribed public health action
Systematic review and metanalysis	A quantitative approach providing a systematic, organized, and structured way of integrating individual research studies' findings	Policymaking, regulation, evaluation of interventions
Risk assessment and communication	Quantitative risk assessment is the systematic approach to characterizing the risks posed to individuals and populations by environmental pollutants and other potentially adverse exposures. Risk assessment is considered the "bridge" between science and policymaking	Policymaking, regulation
Economic evaluation	Commonly through cost-effectiveness studies should be an essential component of evidence-based decision-making [39]. These methods provide information to assess the relative appropriateness of expenditures on public health programs and policies	Evaluation of interventions
Public health surveillance	Surveillance involves the ongoing, systematic collection, analysis, and interpretation of outcome-specific health data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury	Evaluation of interventions
Expert panels and consensus conferences	In both executive and legislative branches, most government agencies and voluntary health organizations utilize expert panels to examine scientific studies based on explicit criteria and determine their relevance to health policies and interventions	Policymaking, planning new interventions, regulation

focus on social determinants [41]. In the United States, a number of key public health indicators are monitored by the Centers for Diseases Control and Prevention (Table 12.2) [42].

Several types of regularly collected evidence contribute to the design of interventions to improve health outcomes. They range from research evidence of efficacious health interventions to others like reports and surveys that

Table 12.2 Key public health indicators in the United States

Indicator	Measure
Access to health services	Proportion of persons under age 65 with medical insurance
	Proportion of persons with a usual primary care provider
Clinical preventive services	Age-adjusted proportion of adults aged 50–75 who had received a colorectal cancer screening based on the most recent guidelines
	Age-adjusted proportion of adults aged 18 and over with hypertension whose blood pressure was under control
	Age-adjusted proportion of adults aged 18 and over with diagnosed diabetes whose A1c value was greater than 9%
	Percentage of children aged 19–35 months who received the recommended doses of diphtheriatetanus-acellular pertussis (DTaP); polio; measles, mumps, rubella (MMR); Haemophilus influenza B (Hib); hepatitis B (HepB); varicella; and pneumococcal conjugate vaccine (PCV)
Environmental quality	Number of days the Air Quality Index (AQI) exceeded 100
	Proportion of children aged 3–11 years who were exposed to secondhand smoke
Injury and violence	Age-adjusted rate of injury deaths per 100,000 population
	Age-adjusted rate of homicides per 100,000 population
Maternal, infant, and child health	Infants deaths under age 1 year per 1000 live births
	Total preterm live births born before 37 completed weeks of gestation
Mental health	Age-adjusted rate of suicide per 100,000 population
	Proportion of adolescents aged 12–17 with a major depressive episode in the past 12 months
Nutrition, physical activity, and obesity	Age-adjusted proportion of adults aged 18 and over who met the physical activity guidelines for both aerobic (150 min or more of light/moderate or 75 min or more of vigorous physical activity per week or equivalent combination) and muscle strengthening physical activity (at least twice a week)
	Age adjusted proportion of adults aged 20 and over with obesity
	Proportion of children and adolescents aged 2–19 years with obesity
	Age-adjusted mean daily intake of total vegetables by persons aged 2 years and over
Oral health	Age-adjusted proportion of persons aged 2 years and over who visited a dentist in the past year
Reproductive and sexual health	Proportion of sexually active females aged 15–44 who had received reproductive health services in the past year
	Proportion of HIV-positive persons aged 13 and over who were aware of their HIV infection status
Social determinants	Proportion of students who graduated from high school 4 years after starting ninth grade
Substance abuse	Proportion of adolescents aged 12–17 who had used alcohol or illicit drugs in the past 30 days
	Proportion of adults aged 18 and over who engaged in binge drinking in the past 30 days
Tobacco	Age-adjusted proportion of adults aged 18 and over who were current cigarette smokers
	Proportion of students in grades 9–12 who smoked cigarettes in the past 30 days

facilitate contextualization. However, one of the biggest challenges in global health today is the delay in integrating evidence from public health research into policy and practice [43]. This problem is commonly referred to as the "know-do gap", although other synonyms like "research-to-practice gap" or "knowledge-to-action gap" are sometimes used [44, 45]. It is

estimated that nearly two decades (approximately 17 years) is taken for 14% of research evidence to get integrated and used in routine practice [46, 47]. Furthermore, only about half of the efficacious interventions that are developed are ever used [48]. This delay and non-usage of efficacious interventions is even higher in low-income countries, and could be an important contributory factor to the poor health indices in these settings [49].

Bad polices lead to the wastage of scarce resources, and poor health outcomes persist in communities due to the know-do gap. Suppose the gap between what we know (from research and other sources) and what we do (in practice settings) continues to persist. In that case, it could deter the timely attainment of global aspirations for resilient health systems and equitable healthcare for the whole population. Several factors can cause the know-do gap, and we have outlined them in Fig. 12.4.

In 2004, the WHO published a report entitled "*World report on knowledge for better health*" which raised the global community's attention to the need for more data communication and sharing [50]. The report also emphasized the need to enable easy access to relevant information and closer collaboration between researchers and other stakeholders so that research can be tailored to specific needs at a particular point in time [50]. This was followed by a ministerial summit convened in Mexico in which a mandate for health stakeholders to communicate and apply relevant and good quality health information was issued [51]. Afterward, the World Health Assembly, called on all WHO member states to "establish or strengthen mechanisms to transfer knowledge in support of evidence-based public health and healthcare delivery systems, and evidence-based health-related policies" and mandated the WHO's Director-General to develop mechanisms to bridge this divide between knowledge generation and utilization

12.1.2.1 What Is Knowledge Translation?

This mandate to effectively link health research to action soon became a global cause, and the concept of knowledge translation (KT) emerged [52]. Today, KT is both a research and practice paradigm dedicated to closing know-do gap in health systems globally [43]. Although the most widely known definition of knowledge translation was the one proposed by the Canadian Institutes of Health Research, the WHO adapted it to reflect a

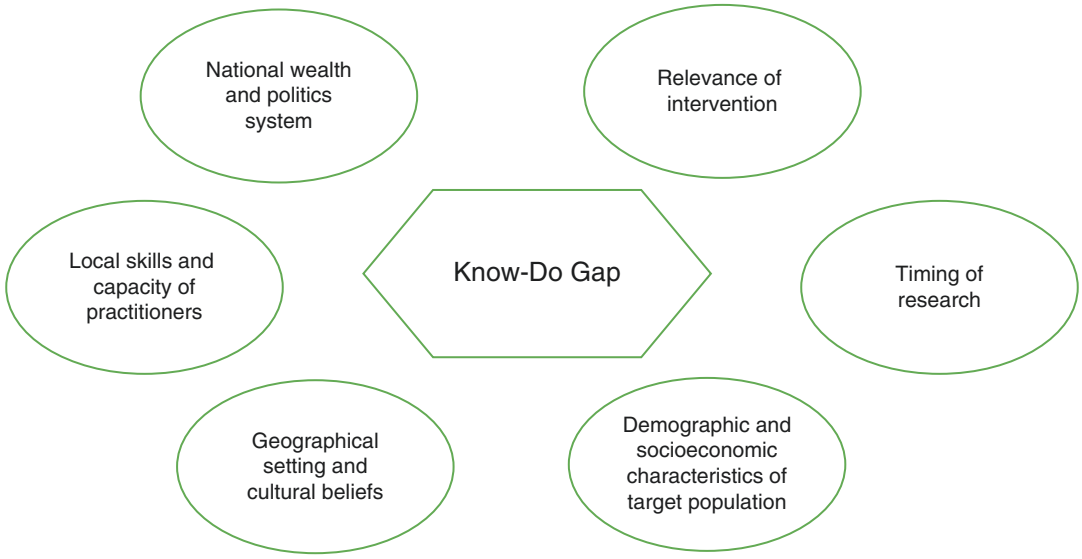

Fig. 12.4 The know-do gap hexagon: a conceptual framework of factors that cause know-do gap

more global context: "*the synthesis, exchange and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovations in strengthening health systems and improving people's health*" [43].

Let's unpack this definition:

Synthesis This is the identification of all available and relevant knowledge and combining it in a meaningful way that stakeholders can understand and use. The term "knowledge" is used instead of "research evidence" because research evidence is only one form of knowledge.

Over the years, many scientific methodologies have been developed to aid transparent and reproducible research evidence synthesis. These include systematic reviews, scoping reviews, and evidence mapping, which require specific skills to perform. Therefore, to influence action in clinical settings, researchers can synthesize evidence from randomized controlled trials of interventions and strategies to inform clinical guidelines development [53]. Similarly, to influence health policies, researchers can synthesize trials of policy-relevant interventions and observational studies and reports to explore context-specific factors [54].

Exchange Scientists and researchers who engage in knowledge synthesis must share information with other stakeholders so that relevant findings can be used to support the policymaking process or inform decisions in practice settings. Such exchange can occur either directly or via repositories and databases. In a direct engagement, knowledge producers (e.g., researchers) can use stakeholder-mapping techniques to identify and strategize their engagement with policy and decision-makers who would find their information useful. It is essential always to remember that knowledge users also include members of the public.

Application This occurs when relevant and context-specific knowledge is incorporated into guidelines and/or policies, and is being used in practice settings by decision-makers to improve the lives of individuals and communities. Ultimately the goal of KT is to hasten the use of valuable evidence to strengthen health systems and improve lives.

12.1.2.2 Engaging in Knowledge Translation

With the numerous knowledge translation theories and frameworks that exist, national research institutions and other research centers now have better guidance on conceptualizing the process.

Examples of frameworks:

- Knowledge to action framework: This framework was developed by Graham and colleagues to provide a conceptual model for people engaged in knowledge translation in order to clearly distinguish all the key elements of the knowledge translation process [55]. It divides KT process into two components; knowledge creation and action cycle [55]. This framework was applied in the Democratic Republic of Congo to inform an educational intervention for primary prevention of spina bifida [56].
- Interactive systems framework for implementation and dissemination: This framework was developed by Wandersman and colleagues [57]. They categorized stakeholders into three systems: knowledge synthesis system (which include stakeholders such as researchers in universities and research institutions), support system (which include government agencies and their implementing partners, funders who provide the policy guidance and technical capacity for an intervention), and the delivery system (which are the front-line practitioners like doctors, nurses, community health workers involved in using the technical skills provided by the support system to provide services) [57]. This framework has been used by the United States Centers for Disease Control and Prevention (CDC) in its violence prevention program [58].

12.1.2.3 Institutionalizing Knowledge Translation

Ever since the global call for more attention to translating research to action—in policies and

practice—several governmental, non-governmental, multilateral, and research institutions have responded by creating dedicated knowledge translation departments/units.

- At a global level, the World Health Organization (WHO) has since established a Knowledge Management and Sharing (KMS) department to support member countries in knowledge translation.
- The Regional East African Community Health-Policy Initiative (REACH) is an example of a regional institution established as a "knowledge broker" between researchers and policy makers to improve evidence-informed health policymaking and bridge the gap between knowledge and action.
- The South African Medical Research Council (SAMRC) is an example of a research institution with a national mandate that engages in knowledge translation to hasten the transfer of beneficial health interventions to routine practice to benefit all South Africans.

University research centers like the Center for Evidence-Based Health Care (CEBHC) at the Faculty of Medicine and Health Sciences at Stellenbosch University, and the Lung Institute at the University of Cape Town, all have dedicated knowledge translation units that support a wide range of stakeholders to promote uptake of evidence in health policy and practice.

Translating evidence from public health research is not as seamless as its ideally supposed to be. Evidently, in recent years, the know-do gap has gained increased recognition among health researchers, including a desire to better understand innovation fit and adaptation to context [59, 60]. In fact, understanding why these challenges occur and how to mitigate them has even necessitated the emergence of a new field of study called implementation science.

Although several authors have defined implementation science in the past, the definitions by Eccles and Mittman, and Odeny and Colleagues best reflect the purpose of this session [59, 60]. Eccles and Mittman defined it as "*the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services*", while Odeny and colleagues defined it as "*a multidisciplinary specialty that seeks generalizable knowledge about the behavior of stakeholders, organizations, communities and individuals in order to understand the scale of, reasons for, and strategies to close the gap between evidence and routine practice for health in real-world contexts*" [59, 60].

12.1.3 Application of Big Data to Healthcare and Public Health

While big data may refer to many different concepts, the general understanding is that big data is a term that describes the large volume of structured, semistructured, and unstructured data from different sources and in different sizes ranging from terabytes to zettabytes. These datasets are often so large and diverse in terms of content (video, audio, text, etc.) that traditional statistical approaches and statistical programs cannot be used to manage and process these data. These healthcare data sources include Electronic Health Records (HER), data originating from sensors, imaging data (such as MRI), data from wearable devices, video/audio, networks, telemedicine, etc. In medicine, much of these data are generated in real-time and on a vast scale. While there are many big data applications in healthcare and public health (outlined in Fig. 12.5), the focus of this chapter will be on the use of big data on rare disease and rare malignancy research.

Rare malignancies pose significant morbidity, mortality, and disease burden for the population in the US and around the world. Gynecologic malignancies are particularly burdensome among the US women, resulting in significant morbidity, mortality, and poor quality of life among the survivors. Gynecologic cancers represent many rare conditions that are under-investigated. Approximately 95,000 new cases are diagnosed, and about 30,000 deaths occur each year from gynecologic cancers among women in the US

Fig. 12.5 Big data applications in healthcare and public health

[61]. The relatively low incidence inherently makes it more challenging to study populations of patients with rare malignancies. Furthermore, misclassification and extreme variation among these diseases are common and contribute to the poor understanding of their biology, disease course, and treatment [62].

A poor prognosis is a common characteristic of many rare diseases and events, especially for various ovarian cancer histologies. Inadequate domain-specific expert knowledge leading to dearth of standard treatment and delayed diagnosis contributes to poor outcomes associated with some of these malignancies. Insufficient biological and clinical data for research due to their rarity explains the inadequacy of scientific domain knowledge. Since access to data with the number of cases sufficient for statistical power and research funding for these rare gynecologic malignancies have been limited, existing datasets need to be pooled and harnessed for research using innovative approaches and tools to promote and accelerate the discovery of novel treatments and to improve the fertility, morbidity and mortality outcomes of women affected by these diseases.

The development of consortia for pooling data supporting research purposes, including investigating rare malignancies, has been the focus of many recent ongoing national and international efforts [63, 64]. The National Mesothelioma Virtual Bank (NMVB) is one example of multi-institutional databases and virtual biobanks that successfully pools data and biospecimens from 969 retrospective cases and 593 prospective cases (1562 overall) as of July 2018 [65]. This resource, which is opened to the broad research community, has successfully supported multiple research projects on Mesothelioma internationally, resulting in publishing 13 research papers [65]. Cancer Research Network (TCRN) [66], a federated network of cancer centers, which facilitates data and biospecimen sharing among five member institutions, affords capabilities and scale for conduct-

ing research in the area of rare gynecological malignancies. TCRN leverages a data-sharing trust agreement based on a predetermined non-human subject research status of its database, high level of data quality and security, advanced natural language processing, and an extensive federated database of de-identified pathology and radiology reports linked to biospecimens to facilitate research across member institutions.

The TCRN is a National Cancer Institute Informatics Technology for Cancer Research (NCI ITCR). University of Pittsburgh Institute for Precision Medicine (IPM) funded project designed to make available highly annotated and de-identified clinical reports for biomedical research on a wide variety of malignancies [67]. It is vital to highlight that TCRN and similar resources are unique tools for investigating rare malignancies. Using these existing repositories and big data approaches, we can identify sufficient numbers of patients with rare malignancies that can be efficiently identified to conduct impactful research with adequate statistical power to impact the lives of women in the US and around the world.

Another dimension of big data use in healthcare and public health is digital epidemiology, also referred to as digital disease detection (DDD), which is motivated by the same objectives as traditional epidemiology [68]. However, DDD focuses on electronic data sources that emerged with the advent of information technology [69]. DDD operates at the intersection of personal information, public health, information technologies, and increasingly within the so-called big data environment. Precision public health is also a big data application, which is viewed as providing the proper intervention to the right population at the right time. Although genomics is one driver of precision health care, other factors may be as necessary (e.g., health information technology). Public health experts are concerned about the disproportionate emphasis on genes, drugs, and disease while neglecting strategies to address social determinants of health. The prime concern for public health is promoting health, preventing disease, and reducing health disparities by focusing on modifiable morbidity and mortality [70].

A case study: Racial, ethnic, and socioeconomic disparities in confirmed COVID-19 cases and deaths in the United States: a county level analysis as of November 2020 [71]

Objective

The objective of this study was to investigate potential county-level disparities among racial/ethnic and socioeconomic groups in confirmed COVID-19 cases and deaths in the United States in 100,000 population.

Design

Secondary data analysis using county-level data for 3142 US counties was conducted in 2020. Hierarchical linear regression and concentration curve analyses were performed. The combined association of COVID-19 cases and deaths was examined separately by the county population's socioeconomic characteristics. Data from the American Community Survey (ACS) 5-year estimates (2014–2018), Area Health Resources File (AHRF) 2018–2019, Kaiser Health News 2020, and 2020 COVID-19 data from Johns Hopkins University were used in this study.

Results

After adjusting for covariates, US counties with a higher proportion of the Black population and a higher proportion of adults with less than a high school diploma had disproportionately higher COVID-19 cases and deaths ($\beta > 0$, $p < 0.05$ for all relations). A higher proportion of the Hispanic population was associated with higher confirmed cases ($\beta = 0.68$, 95% CI = 0.48–0.87). The majority observed disparities in COVID-19 deaths persisted even after controlling for all-cause deaths in 2019 and COVID-19 cases per 100,000 county population. This can potentially aggravate the existing health disparities among these population groups (Fig. 12.6) [71]

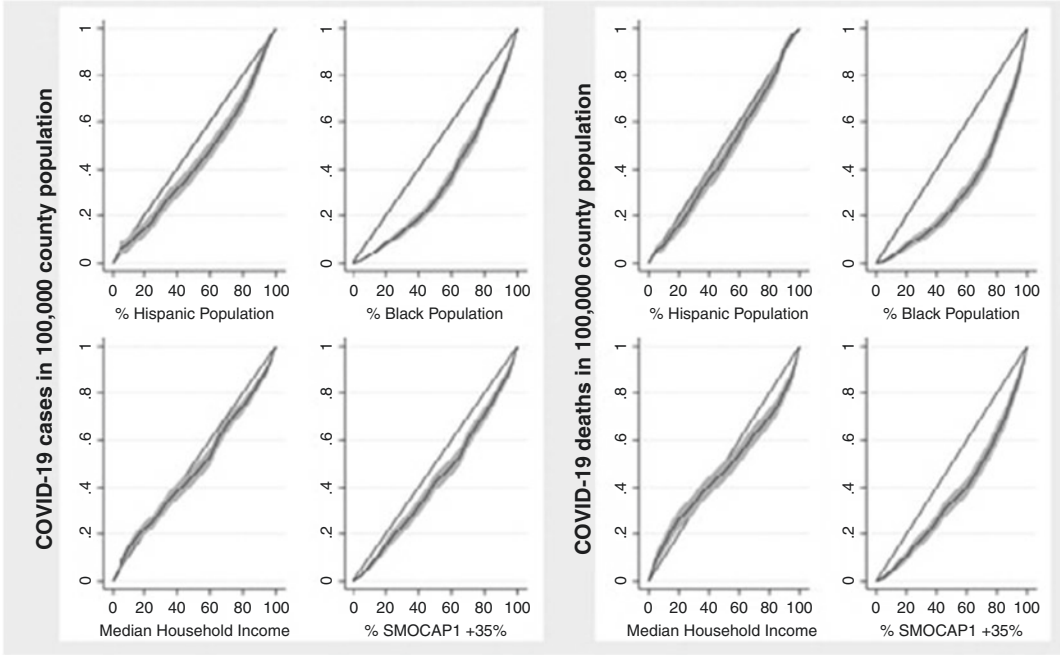

Fig. 12.6 Concentration Curves examining county-level disparities in confirmed COVID-19 cases and deaths in US counties as of November 2020, N = 3142 counties. Note. All variables in x and y axes are ranked cumulative proportions. The diagonal line is the line of equity. The grey area around the concentration curve represents 95% confidence interval (CI). SMOCAPI is selected monthly owner costs as a percentage of household income for housing units

Conclusions

Identification of disproportionately impacted population groups can pave the way towards narrowing the disparity gaps and guide policymakers and stakeholders in designing and implementing population group-specific interventions to mitigate the negative consequences of the COVID-19 pandemic

12.2 Conclusions and Outlook

Data has become essential for decision-making in public health at the local, national, and global levels. Public health decision-making is critically dependent on the timely availably of useful data that needs to be systematically collected, analysed, and disseminated. This chapter has introduced the various sources of data in public health and how different sources of public health data are used to guide public health activities, policies, advocacies and research and decision making.

12.3 Links to Online Materials (Table 12.3)

Questions and Answers

1. The following are types of active surveillance except
   a. National household surveys gathering information on the social status and health status of people in a particular country
   b. Notification of diseases by health workers in health facilities is required by law.
   c. Observing groups of patients over some time for a particular outcome of interest among groups of exposed and unexposed groups

Table 12.3 Links to major sources of administrative data and online materials

International data	
United Nations Statistics Division	https://unstats.un.org/home/
World Bank Group Data and Statistics	http://www.worldbank.com/data/
World Health Organization-Statistical Information System (WHOSIS)	http://www3.who.int/whosis/menu.cfm
Pan American Health Organization (PAHO)	http://www.paho.org/
Organisation for Economic Co-operation and Development (OECD)	http://www.oecd.org/home/
United States federal statistics	
National Library of Medicine, MedlinePlus—Health Statistics	https://medlineplus.gov/healthstatistics.html
Centers for Disease Control and Prevention	https://www.cdc.gov/nchs/nvss/index.htm https://wonder.cdc.gov/ https://www.cdc.gov/DataStatistics/
Agency for Healthcare Research and Quality	https://www.ahrq.gov/data/hcup/hcupnet.htm https://www.ahrq.gov/data/hivnet.htm
Centers for Medicare and Medicaid Services (CMS)	http://cms.hhs.gov/researchers/statsdata.asp
Substance Abuse and Mental Health Services Administration (SAMHSA)	http://www.samhsa.gov/oas/SAMHDA.htm
Environmental Protection Agency (EPA)	https://www.epa.gov/
Health Resources and Services Administration (HRSA)	https://www.hrsa.gov/data.htm
Hospital and health care records	
National Hospital Discharge and Ambulatory Surgery Data	https://www.cdc.gov/nchs/about/index.htm
Medical Expenditure Panel Survey (MEPS)	https://www.ahrq.gov/data/meps.html
Mortality and Morbidity Data	https://www.cdc.gov/epo/dphsi/nndsshis.htm
Medicare: US Renal Dialysis System	http://www.usrds.org
Medicaid through HCFA	http://www.resdac.umn.edu
Veterans Affairs	http://www.virec.research.med.va.gov
Medicare Current Beneficiary Survey	http://www.hcfa.gov/mcbs
National Hospital Discharge Survey	http://www.cdc.gov/nchs
Other online materials	
Supercourse: Epidemiology, the internet and global health	https://www.pitt.edu/~super1/

   d. Surveillance of Acute Flaccid Paralysis in Nigeria
   e. All the options listed above are true
2. The following are methods used to evaluate public health data and scientific evidence except
   a. Use of standard criteria by experts
   b. By combining the results of multiple scientific studies that are examining the same question
   c. By conducting an intervention study
   d. Economic evaluation
   e. Public health surveillance
3. Which of the following statement is true about data needs and data collection tools?
   a. Knowledge, Attitude and Practices (KAP) studies are useful at the community-level
   b. Modelling and estimates are derived from districts
   c. It is appropriate to collect facility records, birth registers, outpatient, and surveillance data from health facilities
   d. Provincial governments are responsible for the collection of vital registration, census, and national household surveys.
   e. Service availability mapping, administrative and surveillance data are collected at the district level
4. Which of the following is not true:
   a. Vital statistics include birth, migration, marriage, divorce, and death
   b. Administrative data can be obtained from the Centers for Disease Control and Prevention in the United States of America.

c. Electronic data collection for census can make the process of data collection easier and cheaper
d. Public health and healthcare research, planning, and policymaking are the primary purposes of surveys.
e. Community-based research focuses on only social inequalities by actively involving the community members

5. In the public health approach that systematically links data collection with decision systems and appropriate public health action, the steps are chronologically listed as:
   a. Surveillance—intervention evaluation—risk factor identification—implementation
   b. Surveillance—risk factor identification—intervention evaluation—implementation
   c. What is the problem?—what is the cause?—what works?—how do you do it?
   d. What is the cause?—what is the problem?—how do you do it?—what works?
   e. What is the problem?—what is the cause?—how do you do it?—what works?
6. Which of the following is not true about big data application in healthcare?
   a. It can be applied to monitoring events of public health importance
   b. Mostly generated in real-time
   c. It can be used to reduce errors in medical care
   d. To understand rare diseases
   e. It is big data because it contains only video and images of patients' condition

Appendix: Answers and Explanations to Review Questions

Question 1: The correct answer is b.

The notification of diseases by health workers in health facilities that are required by law is a form of passive surveillance. These diseases are called notifiable diseases. However, surveillance that employs household surveys or the use of cohort study designs by observing different groups based on exposure status for over some time are forms of active surveillance that require more resources.

Question2: The correct answer is c

Conducting an intervention study is not one of the tools used to evaluate public health data. However, the intervention study's impact can be evaluated by using systematic reviews, economic evaluation, public health surveillance and use of expert panels and consensus conferences.

Question 3: The correct answer is b

See Fig. 12.1

Question 4: The correct answer is e

Community-based research in public health does not only focus on only social inequalities. It also focuses on inequalities in structural and physical environmental inequalities by involving community members, representatives of relevant organizations and researchers in different aspects of the research process

Question 5: The correct answer is b

See Fig. 12.3

Question 6: The correct answer is e

Big data is not big because it contains only videos and audios. It is big data because of the share volume of data.

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Patient Safety and Health Information Technology

13

Yushi Yang, Samantha Pitts, Allen Chen, Nicole Mollenkopf, Taylor Woodroof, and Bridgette Thomas

Abstract

Health information technology (IT) has played an increasing role in patient safety. In this chapter, we first introduced the organizational structure of patient safety and health IT safety improvement at the Johns Hopkins Health System. And then we described a case study: the CancelRx implementation, as an example of the application of the Johns Hopkins health IT safety structure and interdisciplinary health IT safety improvement initiatives. CancelRx is an electronic tool that allows prescribers to send electronic cancellation messages when medications are discontinued or changed. The case study included a proactive risk assessment, the pilot implementation and measures, and the expansion across the health system with a human factors analysis. We demonstrated and emphasized the value of continuous evaluation by an interdisciplinary team to ensure the safe health IT implementations.

Keywords

Patient safety · Prescriptions · Health information technology · Medication reconciliation · Human factors · CancelRx

Learning objectives:

- Understand the health IT safety improvement process and patient safety structure in driving safe health IT implementation
- Understand how the proactive risk assessment and the human factors methods can be utilized in the health IT implementations to prevent unintended consequences

13.1 Introduction

13.1.1 Patient Safety and Health Information Technology

Health information technology (IT) supports clinical care delivery, healthcare quality, and safety [1]. The Health IT Safety Measurement Framework identifies three domains for safe health IT: (a) safe health IT implementation, (b) safe use of health IT, and (c) the use of health IT to improve patient

Y. Yang (✉)
Armstrong Institute for Patient Safety and Quality, The Johns Hopkins Health System, Baltimore, MD, USA
e-mail: yyang162@jhmi.edu

S. Pitts · A. Chen · N. Mollenkopf
The Johns Hopkins University School of Medicine, Baltimore, MD, USA
e-mail: spitts4@jhmi.edu; chenal@jhmi.edu; nmollen1@jhu.edu

T. Woodroof · B. Thomas
Johns Hopkins Home Care Group, Baltimore, MD, USA
e-mail: twoodro2@jhmi.edu; bthoma28@jhmi.edu

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safety [2]. The convergent goals create a need for surveillance that is separate yet intimately linked to patient care. To achieve the goals, we must develop and deploy resources and structures within an organization focused on high reliability [3], systematic data collection [2] and continuous quality improvement including human factors and systems evaluations.

The proliferation of health IT and healthcare data systems have given rise to awareness and concerns [4] that health IT itself may pose unintended safety issues [5] and consequences, as data systems interact with complex care and information processes on multiple levels. To this end, the Office of the National Coordinator for Health Information Technology (ONC) has developed Safe Assurance Factors for EHR Resilience (SAFER) [6] guides as a resource for improving health IT implementation. Recommendations include user-centered design, involvement of multiple stakeholders in implementation, identification of ideal workflows, incremental testing within the context of implementation to confirm anticipated performance, identification of unintended consequences, and post-implementation monitoring to ensure the system performs as expected.

The widespread adoption of networked electronic health records (EHRs) has created a need for interoperability to support communication between hospitals, ambulatory settings, pharmacy, and home care services. In this chapter, we described a case study: a continuous evaluation of an electronic tool that sends the medication cancelations to the pharmacies. The case study is an example of how we apply the Johns Hopkins health IT safety structure and interdisciplinary health IT safety improvement initiatives to achieve the multidimensional patient safety goals.

13.1.2 Patient Safety at Johns Hopkins

The Johns Hopkins Health System (JHHS) is an academic health system based in Baltimore, MD, USA with over 40 clinical locations, including 6 academic and community hospitals, a network of primary care practices, 12 outpatient pharmacies, and a home health agency, all linked to the Johns Hopkins University School of Medicine [7]. The principal hospital of the system is the Johns Hopkins Hospital (JHH) which provides a comprehensive range of state-of-the-art tertiary and quaternary care, in addition to ambulatory primary and specialty care.

At JHHS, the Armstrong Institute (AI) aims to eliminate preventable harm to patients and to achieve the best patient outcomes at the lowest cost possible, and to share its knowledge with the world. AI oversees, coordinates, and supports patient safety and quality efforts across the Johns Hopkins integrated healthcare system [8].

The Patient Safety Office is the operational arm of quality and safety work at AI. It provides an infrastructure to ensure representation from each clinical department for regular discussions on risks, priorities, challenges, and latent errors within the system [9]. The infrastructure provides centralized resources, such as educational and training materials, risk surveillance systems, event reporting, human factors, and safety and data analytics that can be deployed to various departments and service areas for the patient safety efforts [10].

13.1.3 Health IT Safety at Hopkins

The Health IT Safety Work Group is a component of the Patient Safety office with dual purposes of (1) monitoring, escalating, and mitigating patient safety risks due to use of health IT; and (2) improving patient safety through redesign of health IT workflows. Through Health IT Safety Workgroup and Action Team (SWAT) meetings, a multidisciplinary group of medical and nursing informatics officers, pharmacy informaticists, patient and medication safety officers, human factors engineers, physician champions, and health IT application managers, review risky health IT-related events and recommend investigation and risk mitigation strategies. The team also

conducts proactive risk assessment and analysis of new features and functionalities of health IT prior to implementation to ensure safe implementation and to prevent unintended consequences.

The Health IT safety work group takes a socio-technical systems perspective and utilize a systems-based approach, the Systems Engineering Initiative for Patient Safety (SEIPS) model [11, 12]. The group evaluates the systems with health IT and focuses on identifying the system barriers and "misfits" among work system components (e.g., in the interactions of people, technology, environment, task and organization) [13]. The group utilizes design thinking to develop system recommendations to address the barriers and "misfit". In this process, human factors and work system analysis are integrated, as well as the quality measures. The group also provides feedback to the health IT vendors (e.g., to request new functionalities).

13.2 Case Study: CancelRx

Management of ambulatory medications is a complex process that involves multiple stakeholders supported by interoperable electronic systems (e.g., EHRs, e-Prescribing platform, pharmacy management systems). The Johns Hopkins community pharmacies use pharmacy management software that is separate from the EHRs used by prescribers. Similar to other prescription communication with other community pharmacies, prescriptions are sent electronically from the Johns Hopkins EHR through a health information network (at Johns Hopkins, Surescripts) to pharmacy management software.

To reduce medication dispensing errors in pharmacies, e.g., the continuation of prescriptions that a prescriber has intended to discontinue, the National Council for Prescription Drug Programs (NCPDP) has recommended electronic notification of prescription cancellations within its SCRIPT standard [14]. CancelRx is a functionality that allows the electronic cancellation messages, or "e-cancellations" to be sent from EHRs to pharmacies when medications are discontinued or changed, similar to how "e-prescriptions" are sent. Prior to the advent of this functionality, EHRs did not notify pharmacies when a prescription had been discontinued or changed, relying on prescribers to communicate that information to pharmacies. This was a safety risk creating opportunities for dispensing errors and potentially preventable adverse drug events (ADEs); research has estimated that 1.5–5% of prescriptions are filled after being discontinued by a clinician [15, 16]. The CancelRx functionality has the potential to address this challenge, but the unintended consequences of implementation were unknown.

13.2.1 Phase 1: Proactive Risk Assessment

A proactive risk assessment [17] within ambulatory care was undertaken through direct observations, semi-structured interviews and focus groups with pharmacists and physicians prior to the pilot implementation. The aims were to identify the perceived risks when the CancelRx is introduced.

We identified the perceived system failure modes with the CancelRx, created risk mitigation strategies, and articulated recommendations for health IT vendors (in Table 13.1)

The analysis identified safety risks created by the limitations in e-cancellation functionality. For example, the limited visibility of the transaction status might contribute to e-cancellations not being sent without the prescriber's awareness. We provided the suggestions to the health IT vendors to increase visibility of cancellation status.

This analysis also identified potential system barriers when CancelRx is implemented. For example, prescribers may not be aware of the functionality and send erroneous cancelations to the pharmacy. We developed strategies to provide training to prescribers, increasing the awareness of e-cancellation and its intended use. We also developed educational tip sheets to provide more context on the different e-cancellation scenarios.

Table 13.1 CancelRx failure modes, mitigation strategies, and recommendations for development [adapted from 18]

Failure mode	Mitigation strategies for pilot implementation	Recommendations for development
Prescriber does not recognize when an e-cancellation is not sent	Train prescribers in functionality of CancelRx	Increase visibility of cancellation status (e.g., feedback to prescribers if e-cancelation is not sent)
Prescriber does not recognize that an In Basket message indicates an e-cancellation failure	Route In Basket messages to trained RN Train prescribers to locate status in order report	Increase visibility of cancellation status (e.g., increased visibility of the feedback to prescribers if e-cancelation is not sent) Reduce in basket messages that are not actionable
EHR does not notify prescriber when an e-cancellation is not addressed by a pharmacy	Monitor frequency	Notify prescriber when an e-cancellation is not addressed by a pharmacy
Pharmacist cancels active medication when e-cancellation is sent with a renewal request	Suppress cancellation with prescription renewals	Transmit cancellation reason
User sends e-cancellation in error during medication reconciliation	Train prescribers in functionality of CancelRx	Error prevention functions Control by discontinuing user
Pharmacist matches e-cancellation to wrong prescription	Monitor frequency	Reduce manual matches Provide decision support for manual matches
Prescriber cannot specify if all prior prescriptions of medication should be discontinued—one to one match only	Assign responsibility for managing e-cancellation messages to pharmacists	Allow prescriber to specify if all prior prescriptions of medication should be discontinued Transmit cancellation reason (e.g. adverse drug event) Consider transmission to multiple pharmacies

13.2.2 Phase 2: Pilot Implementation

Following the proactive risk assessment, CancelRx was implemented in an ambulatory practice and pharmacy in a single location at JHHS. Pilot prescribers and pharmacy staff received training of the use of CancelRx. To evaluate the impact of CancelRx implementation, we matched data from the Johns Hopkins EHR and pharmacy management software to evaluate the proportion of e-prescribed medications that were sold following discontinuation in the EHR.

Following the CancelRx implementation, we found no e-prescribed medications were sold after discontinuation in the EHR. However, medical record review of a sample of discontinued prescriptions identified that some were likely discontinued in error. These unintended prescription cancellations occurred with changes in the directions on a prescription; with removal of the wrong duplicate prescription, leaving an expired prescription on the patient's medication list; and as a result of errors in medication reconciliation.

With the pilot, we confirmed the potential safety benefits of implementing the CancelRx. We also identified system improvement opportunities to reduce the risks, including the strategies to prevent the unintended prescription discontinuations. For example, if the prescriber specifies that the cancelation is due to a wrong duplicate entry, the e-cancelation will not be sent to the pharmacy. Other changes require the EHR vendor, demonstrating the importance of collaborations between EHR vendors and health systems.

13.2.3 Phase 3: Expansion Across the Health System and a Human Factors Analysis

When we started to expand the CancelRx functionality to medications e-prescibed by Johns Hopkins prescribers at hospital discharge set-

tings, a human factors evaluation was conducted. The study was to understand the discharge prescriber's information needs, communication and workflow barriers when they cancel medications at discharge. The findings were used for further identification of the design requirements of the technology.

Hospital discharge is an important occasion when clinicians review and reconcile the hospitalized patient's home medications. Prescribers may change the medications by modifying the specifics of a medication, such as the dose and frequency, and may discontinue some medications, indicating the patient should no longer take them.

The human factors specialist conducted seven semi-structured interviews with inpatient prescribers, including attending physicians, residents and nurse practitioners, in two medicine units. Two physicians and one human factors engineer reviewed the interview data to identify initial themes.

During the interviews, prescribers described a lack of network that connects all the relevant stakeholders, including the primary care providers (PCPs), specialists, home care nurses, as the major barrier. They described when they communicate important medication cancelations information to other stakeholders, such as phone calls and emails, or even relying on patients (their memory, or After Visit Summary (AVS), some with highlighted notes on the AVS) to relay the information to other clinicians. They also described some information is missing in the process of communicating prescription cancelations, such as the discontinuation reasons, the notification urgency, and the duration of a change.

These findings informed the following CancelRx design requirements (Table 13.2).

As one of the significant outcomes of our studies, our recommendations with regards to the need for discontinuation reasons to be transmitted to the pharmacy to improve patient safety was communicated to the National Council for Prescription Drug Programs (NCPDP) CancelRx Task Group and will be implemented in the next SCRIPT Standard.

Table 13.2 Suggested CancelRx design requirements [adapted from 19]

Themes	Detailed descriptions
Expanded communication	Electronic communication of medication changes should • include multiple stakeholders, including the original prescriber, outpatient pharmacists, additional members of the patient's care team (e.g., primary care provider, specialists, home care nurses), and the patients, with the most relevant information sent to each stakeholder in an efficient manner
Specification of discontinuation reasons	Discontinued reasons should • be selected by prescribers during a medication change • be seen by other providers and pharmacists Some reasons, such as anaphylaxis, should result in cancellations of all related prescriptions pending pharmacist's review. The reasons should be tied to the prescriptions to make it easy to track the changes
Indication of urgency of notification	Prescribers should be able to indicate the urgency of a change notification to ensure that critical changes can be identified quickly. The urgency should be tied to the prescription
Specification of the duration of a change	Prescribers should be able to specify duration for a medication change: a temporary pause vs. a discontinuation. It should send a reminder to the right stakeholders for medication resumption

13.2.4 Future Steps

Researchers are involved in the patient safety operational studies for quality improvement purposes, and results can be used as a baseline to inform further research opportunities. As an example, we conducted the operational studies that identified the design requirements of CancelRx and the system improvement opportunities. We also informed follow-up research opportunities to validate the technology enhancement and refine the recommendations, as well as to develop in-depth design guidelines and sociotechnical systems design interventions that facilitate effective

communications during medication transitions. Rigorous and systematic qualitative research studies are expected to be conducted to understand the impact of new health IT implementations, such as CancelRx, and their impact on clinical workflows, medication safety risks, and patient outcomes. Research should include multiple perspectives, such as PCPs, patients, pharmacists and other prescribers. An understanding of information needs of each user type may help determine an optimized information flow (e.g., to send the right information to the right users at the right time) supported by an improved, safer and more efficient socio-technical work system.

13.3 Conclusion

In this chapter, we introduced the health IT safety improvement process and patient safety structure at the Armstrong Institute at the Johns Hopkins. We described the CancelRx implementations process, the approach to proactively identify system barriers, and the recommendations to address the barriers. We also emphasized the need of a structure and interdisciplinary health IT safety improvement teams to ensure the safe implementation of health IT.

Question and Answer

1. In assessing a health IT work system, the Systems Engineering Initiative for Patient Safety (SEIPS) model's socio-technical perspective approach evaluates barriers and "misfits" in the interactions among what system components?
   a. People, Technology, Environment, Task and Organization. In this process, human factors and work system analysis are integrated, as well as the quality measures.

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Digital Health in Chronic Care and Self-Management

14

Malinda Peeples and Bhagyashree (Disha) Maity

Abstract

Chronic disease management presents great challenges and opportunities to improve individual, population, and global health. Developments in digital health technology, data analytic tools and the ubiquitous adoption of smartphones, have made it possible for the first time to provide real-time clinical and behavioral education and support to people with chronic disease. This contextual, real-time support improves health outcomes for individuals through a scalable, population approach.

The creation of digital health tools to support a person-centered chronic disease care requires understanding the disease, leveraging information tools to match individual needs and self-management goals, as well as navigating industry, regulatory and policy constraints. To gain understanding of this process, the development and implementation of a digital health solution for diabetes is discussed.

Keywords

Wearables · Sensors · Telehealth · Digital health · Chronic condition · Diabetes

Learning Objectives

- Define digital health and discuss the significance as an emergent component of healthcare.
- Define and describe digital therapy (digital therapeutics, Software as a Medical Device SaMD)
- State clinical and information workflow challenges that face implementation of digital health
- Cite and describe the application of Digital Health in diabetes care "Leveraging Technology to Transform Diabetes Self-Care"

14.1 Introduction

Chronic disease presents a significant financial and societal burden in the United States and globally. It is estimated that 90% of the nation's 3.8 trillion in annual healthcare expenditures are spent on individuals with chronic and men-

M. Peeples (✉)
Clinical Services and Research, Welldoc, Inc, Columbia, MD, USA

Department of Medicine, Division of General Internal Medicine, Johns Hopkins Medicine, Baltimore, MD, USA
e-mail: mpeeples@welldoc.com

B. (Disha) Maity
Clinical Informatics Lead, San Francisco, CA, USA

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tal health conditions. More than a third of Americans die annually of stroke and/or cardiac disease, with obesity, cancer, arthritis, and other chronic conditions creating a massive burden on the US healthcare system. Over 10% of the population is diagnosed with diabetes (with an additional 27% being diagnosed as prediabetic) [1]. In the early 2000s, the Chronic Care Model (CCM) evolved as a systems-based framework for how we treat chronic disease in a health system that was designed to manage acute—not chronic illness. The CCM identified six key elements for connecting an individual's provider and care teams in a partnership to improve health: the community resources, the health system, self-management support, the health delivery system design, decision support and clinical information systems [2]. It is through a systematic application of the elements to the individual-provider and care team interaction that health outcomes are achieved.

Chronic disease management requires scalable interventions that connect individual, provider, care team, and services (specialists, testing, pharmacy, coordination) over time. As a holistic model, the CCM moves away from physician-centric, acute, hospital-based interventions to individual-centric, self-management and community support by using technology to guide best practices into care workflow. Additionally, care delivery models are shifting from a fee-for-service, transaction-based, one-to-one system to a value-based, outcomes driven, population-focused design.

Concurrently, technology evolved to support individuals as healthcare consumers. The proliferation of smartphones in the twenty-first century revolutionized healthcare by empowering millions (who could not otherwise afford computers or laptops) to access information. The development of body sensors, wearable technologies, and the Internet of Things (IoT) provided previously unavailable opportunities for daily self-management of health. Real-time capture of an individual's data and delivery of information to individuals through mobile phones presented opportunities for providing evidence-based, personalized interventions. According to a McKinsey & Company's international survey, more than 75% of all individuals expect to use digital services in the future [3]. These technologies empower better monitoring of disease progression and health tracking, timely personalized care, and diagnosis of individuals based on data. As more and more digital health solutions enter the market, physicians and individuals alike are adopting these technologies in practice.

14.2 Types of Digital Health Technologies

A satisfactory definition of "digital health" is elusive. The Healthcare Information and Management Systems Society (HIMSS), in order to provide clarity to the industry, reviewed current definitions of digital health and emphasized what digital health *does* to make it more outcome driven. HIMSS's current definition is as follows:

> Digital health connects and empowers people and populations to manage health and wellness, augmented by accessible and supportive provider teams working within flexible, integrated, interoperable, and digitally-enabled care environments that strategically leverage digital tools, technologies and services to transform care delivery [4].

This definition highlights two important concepts: *What* does digital health *achieve* (outcomes), and *how* does it achieve it (process)? Digital health empowers people to self-manage their health and wellness and connects consumers, clinicians, and consumers to help optimize it.

Categories of digital health technologies and their delivery solutions are as described in Table 14.1.

Table 14.1 Categories of digital health solutions

Digital health category	Technologies	Delivery solutions
Wearables Small electronic devices that can collect physiological data about an individual for prolonged periods of time without hindering daily activities or obstructing mobility. They interact with computers and with each other to collect, store, and analyze data	*Activity trackers and smartwatches*	Devices that have the capability to capture and track metrics such as steps walked, distance walked/ran, calories burned. Some advanced devices can also detect biometrics such as heart rate, respiratory rate, heart rate variability, sleep, blood pressure, oxygen levels, and galvanic skin responses like sweat to detect emotional changes
	Smart fabrics	Textiles that sense and respond to changes in their environment. Electronics such as batteries, light, chips, or sensors can be woven into clothes that are worn on an everyday basis, thus allowing the user's data to be continuously captured in their natural environment [5]
	Epidermal electronic systems (smart tattoos)	Circuits, conductors, and adhesives that can be placed on the skin to gather information such as temperature, heartbeats, brain activity, and muscle contractions [6]
	Smart Implants	Implantable devices that provide therapeutic benefits and have diagnostic capabilities. It offers the benefit of providing information about an environment we don't otherwise have access to--the internal human body
	Body area networks (BAN)	Systems composed of a network of wearable devices that can be implanted in the body, placed on the body in fixed positions, or carried by the person in their clothes, pockets, by hand, or in a bag. These sensors communicate wirelessly to send that sensor data elsewhere [7]
Telehealth		Broad, catch-all term that encompasses technologies and methodologies enabling remote care, health education, and health information services. Synchronous telehealth requires the presence of both parties at the same time, and a communication link that allows a real time interaction to take place, such as a video conferencing platform [8]. Asynchronous/ (store-and-forward) telehealth involves acquiring medical data (like medical images, voice recordings, etc.) and then transmitting this data to a doctor or medical specialist at a convenient time for assessment offline. It does not require both parties to be available at the same time [8]
	Mobile health	A set of apps, devices, or connections on a mobile phone that allow the user to achieve improved health goals
Software as a Medical Device (SaMD)		Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device [9]
	Digital therapeutics	Deliver medical interventions directly to individuals using evidence-based, clinically evaluated software to treat, manage, and prevent diseases and disorders [10]

14.3 Diving Deep: Software as a Medical Device and Digital Therapeutics

Two digital health technologies that have a great potential to transform care delivery and individual engagement will be discussed in further detail: Software as a Medical Device (SaMD) and Digital Therapeutics (DTx).

14.3.1 Software as a Medical Device

Software as a Medical Device (SaMD) accomplishes one or more medical functions without the need for actual hardware--the software itself *is* the device. While software may be embedded *in* hardware, the software must *perform* the medical function to be classified as a SaMD. SaMD can work on general (non-medical) computing platforms, be used in conjunction with other medical devices, and can interface with other medical devices or other general hardware and software.

SaMD can encompass software that is intended to diagnose, treat, prevent, mitigate, or cure disease. SaMD can:

- perform screening and diagnosis of disease
- conduct monitoring and alerting of disease
- assist with chronic condition and disease management
- suggest treatments

The FDA has specific guidelines that standardize labeling of what is considered a SaMD [11]. In general, creators of SaMD products are required to gather specific types of information pertaining to a product, analyze that data, and deliver it for evaluation with the software as evidence that the software in question has been designed for safety and effectiveness [12]. As SaMD technology becomes more ubiquitous, cheaper, accessible, and more sophisticated, it has potential to play an important role in chronic disease management, personalized medicine, medical research, and health care delivery.

14.3.2 Digital Therapeutics: A New Category of Medicine

Digital Therapeutics (DTx) is a category under Software as a Medical Device (SaMD). The Digital Therapeutics Alliance defines it as:

> Digital therapeutics deliver therapeutic interventions directly to patients using scientifically developed, evidence-based, and clinically evaluated software to treat, manage, and prevent diseases and disorders. DTx products undergo rigorous patient-centered core principles, industry code of ethics, and product development best practices. These products are used independently, alongside medications, or alongside clinician-delivered therapy. They are different from merely lifestyle, wellness, adherence, diagnostic, and telehealth products, and are distinct from the over 350,000 digital health apps available online [13].

To be labeled as a digital therapeutic, the software must fulfill the following principles:

Every digital therapeutic must fulfill the above (Table 14.2) to satisfy regulatory compliance and be deemed appropriate for clinical use. They are held to the same standards of evidence and regulatory oversight as traditional medical treatments.

Table 14.2 Digital therapeutics principles

All products claiming to be a digital therapeutic must adhere to these foundational principles:
Prevent, manage, or treat a medical disorder or disease
Produce a medical intervention that is driven by software
Incorporate design, manufacture, and quality best practices
Engage end users in product development and usability processes
Incorporate user privacy and security protections
Apply product deployment, management, and maintenance best practices
Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals
Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
Make claims appropriate to clinical evaluation and regulatory status
Collect, analyze, and apply real world evidence and/or product performance data

Adapted from: https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf [14]

Within these parameters, digital therapeutics have evolved to assist in the treatment, support, prevention, and management of a wide array of conditions. The software must be designed with the goal of either addressing a medical condition, managing, or preventing a medical disorder or disease, optimizing medication (an individual's medication or class of pharmaceuticals), or treating a medical disease or disorder. [15] Individuals usually receive access to DTx products through a prescription, referral from a clinician, or delivery of an activation code via an electronic health record, employer, or third-party payor [13].

In the past decade, digital therapeutics have been developed for chronic diseases such as: asthma, ADHD, obesity, sleep disorders, diabetes, hypertension, behavioral health issues, stroke, chronic pain, substance use, smoking cessation, among others.

Most DTx interventions are delivered through Android and iOS smartphones/tablets. Since the majority (81%) of Americans now own a smartphone, digital therapeutics have the potential to promote more equitable care. They can aid individuals who experience limited access to providers and care teams, lack transportation to go to a hospital, who are of lower socioeconomic status, or those who face language barriers in a traditional healthcare setting. The impact DTx can have on underserved populations, regardless of the individual's age, language, culture, income, etc. is summarized in Table 14.3.

Table 14.3 DTx and overcoming barriers

Addressing challenges in global healthcare DTx can address care gaps by:
Delivering therapies using smartphones, tablets, and similar technologies
Increasing individual access to clinically safe and effective therapies
Lowering stigma associated with the delivery of certain traditional therapies by offering at-home convenience and privacy
Extending clinicians' ability to care for individuals
Providing therapies in various languages
Providing meaningful results and insights on personalized goals and outcomes to individuals and their clinicians

Adapted from: https://dtxalliance.org/understanding-dtx/ [10]

14.3.3 Navigating Infrastructures for Digital Health Development

Digital health tools are subject to regulatory and practical constraints. During design/implementation, deployment and operation, developers must consider:

- *Privacy and Security*—Digital health tools must conform to Health Information and Accountability Act (HIPAA) protections to prevent protected health information (PHI) from being disclosed without consent. Telehealth and digital health tools create opportunities for unintentional PHI loss due to human and/or technical errors, resulting in violations and other liability risks. Various certifications such as HITrust are available to assure customers that the product(s) have the appropriate risk management and compliance to ensure privacy and security of individual information [16].
- *Reimbursement*—In 2018, the Center for Medicare & Medicaid Services (CMS) began payment for Remote Patient Monitoring (RPM). In 2019, the Medicare Physician Fee Schedule introduced three new RPM reimbursement codes and physician codes for "virtual check-ins" and Internet consultations [17]. In 2020, CMS authorized telehealth reimbursement for the COVID-19 medical emergency. It is currently unclear what reimbursements will be introduced post-pandemic [18].
- *Data Governance*—Comprehensive rules, procedures and agreements must be established, for all stakeholders, for access, ownership, sharing, use and reporting, with respect to health data collected and managed by digital health companies.
- *Clinical Validity*—Digital health tools and methods must be developed and evaluated with clinical rigor to ensure the quality of the data captured, the reliability of algorithms and the results produced all align with user safety.
- *Interoperability*—Digital health solutions must connect, send, and receive data from other solutions to maximize the benefits and reduce the data silos that currently exist [19].

The industry requires the consistent adoption of international specifications and standards as promoted by standards initiatives like DICOM (Digital Imaging and Communications in Medicine), HL7 (Health Level 7), and Logical Observation Identifiers Names and Codes (LOINC). Through application programming interfaces (APIs), mobile applications are quite flexible for integration into existing technology platforms and have the potential for addressing workflow integration challenges.

- *Alignment of all Stakeholders*—There is a need to increase collaboration between the healthcare and technology sectors (where digital health products are created). Stakeholders in different teams can have competing interests and priorities, be siloed, or lack understanding and awareness of the other. In addition, cultural barriers that exist between corporate and clinical sectors can impede development of practical products. Using frameworks such as the "Waterfall" model to assist in the clarification of product objectives and development of design features can address some of these challenges [20].
- *Regulations*—The regulatory landscape for digital technologies includes the Food and Drug Administration (FDA) review of specific mobile medical applications. State and federal legislations regarding clinician scope of practice, delegation of tasks, prescription or reimbursement of mobile applications, teleworking of clinicians, and remuneration of telehealth activities are also key considerations [21].

These barriers are significant, but progress is being made. In a later section of the chapter, you can see how one company is addressing some of these issues through the case study of a digital health solution for diabetes.

14.4 The Role of Digital Health in Chronic Disease

Leveraging digital health into individual self-management of chronic disease requires consideration of:

- Goals of person-centered chronic disease management
- Electronic data workflow to meet the goals of effective self-management and treatment plan optimization

14.4.1 Goals of Chronic Disease Management

Common goals in achieving optimal health and cost outcomes for chronic disease include:

14.4.1.1 Empowering Individual Self-Management

Digital health tools (e.g. mobile phones, wearables, etc) provide a technology-enabled way to provide self-management support anytime, anywhere. This real-time, longitudinal tracking provides "new" data that allows for the development of micro clinical and behavioral interventions that can be contextualized and customized not only for the individual's preferences but also specific to the treatment plan and delivered "just in time". The mobile phone screen real estate limits the presentation of the number of concepts per screen, encouraging the use of simple, plain language. This timely, individualized, data-driven "digital coaching" supports self-management engagement which leads to contextual learning, problem solving, and goal setting at a person-centered pace.

14.4.1.2 Optimizing (Evidence-Based) Treatment

Typically, people with chronic disease may see their provider and care teams quarterly for a "check-in" visit at which time, much of their discussion about the status of their condition "in-between visits" is primarily anecdotal with some manual or electronic records. The engagement with and adherence to treatment recommendations and lifestyle plans has mostly been data that was unavailable to health care teams—leaving the provider and care teams to depend primarily on lab data, in-office measurements, and

individual verbal reports. The digital health revolution has provided new tools and data to accelerate the visit interaction in a way that puts the person with the chronic disease at the center and supports providers and care teams with new data—patient generated health data (PGHD). Previously, even when users were monitoring their blood glucose (BG) or blood pressure (BP), providers and care teams often only had manual records or printed reports of many data points with no contextualization of the data—making it a challenge to determine cause and effect for overall management. Now, digital health tools can present this longitudinal data in a format that allows providers and care teams to visualize trends over time and analyze whether particular medication or interventional changes were effective [22].

14.4.1.3 Improving Outcomes

Individuals with chronic disease often struggle to understand how to integrate lifestyle changes and medication management in the midst of their daily lives. Education and ongoing support are essential to prepare and support people to adopt, change, or maintain these healthy self-management behaviors. Providers and care teams make decisions about medications, examinations, and other treatment activities based on evidence-based guidelines, expert opinion, and via discussions with their patients. As more patient data is available for the provider and care teams, the more informed the shared decision making can become. When both the self-management and the provider and care team treatment plans are optimized, the positive health, quality of life, and cost outcomes also improve. This is depicted in the following equation:

Effective self-management + Optimized treatment plans = Improved outcomes

14.4.2 Mapping Data for Digital Health

The goal of SaMD and digital therapeutics is not only to provide individuals with clinically validated interventions, but also to engage and empower individuals to be participants in their treatment plan through data-driven, shared decision making. Individuals are encouraged to be an active user of the software, upload their data, receive customized interventions, and participate in tasks in order to make it a customized and engaging experience for both the individual as well as the provider and care team. These devices generate "new" data for the individual and the care team. This patient-generated health data (PGHD), captured outside of traditional healthcare settings, should be analyzed and visualized to support efficient, effective individual- provider and care team communication which can lead to improved outcomes. Of note, 60% or more of the impact on health outcomes is associated not with biologic information but with a combination of behavior, the environment, and social determinants [23]. As such, it is important that this PGHD includes not only health history, biometric data, treatment history, lifestyle choices, but also psychosocial and other information that is created and shared by the individual. This provides a holistic view of the individual's lifestyle and is the true definition of person centered.

For maximum benefit, the provider and care team should strive to optimize the PGHD workflow in their practice by examining how the data flows through their practice in these three steps:

- Data capture—the data must be created/measured, captured and stored (passively or actively) in an electronic form by a device (hardware or SaMD)
- Data transfer—the data must be communicated/transferred electronically to the healthcare/HIT team
- Data review—the data must be received, interpreted and integrated by the healthcare/HIT team for use in individual care (by provider, care teams and/or individuals or both)

In each step, individual safety and privacy and technical and regulatory issues with respect to

information assurance (confidentiality, integrity, availability) must be considered and documented for intended use and sharing among stakeholders [24].

14.5 Case Study: Welldoc—Leveraging Technology to Transform Diabetes Self-Care

Welldoc®, a digital health leader revolutionizing chronic care, is integrating personalized, real-time and actionable insights into the daily lives of individuals living with chronic conditions, enabling improved health and outcomes. Welldoc's comprehensive chronic care platform provides multi-condition support across diabetes, pre-diabetes, hypertension, heart failure and integrated behavioral health. Welldoc's flagship product, BlueStar®,[1] an FDA-cleared digital health solution, guides individuals through the complicated journey of living with diabetes by enabling them to self-manage their care while enhancing connections to their healthcare team. Welldoc partners with health plans, health systems and employers with the goal of extending care, improving health, and reducing costs.

14.5.1 Diabetes as a Clinical Model for Chronic Disease Self-Management

Diabetes is a chronic disease that affects over 8.5% globally and provides challenges for the person with diabetes, the provider and care teams, and the healthcare ecosystem [25]. The disease is complex and is categorized into type 1 diabetes, pre-diabetes, type 2 diabetes and gestational diabetes. For the person with type 1 diabetes, insulin therapy is required and may result in extreme fluctuations of glucose with accompanying challenges for self-management and emergency care. For the other types of diabetes medication management may involve oral medications, non-insulin injectables, and insulin. In all types of diabetes food, activity, and sleep management are an important part of the treatment paradigm—all activities that are completed by the person with diabetes (PWD) between visits with the provider and care team. The challenge for the management of this complexity for both parties has led to the state of diabetes control being sub-optimal, despite a proliferation of therapies and technologies to support the disease [26].

14.5.2 Digital Health Solution Development and Objectives

The Welldoc clinical, analytic and software developers focused on the Chronic Care Model (CCM) elements of self-management and clinical decision support to leverage the real-time capabilities of mobile phone technology to create a software solution for people with diabetes. Analysis of patient-generated health data (PGHD) and the integration of evidence-based clinical and behavioral guidelines formed the basis for an individual-provider and care team platform, Welldoc, that affords real-time, automated coaching for individuals and clinical decision support for providers and care teams.

The goals of the Software as a Medical Service (SaMD) Welldoc Platform are to:

- Support self-monitoring of blood glucose (SMBG/CGM) and other metabolic measures (i.e. BP, weight)
- Support the daily activities of medication management, food, activity and sleep tracking, and education on glucose and overall health
- Provide real-time, longitudinal coaching to support healthy individual behaviors for optimal BG control
- Provide usable data summaries of individual diabetes health and therapy over time for the

[1]Welldoc Diabetes Rx/OTC is an FDA-cleared medical device ("BlueStar"), intended for use by healthcare providers and their adult patients with type 1 or type 2 diabetes. For full labeling information, visit www.welldoc.com. The other Welldoc products are non-FDA-cleared and intended to promote general wellness and education/self-management of various chronic disease states.

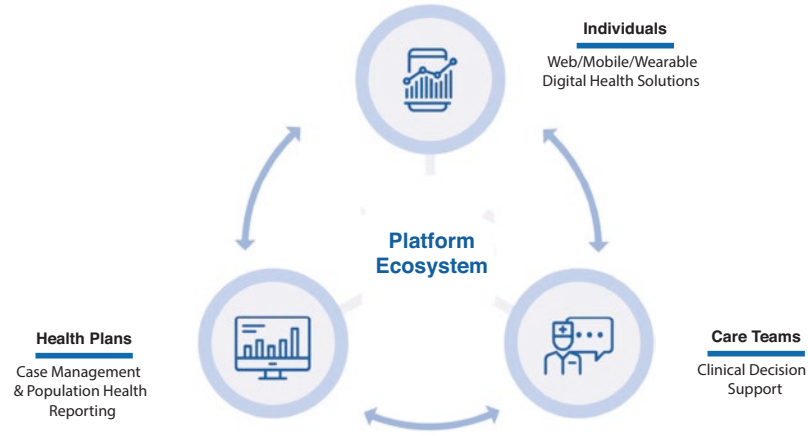

Fig. 14.1 Digital health platform

provider and care team to support and guide evidence-based treatments and population health initiatives

14.5.3 The Welldoc Digital Health Ecosystem

Welldoc, a FDA-cleared digital platform for type 1 and type 2 diabetes, provides automated, data-driven coaching and education to the person with diabetes (PWD) on their mobile devices (smartphones, tablets, and/or computers.) This automated, tailored coaching is available to the user anytime, anywhere in both a secure, online and offline mode. For the provider and care team, PGHD is analyzed and presented in individual or population views with evidence-based guidelines and recommendations. In addition, health plans are using digital health platforms for case management to reach broader sectors of their population (Fig. 14.1).

14.5.4 The User Experience with Welldoc

For PWD, the Welldoc automated digital coaching is tailored to specific diabetes medications (e.g. oral agents and/or insulin), daily food, sleep, and activity schedules, and blood glucose, blood pressure, and weight data entered manually or brought in from their monitoring or wearable devices.

Coaching or messaging interventions include the following:

- Real-time messages: educational, motivational, or behavioral messages in response to a blood glucose, blood pressure, or weight entry
- Trending messages: educational or prompting for provider and care team outreach based on rules-based longitudinal data
- Weekly messages: data visualizations for the week's activity (e.g. blood glucose, medication taking, etc) with insights that encourage the development of self-management problem solving expertise

On-going education is supported by a library of video resources, articles and a Diabetes Self-Management Education (DSMES) Curriculum that was digitized in collaboration with the Association of Diabetes Care and Education Specialist (ADCES). This curriculum is organized by the ADCES7 Self-Care Behaviors™—healthy coping, healthy eating, being active, medication taking, monitoring, problem-solving and reducing risks.

Additional features include food tracking with bar scanner and photo capabilities, a GIS-powered restaurant locator, a rewards system and message capabilities with provider and care team (Fig. 14.2).

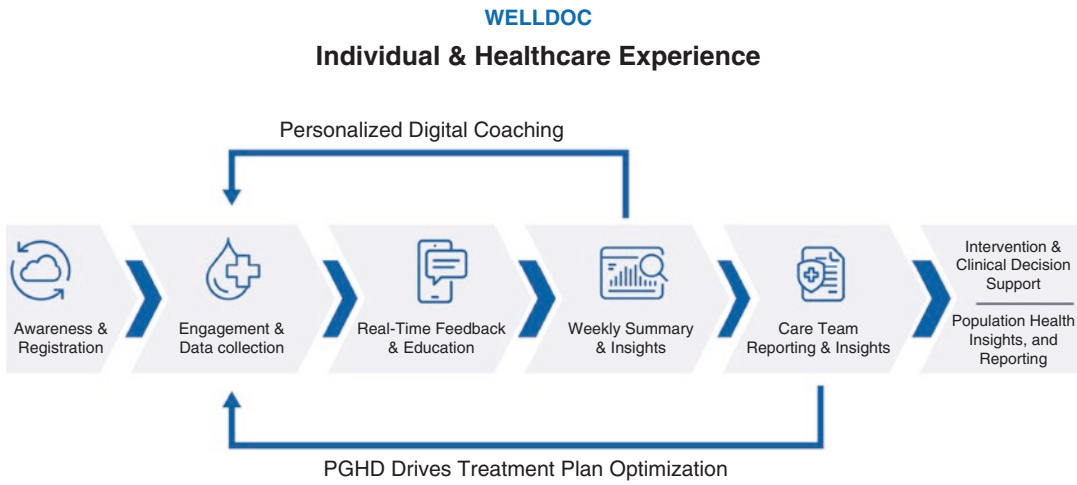

Fig. 14.2 The Welldoc platform individual and provider/care team experience

14.5.5 The Provider/Care Team Experience with the Welldoc Platform

Welldoc uses PGHD to provide the provider and care team a glimpse into the between visit activities of the individual. The Welldoc PGHD is visualized and analyzed to provide clinical decision support to the various members of the care team to support their role in diabetes management. For the prescribing clinician who makes treatment decisions including medications, labs, and exams there is specific information about glucose control, blood pressure monitoring, and weight tracking. For the diabetes care and education specialist, additional information about self-management behaviors, diabetes education curriculum completion and food diary are included. For the care manager or population health manager, there is information on the status with standards of care and social determinants of health. PGHD can be provided in the clinician's workflow by fax, email, or through the EHR, depending on the organization's implementation of the Welldoc solution. Individual data can be aggregated to provide a population view for the organization (Fig. 14.2).

Multiple iterations of the product's design, development, and evaluation have been conducted over the years. Improvement in clinical outcomes, cost outcomes, and engagement have been demonstrated via randomized controlled clinical trials [27, 28], demonstration projects [29, 30], ROI analysis [31], and real-world observational studies [32–34].

14.5.6 Digital Health Integration into Practice

No matter how effective the tool, simply creating a digital health product does not ensure adoption. To achieve the maximum benefits of platforms such as Welldoc, the technologies must be intuitive, easy to use, and be integrated into the everyday life of the individual and the provider and care team's clinical workflow. In order for digital health tools to be successfully adopted by clinicians and integrated into their practice, it is important to recognize the current technology they use and analyze where and how the new tool can fit in. This requires a thorough understanding of the daily workflow via discussions with the end users (clinicians and individuals) and identifying clinical champions that can support the use of the product. It is important to complete this analysis at the beginning of the process, identify potential pain points, and identify strategies to address them.

To enhance the integration process, ongoing collaboration with the software manufacturers and stakeholders is needed. These collaborations can happen with academic medical centers,

community-based programs, health system demonstration projects, patient advisory groups, academic data analytic centers, and professional associations in order to inform people, process, and program activities. It is important to use lessons learned from these interactions to develop frameworks and begin to define best practices. As such, two frameworks that evolved through these collaborations will be discussed.

1. A framework that evolved out of Welldoc's early work with implementation of digital tools into provider and care team practices, health plan implementations, and their collaboration with the Association of Diabetes Care and Education Specialists (formerly AADE) was the development of the Identify-Configure-Collaborate (ICC) Framework [35]. The ICC provides a structured way for clinicians to think about integrating technology solutions into their practice to optimize the individual-provider and care team experience and maximize outcomes.

Identify: Assess the self-management needs and goals to determine the right technology for the right person/population at the right time to achieve outcomes.

Configure: Setup the technology based on the user preferences, the treatment plan, and the need for ongoing support. This setup can be guided by an on-line tutorial or may require more consultation based on the user's technology experience and the goals of the technology (e.g., Bluetooth® blood pressure cuff or insulin pump).

Collaborate: Develop and implement a plan for data-driven conversations, shared decision-making, provider and care team integration to support health behaviors and make treatment modifications for individuals and populations.

2. Through a collaboration with a physician practice of a large academic medical center, Welldoc applied the Architecture for Integrated Mobility (AIM) Framework to the integration of Welldoc into the electronic health record (EHR) to optimize the individual-provider and care team use of a digital health solution. AIM is a mobile solution reference architecture that was developed by the telecommunications industry to define the "layers" and best practices for integrating mobile-enabled solutions into mainstream management systems. The eight layers include: users, application, environment, devices, network connectivity, services, core integration, and operating business model. Using the AIM model to capture lessons learned provided a systematic way to categorize lessons learned from the research and guide further work in understanding the technical, people, process, and business issues of integrating digital health solutions into practice [30].

14.5.7 Digital Solution Evolution

Unlike traditional physical tools or machines, a key benefit of mobile software solutions is the ability to make rapid changes and upgrades to the software via mobile app stores without the need to disrupt clinical or individual workflow. Also, the fact that the software is downloaded to a device that people already own, and are comfortable using, supports the delivery of population based, scalable interventions at relatively low cost.

Welldoc has evolved the Welldoc Platform solution to extend its six-dimensional chronic disease management model (individual generated health and lab data, medications, symptom tracking, activity tracking, diet, and psychosocial factors) beyond diabetes to cardiometabolic wellness solutions for pre-diabetes, hypertension, heart failure, and integrated behavioral health. Working in multiple disease states supports the evolution of single disease state solutions into technology-enabled solutions that are responsive to the individual user's chronic condition profile. This solution can combine diabetes and hypertension management, or diabetes and heart failure, and others—making it truly a person-centered solution that manages the overall health of the individual—not just one disease at a time. On a single device, enabled by data analytics and artificial intelligence, integrated clinical and behavioral

interventions are available in the hands of the user. As these types of solutions evolve, their safety and efficacy must be considered. Ongoing research into the development and evaluation of these solutions is essential going forward.

The Food and Drug Administration (FDA) has recognized the value and safety risks for individuals and care teams of digital health and mobile health apps, leading to the first guidance on mobile medical applications in 2013 with updates in 2015 and 2019. "The Policy for Device Software Functions and Mobile Medical Applications" covers mobile platforms (apps) and general software that functions AS a medical device (SaMD) or IN a medical device (SiMD) [36]. Of note, the iPhone (2007) and the Android (2008) phone systems were only introduced 6 years prior to FDA response—an indication of the rapid development and adoption of digital health by all.

There is a plethora of research on the impact of technology-enabled solutions. As for technology-enabled diabetes self-management research, a 2017 umbrella review of systematic reviews reported on 25 high quality reviews in which the various technologies evaluated revealed heterogeneity in interventions and methodologies. Technology-enabled diabetes self-management education and support was effective in reducing A1c when a complete feedback loop was present. This review identified a model for this type of feedback loop—Technology-Enabled Self-Management (TES) Framework. The TES components include PGHD, tailored feedback, general education, and two-way communication as essential for achieving the maximum benefit for technology-enabled solutions [37]. An update to this review presents the TES Taxonomy as a standard approach to describe technology-enabled interventions [38].

14.6 Moving Ahead

Technology and patient-generated health data present an opportunity for transforming health care for individuals, provider, care teams, and the healthcare ecosystem. Virtual care, including digital health and telehealth, are gaining increasing attention from health-care organizations across the globe, and the body of evidence supporting virtual care and outcomes continues to grow. The COVID-19 pandemic has spurred an incredible uptake of virtual visits in hospitals, especially in outpatient environments. Organizations are observing high individual engagement and satisfaction rates with this new mode of service. Individuals are now not only willing to accept virtual care but are beginning to prefer it. Many have expressed their preference for telehealth visits because it saves time, transportation, and overall costs. As reimbursement policies with telehealth visits and remote patient monitoring are further addressed, we can expect these options to remain even post COVID-19. As more of the world's population receives access to smartphones and computers, the potential for digital health solutions to reach a wider audience and improve health outcomes becomes increasingly more realistic.

Questions and Answers

1. What is the impact of chronic disease in today's healthcare landscape?
   (a) [From the Introduction] "Chronic disease presents a significant financial and societal burden in the United States and globally. It is estimated that 90% of the nation's 3.8 trillion in annual healthcare expenditures are spent on individuals with chronic and mental health conditions, with more than a third of Americans dying annually of stroke and/or cardiac disease, with obesity, cancer, arthritis, and other chronic conditions creating a massive burden on the US healthcare system.
2. How might digital health evolve as technology continues to improve in the future?
   (a) [From Moving Ahead] Digital health, along with telehealth and virtual care are transforming healthcare delivery and individual health. An increasing body of evidence shows that these technologies can and do improve health outcomes within the context of an engaged, active and informed individual-provider and care

team relationship. The experience of the COVID-19 pandemic has increased uptake of technology and extended it in inpatient and especially outpatient environments. Organizations are observing high individual engagement and satisfaction rates with this new mode of service, with individuals accepting and actually preferring virtual care, as they save time, effort and costs, and payors recognizing and reimbursing it.

3. For personal reflection on health after reading this chapter: "What health applications do you use on a day-to-day basis?"
   (a) [No specific answer]

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Algorithmic Fairness and AI Justice in Addressing Health Equity

15

Yoonyoung Park, Moninder Singh, Eileen Koski, Daby M. Sow, Elisabeth Lee Scheufele, and Tiffani J. Bright

Abstract

This chapter will focus on some of the technical aspects of addressing health equity associated with using Artificial Intelligence (AI) and Machine-Learning (ML) in healthcare systems and applications. We will examine this issue from both technical and sociological perspectives, describing the impact of algorithmic bias through specific examples of AI algorithms that have been demonstrated to produce biased outcomes in healthcare, and in other arenas that have important implications for healthcare. We will review a variety of analytic methodologies that can be used to address sources of algorithmic bias, including an assessment of the considerations for selecting the best method in different analytic contexts. We will conclude with an examination into the broader societal impact of algorithmic bias and enumerate on the environmental scan we conducted of organizations actively involved in addressing algorithmic bias and AI justice. We will describe some of the projects and efforts that are particularly relevant in the context of addressing health disparities.

Keywords

Artificial intelligence (AI) · AI fairness · AI justice · Algorithmic bias · Algorithmic fairness · Machine-learning (ML)

Y. Park
IBM T. J. Watson Research Center, Cambridge, MA, USA
e-mail: yoonyoung.park@modernatx.com

M. Singh · E. Koski (✉) · D. M. Sow
IBM T. J. Watson Research Center, Yorktown Heights, NY, USA
e-mail: moninder@us.ibm.com; ekoski@us.ibm.com; sowdaby@us.ibm.com

E. L. Scheufele
IBM Watson Health, Boston, MA, USA
e-mail: elisabeth.scheufele@childrens.harvard.edu

T. J. Bright
IBM Watson Health, Sandy Springs, GA, USA

Learning Objectives

On completion of this chapter, the reader should be able to:

- Describe this issue from both technical and sociological perspectives and cite specific examples of AI algorithms that have been demonstrated to produce biased outcomes that are relevant to healthcare.
- Have a basic understanding of both the variety of analytic methodologies that can be used to address algorithmic bias, and the relevant factors that must be considered when selecting

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the best methodology to use in a specific analytic context.
- Appreciate the broader societal impact of algorithmic bias as well as the types of mitigation strategies deployed by organizations actively involved in addressing algorithmic bias and AI justice.

15.1 Introduction

Recent advances in Artificial Intelligence (AI) and Machine-Learning (ML) algorithms bring previously unseen opportunities for advances in medicine and healthcare on many levels. Application of these tools is fueled by the increasing availability of population-level electronic medical data, advanced computing power and new techniques to parse and analyze both free text data and other information rich, but highly complex, medical information such as genomic data. At the same time, equally complex issues relating to the use of data and both interpretation and application of algorithmic output have surfaced as important and salient concerns. This is particularly true at a time of increasing awareness of how societal inequities have resulted in serious health disparities among many segments of the population.

Addressing all the underlying causes of inequity and health disparities is an undertaking that extends well beyond the capabilities of the healthcare system, however, improvements in health care can certainly mitigate at least some aspects of health disparities. As we look for ways in which AI can be used to reduce disparities, we must first recognize and redress how AI can both perpetuate and even exacerbate disparities if not deployed appropriately.

This chapter specifically addresses understanding the types of algorithmic bias that have been identified in a number of healthcare applications, as well as both technical and nontechnical strategies and techniques to mitigate such bias. As we consider the broader focus on addressing inequities, we will also examine the social movement towards algorithmic justice and health equity and the types of initiatives that are underway.

15.2 Algorithmic Bias

An algorithm is essentially a set of rules that determine how a computer will process data in order to answer a question or trigger an action. *Algorithmic bias* refers to a situation in which the outcome is skewed by something inherent in the underlying data or the way in which it is used, leading to inaccurate or misleading results.

There is increasing awareness of bias in ML/AI applications in many domains beyond healthcare. The sources of such bias often arise from conscious or unconscious beliefs that underpin how questions are framed, as well as complex, interrelated effects underlying the data that are used to create and apply them. The potential impact of inequities that are so deeply embedded in almost all aspects of society on healthcare applications can range from invisible to blatant, depending on the user's frame of reference. As a result, it is critical that potential sources of bias in such applications be recognized and addressed.

AI/ML systems often take the form of what are known as "black-box" models, where the input of data leads to an output, such as the probability of a particular outcome, but there is no clear explanation of the methodology, reasoning or process involved. This output may, nevertheless, appear to have *face validity* to the people evaluating and using it, particularly if they are not sensitive to the issues at play. Overconfidence in technology and lack of explainability can obscure the biases in data or models that distort the true nature of this world.

There have been infamous instances of such algorithmic biases. In the criminal justice system, for example, bias in a prediction algorithm discriminated against Black defendants by assigning a higher likelihood of recidivism to them when compared to their White counterparts despite similar observed rates for both races [1, 2]. Other examples include speech recognition algorithms that transcribed recordings from Black speakers with higher error rate compared to that from White speakers [3], facial gender classification algorithms that showed highest error rate among darker-skinned females and lowest in lighter-

skinned males [4], or biased biomedical algorithms with respect to age and gender [5].

Well-known examples of both historical and current use of prediction models in clinical settings have also demonstrated bias. A recent NEJM paper, that evaluated uses of race-based algorithms in research more broadly, illustrated how problematic the use of the variable "race" in clinical prediction models can be due to multiple factors. These included the uncertainties surrounding how and by whom the race of patients was determined; how race may have been correlated to other variables that may have been the true predictors; as well as the intended use of the predictions and how they could lead to either under- or over- treatment [6]. The Framingham Heart Score, a scoring system used to predict the risk of cardiovascular events in practice, was developed in a White-majority population. It was shown later that the score does not perform as well among Black patients as it does among White patients, exhibiting both over- and underestimations of risk [7].

A seminal work by Obermeyer et al. [8] demonstrated the impact of racial bias in algorithms that were used to target patients who might benefit from "high-risk care management" programs by predicting future cost of care based on historical costs, on the assumption that cost of care equated to level of illness. The algorithm did not account for an underlying discrepancy between groups, which was that many Black people had lower costs of care due to the impact of poverty on their ability to access care, not due to their level of illness. Since the purpose of the algorithm was to allocate resources based on cost of care received, this bias would result in White patients receiving access to care management resources at a lower level of disease burden than patients who are Black. In other words, the very people who might need such assistance the most would be the least likely to receive it if decisions were based on this algorithm because of the underlying assumptions in the representation of the variables used.

The potential impact of data and algorithms biased towards or against specific groups of people in healthcare can be profound. They can exacerbate the impact of underlying societal inequities that already predispose affected populations to poorer baseline health, and reduced access to health care. The ripple effects of which have both short and long-term consequences for many aspects of these patients' lives.

15.3 Definition of Bias

Before discussing bias mitigation, we need to understand what the term 'bias' means, as well as what is meant by "algorithmic bias."

The term "bias" has varied meanings and connotations across different fields of study, even within health-related domains. For example, bias in epidemiology usually refers to a spurious or non-causal association observed between a specific exposure and an outcome of interest. In statistics, bias sometimes refers specifically to the degree of discrepancy between an estimated value and a true value. In social science and general medical research, bias is often defined as a type of personal or societal prejudice that confers favor or disadvantage on one group compared to another as a result of some defining characteristic such as race, religion, gender, gender orientation, language or disability with resulting disparities in socio-economic status and/or health outcomes.

In ML/AI, several definitions of bias exist, related not only to data and models but also to history and human behaviors. This reflects the community's effort to identify the source and quantify the level of bias or "fairness." For example, bias can arise from lack of diversity in the sample data used to train models (*representation bias*), from imperfect measures of critical data elements and use of erroneous proxies (*measurement bias*), or from biased benchmarks for algorithms that favor a particular subgroup or population (*evaluation bias*) [9]. Various analytic choices can induce bias in almost every step of ML/AI implementation from data sampling to feature selection to model interpretation. One of the major challenges in mitigating algorithmic bias is that there are many different definitions of fairness and what it means for an algorithm to be "fair," how to measure it, what metric to use, and what to do about it. This will be discussed in the subsequent sections.

15.4 Sources of Bias

Bias in ML/AI solutions in healthcare emerges in many different ways. Core concepts of bias and fairness might only be loosely defined from a technical perspective. Focusing on computational health and the development of data driven solutions for clinical decision making, we have identified two main sources of bias:

1. The data used to build AI solutions: For reasons outlined in detail in a Chap. 26 (some of which include socio-economic factors and barriers to accessible healthcare), different groups within our society are often underrepresented in clinical data sources, resulting in data that may be incomplete, inaccurate, or misleading.
2. AI modeling activities: In computational health, existing domain knowledge is often injected during the modeling process. For instance, a readmission score may draw its conclusions from the computation of the Charlson co-morbidity score. As illustrated by Obermeyer, et al. [8] commonly used comorbidity scores are sometimes biased against minorities, most notably Black people.

Figure 15.1 illustrates how representative examples of factors resulting from historical discrimination or marginalization of populations translate into a direct impact on medical data which can then lead to varying types of bias when such data is used to develop and train AI systems, resulting in algorithmic bias.

Addressing these issues calls for a two-pronged approach - first seeking efficient ways to detect, assess, and measure bias, followed by mitigation strategies to reduce such bias as much as possible. Both of these aspects are discussed in this section.

15.5 Metrics for Bias and Fairness Assessment in AI Solutions

Bias and fairness in AI solutions can be perceived and measured in different ways, depending on context. The choice of fairness metric must, therefore, be driven by the clinical context and intended use of the algorithm.

15.5.1 Individual vs. Group

Fairness may be evaluated at either an individual or group level. An AI solution achieves fairness at the individual level if it can guarantee that all similar individuals are treated similarly by the solution. *Sample distortion metrics* [10] are particularly suitable for the evaluation of fairness at the individual level.

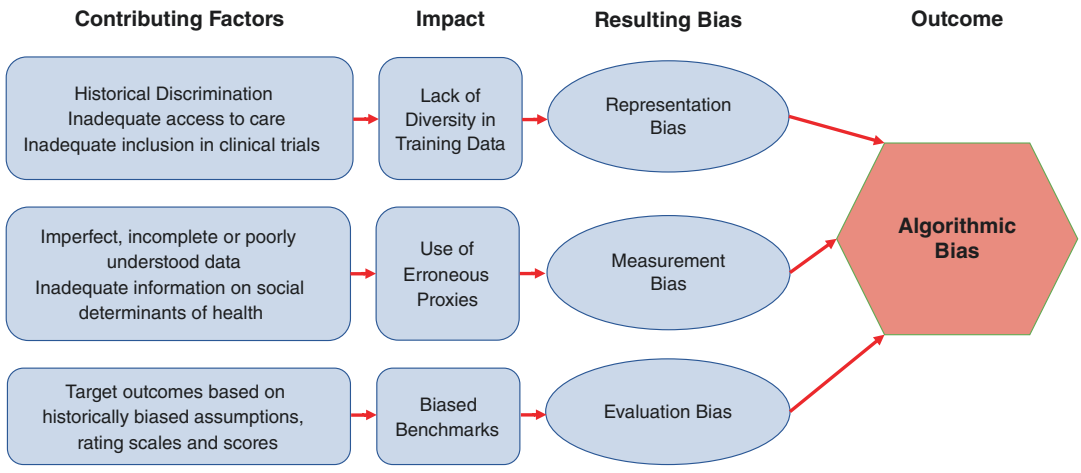

Fig. 15.1 Sample sources of algorithmic bias arising from the impact of selected contributing factors

At the group level, an AI solution achieves fairness when its performance is invariant across groups. A group is said to be *protected* when it is at risk for harm on the basis of attributes such as gender, age or race that have historically been associated with social, economic, and/or environmental disadvantage. In contrast, the *privileged (unprotected)* group has implicitly been advantaged. In the case of racial disparities, race is the *protected attribute* with respect to achieving fairness - Black being a *protected value*, as opposed to White, which would be the *privileged value* (sometimes referred to as the *unprotected value*). In the methods we will discuss below, bias generally refers to the statistical association between *protected attribute* and *predicted outcome label*.

There are also some metrics, such as the *generalized entropy index* and its extensions, that can be used to assess both individual and group level fairness.

15.5.2 Approaches to Achieving Group Fairness

There are two opposing approaches to assessing group fairness: we are all equal (WAE) and what you see is what you get (WYSIWYG) [11, 12]. The WAE view assumes that all groups are treated equally by the AI, despite potential observed discrepancies across groups, while the WYSIWYG view assumes that such discrepancies affect the performance of the AI.

Depending on the view adopted, different metrics may be used to assess bias. WAE applications may use demographic/statistical parity metrics such as *disparate impact* (DI) and *statistical parity difference*, which assume similar outcome rates for different groups. This generally makes sense where a biased decision may result in harm, especially if the assumptions about underlying data may be untrustworthy or biased [8]. Conditional statistical parity metrics may be used where the base rate for the condition is different for the groups.

WYSIWIG applications are more likely to consider both actual and predicted outcomes and focus on whether or not the AI model is equally accurate for both protected and *privileged* groups. The strongest measure of fairness, in this regard, is imposed by metrics such as *average odds difference* and *equality of odds*. A similar metric, *equal opportunity difference* (EOD), checks for equality of precision [13]. Verma et al. provides a detailed description of these as well as other fairness metrics.

As indicated, the use of a fairness metric depends on the specific application, as well as the risk associated with errors. Rajkomar [14] and Makhlouf [15] provide detailed discussions on the tradeoffs associated with different metrics, particularly in the area of health.

15.6 Bias Mitigation Strategies

Over the last few years, several methods have been developed to mitigate bias in AI models. Based on the stage in the model development pipeline where the mitigation is performed, these techniques can generally be broken into three groups: *pre-processing*, *in-processing*, and *post-processing* [16].

15.6.1 Pre-Processing

Pre-processing algorithms are used to mitigate bias in the training data itself before the model is developed. These methods work by adjusting the labels, making changes to the data, or changing the weights of individual data records. *Reweighing* [17] is one such technique in which weights are assigned to each combination of group (privileged/unprivileged) and label (favorable/unfavorable) in the data in such a way as to reduce the unfairness between the groups.

Another pre-processing technique is *Disparate Impact Remover* [18] in which the actual feature values are modified to break the dependencies between the protected attribute and the other independent features, while preserving the ranking within the groups. This increases group fairness while simultaneously preserving the predictive relationship between the features and the label.

Other methods include *Optimized preprocessing* [10], which probabilistically transforms the features/label values to reduce discrimination, and *Learning Fair Representations* [19], which maps the data to a new probabilistic representation that hides information about the protected feature while retaining information about the other features.

An obvious advantage of pre-processing techniques is that they are used early in the model building process to remove bias from the data. Moreover, once the data has been transformed, any algorithm can be applied to learn the final model. These approaches are especially useful in cases where the dataset is to be made public or the modeling is performed by external parties. On the flip side, if the original data is to be preserved and cannot be changed, then these methods (except for reweighing) cannot be used. Another drawback of techniques such as reweighing and disparate impact remover is that they try to remove direct bias with respect to a single feature, and thus there is no guarantee that the transformed data is bias free, nor is there any measure of how much bias has been removed or how the transformation affects performance of the resultant model.

15.6.2 In-Processing

In-processing techniques change the machine learning algorithm itself to produce fairer models. One such approach, *Prejudice remover* [20], modifies the standard logistic regression algorithm by adding a regularization term to the objective function that penalizes unfairness. Similarly, *discrimination aware decision tree learner* [21] imposes a non-discrimination constraint on the decision tree learning algorithm by changing its splitting criterion and pruning strategy.

Another in-processing technique, *adversarial debiasing* [22], simultaneously learns a classifier and an adversarial model, with the aim of maximizing the classifier's ability to predict the label while simultaneously reducing the adversary's ability to determine the protected feature. The result is a fair classifier that does not lose much accuracy during mitigation. *Exponentiated gradient reduction* [23], on the other hand, reduces fair classification to a sequence of cost-sensitive classification problems. The solutions to these problems result in a randomized classifier with the lowest empirical error subject to fairness constraints.

An obvious disadvantage of in-processing techniques is that special-purpose methods, rather than standard machine learning algorithms, are used. Moreover, techniques such as prejudice remover and discriminant aware decision tree learner are restricted to specific types of models which may not be best for every use case. In that sense, the other two methods are more flexible and applicable to multiple definitions of fairness as well as learning methods.

15.6.3 Post-Processing

Post-processing involves changing the final decisions of the AI models to make them fairer. In *Reject option classification*, a critical region with high uncertainty around the decision boundary of a classifier is chosen (where the classifier prediction is ambiguous), and the predicted labels are chosen in a way that favorable outcomes are assigned to the unprivileged group and unfavorable outcomes to the privileged group to reduce bias [24]. In a similar vein, *Equalized odds post-processing* solves a linear program to find probabilities with which to change output labels to optimize equalized odds [25].

Post-processing methods are useful in situations where neither the data nor the learning algorithm is accessible and/or modifiable. However, since the decisions of the model itself are changed, the training data can no longer be published, the modeling can only be performed by the data owner. Moreover, these methods require access to the protected attribute at deployment, something that may not always be available.

15.7 Algorithmic Fairness in Action

While there are numerous technical approaches to bias mitigation, there is also a growing societal imperative to assure that algorithmic fairness on a population basis is a fundamental requirement for achieving equity.

In order to assess the current state of this emerging field, we performed web searches, and searches of reference lists and a previously compiled resource list from AIethicist.org (https://www.aiethicist.org/ai-organizations) from January to February 2021 to identify organizations that examined AI fairness or algorithmic bias and then reviewed material available on each site. Organizations were included based on the following criteria:

- Academic or non-profit organization
- Demonstrated commitment to algorithmic fairness and/or algorithmic bias as a key area of focus or organizational theme
- Website included at least 10 algorithmic bias projects, publications or other activity with content that promoted action

The search identified 115 AI organizations across academia, civil society organizations, government, and industry, of which eight met our inclusion criteria (Table 15.1).

These included one academic organization and seven non-profit organizations. The majority of organizations had 10–25 work products; two organizations' libraries featured more than 75 elements. Projects and publications focused on the applied use of AI and the impact of algorithmic bias across similar and different topics such as criminal justice sentencing, hiring algorithms, COVID-19 resource allocation, housing allocation, as well as deepening the science of understanding algorithmic bias, definitions, detection, deployment, and evaluation. While these organizations are not specifically focused on healthcare, it is telling that several of them have projects or efforts that are directly related to some aspect of healthcare—from COVID-19 to disability to renal transplantation. In addition, the broader social issues that many of these organizations address—such as discrimination in hiring, and criminal justice practices—represent some of the underlying causes of health disparities.

A brief description of each organization follows. Some of their reports, projects and programs are highlighted and can be found on the organizations' web sites.

15.7.1 Ada Lovelace Institute

https://www.adalovelaceinstitute.org/

Founded in 2018, the Ada Lovelace Institute seeks to honor the legacy of its namesake by

Table 15.1 Included organizations, organization type and volume of selected activities

Entity	Type	Project	Publication	Conference or workshop	Talk	Advocacy effort	Exhibition	Blog
Ada Lovelace Institute	Non-profit	7	9	0	0	0	0	0
AI Now Institute	Non-profit	0	13	7	0	0	0	0
Algorithmic Justice League	Non-profit	5	4	0	8	12	10	0
Data and Society	Non-profit	0	86	0	36	0	0	53
Montreal AI Ethics Institute	Non-profit	0	78	0	0	0	0	0
Partnership on AI	Non-profit	0	3	0	2	0	0	5
USC Center for Artificial Intelligence in Society	Academic	6	17	0	0	0	0	0
Upturn	Non-profit	0	11	0	5	2	0	1

ensuring data and AI work for people and society. The institute's core belief is that data and AI must be justly and equitably distributed to enhance individual and social well-being, which is woven throughout their workplan, projects, and interdisciplinary partnerships.

Three themes guide the institute's work in the application of data-driven systems, AI and society:

1. Algorithm accountability
   (a) Projects focus on addressing the lack of transparency that often accompany the design and deployment of algorithms and AI.
   (b) Example projects seek to provide transparency and accountability in the algorithmic decision-making process by building the evidence of these systems development tools and methodologies to enable algorithms and AI to be assessed for societal impact, and regulatory and normative compliance, and educate policy makers and regulators with the skills to inspect and understand AI capabilities.
2. Justice and equality
   (a) Projects focus on achieving racial justice in the use of data and algorithmic systems, aim for economic justice, reinforce environmental justice, and reconceptualize structural justice.
   (b) Example projects include partnering with the Health Foundation to examine the interaction between data-driven systems and health and social inequalities during the COVID-19 pandemic, development of tools to enable accountability of public administration algorithmic decision-making systems, and visually mapping terms common to the AI and data ethics community to compare how the terms are defined and used across disciplines and application contexts.
2. Data for the public good
   (a) Recent work includes investigations into COVID-19 data practices and technologies.

15.7.2 AI Now Institute

https://ainowinstitute.org/

The AI Now Institute at New York University is an interdisciplinary center examining the social implications of AI in practice across four core social domains: Rights and Liberties, Labor and Automation, Bias and Inclusion, and Safety and Critical Infrastructure.

As a non-profit organization, AI Now works with a broad group of stakeholders to conduct research to examine the social implications of AI, with a focus on promoting justice and equity through. Since its inception in 2017, the institute has published over ten reports, held four symposiums, and published several other articles and toolkits.

The 2019 Institute Report [26] notably documented that the change to implement more ethical and accountable AI was forged by community groups, employees, researchers, and journalists—not motivated by tech companies and/or government regulation. The report provides several poignant examples where the technology amplified long-standing discriminatory policies and how local activists were the ones providing evidence regarding the safety of the technology in our society.

Another publication based on a workshop conducted in March 2019, Disability, Bias and AI by Whittaker et al. [27] examined how people with disabilities are captured and represented in the design and development of AI systems, and the biases at the intersection of AI and disability.

The website also contains resources including a series of workshops, symposiums, and several publications.

15.7.3 Algorithmic Justice League

https://www.ajl.org/

The Algorithmic Justice League was founded in 2016 by Joy Buolamwini. The League combines art, research, policy guidance, and media advocacy to raise awareness about the social implications and harms of AI and lead in the design and implementation of equitable and accountable AI. The organization seeks to

increase awareness about the impact of AI, equip advocates with research, and help equip researchers, policymakers, and industry practitioners with the skills to mitigate AI bias and harms.

The organization promotes four principles to address equity and accountability in AI:

1. Affirmative consent
2. Meaningful transparency
3. Continuous oversight and transparency
4. Actionable critique

One of the most prominent projects described on their web site was Gender Shades, which evaluated bias in facial analysis algorithms and datasets with respect to phenotypic subgroups. The study evaluated three commercial gender classification systems and found that darker-skinned females were the most misclassified group. This work led to other research projects such as examining the impact of algorithmic audits, creation of FDA-inspired models to categorize facial recognition technologies, and uncovering AI bias and harm in speech recognition. The website library provides access to additional content, including publications, talks, advocacy efforts, and exhibitions.

15.7.4 Data and Society

https://datasociety.net/

Data & Society was formed in 2014 as a nonprofit research organization to study the social implications of data and automation. Data & Society uses academic rigor to produce original, evidence-based research about emerging technology. The website features several research tracks, along with relevant work.

The organization seeks frame-breaking research questions informed by real-world experiences of those who may be adversely affected by the integration and implementation of these technologies. The AI on the Ground Research Track highlights research using social sciences methods to develop guidelines, best practices, and recommendations for regulatory approaches; this work applies a sociotechnical understanding to develop robust analyses of AI systems.

A key research product was a 2019 ACM Conference on Fairness, Accountability, and Transparency paper that discussed the importance of including the social context in which the algorithms will be deployed and the types of abstraction errors this creates, when trying to create fairness-aware machine learning [28].

Additionally, as of early 2021, the website library contained over 80 publications, 53 blog posts, and 36 talks discussing algorithmic bias.

15.7.5 Montreal AI Ethics Institute

https://montrealethics.ai

Since 2017, the Montreal AI Ethics Institute has been defining humanity's place in an algorithm world driven by creating tangible and applied technical and policy research in the ethical, safe, and inclusive development of AI. The institute aims to educate, empower, and equip the public and stakeholders about the society impacts of AI so that there are diverse voices represented and engaged in how AI systems are developed and deployed.

As a community-focused organization, the institute has developed a framework for empowering citizens who champion applied AI ethics into local communities. This commitment is woven throughout the issues they address across six foci areas, such as AI and Law, the Malicious use of AI, Algorithmic Discrimination, and Algorithmic Impact Assessments.

From its inception to early 2021, the institute had grown to over 4500 members and had hosted over 70 local meetups. Under the *Content* tab, the site also provided not just a listing, but also *Research Summaries* of many different projects conducted and published elsewhere on related topics such as examining social biases in NLP models as barriers for persons with disabilities, a review of algorithmic audits, examining commonalities between Domain Generalization and Fair-ML in pursuit of algorithmic fairness, and a biases in hiring algorithms.

15.7.6 Partnership on AI

https://www.partnershiponai.org/

The Partnership on AI was created in 2016 to advance the public's understanding of AI and by bringing together diverse stakeholders across sectors, serves as a convenor for discussions about AI and its influences on people and society.

The partnership is guided by four goals:

1. Develop and share best practices
2. Advance public understanding
3. Provide an open and inclusive platform for discussion and engagement
4. Identify and foster aspirational efforts in AI for socially beneficial purposes

In addition, the work is organized into six thematic pillars:

1. Safety-Critical AI
2. Fair, Transparent, and Accountable AI
3. AI, Labor, and the Economy
4. Collaborations Between People and AI Systems
5. Social and Societal Influences of AI
6. AI and Social Good

The partnership's collaborative projects focus on addressing tangible societal challenges, as well as investing in ambitious big ideas. Reports have examined the use of algorithmic risk assessment tools in the US criminal justice system such as minimum requirements for responsible deployment, the misalignment between ML definitions of fairness and legal concepts based in US anti-discrimination law, and the role and use of demographic data in detecting algorithmic bias.

15.7.7 USC Center for Artificial Intelligence in Society

https://cais.usc.edu/

The University of Southern California (USC) Center for Artificial Intelligence in Society launched in September 2016 as a joint venture between the USC Suzanne Dworak-Peck School of Social Work and the USC Viterbi School of Engineering. The center advances research in both AI and social work though interdisciplinary partnerships that focuses on seven core areas, including fairness, equity, and bias.

Using resources such as the Grand Challenges for Social Work, the National Academy of Engineering Grand Challenges for Engineering, and the United Nations Sustainable Development Goals, the research is oriented to develop solutions that enhance social services and healthcare interventions for individuals living in impoverished or marginalized communities.

Project examples include developing a novel data-driven approach for COVID-19 resource allocation, optimizing algorithms to accurately predict kidney transplant wait times and assist with disease management decisions, predicting suicidal thinking through mining social network data of youth experiencing homelessness, and creating fair and transparent algorithms to improve housing placements for persons experiencing homelessness.

15.7.8 Upturn

https://www.upturn.org/

Upturn is a non-profit organization centered in a belief that technology should advance justice, not amplify racial and economic inequities. Through interdisciplinary partnerships, they utilize research, legal and policy advocacy to advance policy change in two focal areas: safety and justice; and economic opportunity.

Their work seeks to expose how predictive tools are employed by police and in the legal system to make decisions, examine biases in hiring algorithms that are an avenue for employment, and uncover online advertising discrimination in housing, employment, and credit.

Published reports (as of publication is available on their website under the "Our Work" heading by filtering on "Reports and Scholarship"), have examined issues as diverse as bias in hiring algorithms, Facebook's "Special Audiences" ad targeting tool, and pretrial algorithms. The website includes additional content highlighting

their work in driving policy outcomes through regulatory comments, advocacy, articles, op-eds, and presentations.

15.7.9 Potential Limitations

There are several potential limitations to this environmental scan. First, there is a selection bias. The organizations that were scanned were chosen to include a broad range of AI organizations. However, given the proliferation of AI, this is still just a sample. In 2020, we witnessed the power of activism to move industry practices and hence, wanted to expand that specific focus for this environmental scan by limiting the inclusion criteria. Second, our assessments about an organization's commitment were limited to publicly available data posted on the website. Along with that, in some cases what is a clear focus for an organization might not have resonated in what we gleaned from the website. Lastly, there were a few websites that were inaccessible, and we were unable to assess the organization's commitment or activities pertaining to algorithmic bias.

15.8 Conclusions

There is a societal imperative to reduce health disparities. From an AI/ML perspective, this requires addressing bias in AI algorithms that are used in healthcare and that can either help identify ways to improve the healthcare system or can further exacerbate existing problems if not deployed appropriately.

From a technical perspective, there are many new methodologies for mitigating bias and enhancing fairness that can be applied at different stages of AI algorithm development and use. Each of these methodologies has different strengths and weaknesses depending on the context in which they are used, so care must be taken to match the appropriate algorithm to the specific need.

From a sociological perspective, the movement to address algorithmic bias has expanded beyond the realm of data scientists to the involvement of numerous organizations focusing on the societal impact of these tools. We conducted an environmental scan and explored the activities of 115 AI organizations that address algorithmic bias. Most significantly, we identified eight organizations that were non-commercial and actively promote algorithmic fairness by producing publications, projects, and a host of other activities to further society's understanding of algorithmic bias and to change our relationship with algorithms for the good. Many of these organizations either have projects specifically focused on healthcare, from COVID-19 to disability to renal transplantation, or have projects focused on more fundamental social justice issues that contribute to underlying causes of health disparities such as discrimination in hiring, and criminal justice practices.

Looking at the variety of issues these organizations address is a reminder of the complexity of the landscape of AI and social justice, and that no matter what we do, we will almost certainly never have data that perfectly reflects the circumstances of every single patient a clinician might encounter. Ironically, the more we improve the representation of different populations and social determinants of health in our data sets, and the better they begin to perform, the more assumptions we may make about them in clinical situations when they might not offer the best solution [29].

Nevertheless, the ever-increasing complexity of medical data and the interplay between biological and sociological factors in health makes it increasingly imperative that we use all of the tools we have to derive meaning from data; improve decision-making and predictions; strive to identify and address inequities; and raise the standard of health and healthcare for all. Having both technological and sociological approaches available to address issues of bias and fairness in artificial intelligence and machine learning will help to both create the proper climate and provide the best tools to enable practitioners to deploy AI/ML advances in achieving health equity.

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Managing Clinical Data in Neurocritical Care

16

Peter H. Dziedzic and Jose I. Suarez

Abstract

Intensive Care Medicine (ICM) is the practice and system for treating and supporting critically ill patients to achieve the best possible clinical outcomes. Neuro-Critical Care (NCC) is the branch of ICM that addresses the special medical and technical challenges of managing patients with critical illnesses of the brain and central nervous system. NCC requires (a) timely and accurate monitoring/capture of clinical signals and data that are unique to the brain and (b) effective and efficient transformation of incoming data into meaningful knowledge for timely clinical decisions and response. Multimodality Monitoring (MMM) is the collective technology for seamlessly connecting and integrating multiple types and sources of incoming data (modes) from devices to clinical output. MMM forms the cornerstone and basis for design and implementation of NCC and other units dedicated to critical care.

The Johns Hopkins Hospital (JHH) NCC Unit (NCCU) has established an extensible NCC multimodality ecosystem since 2018 for managing input modes and output functionality for clinical, administrative, population health and research. This multimodality management approach has demonstrated utility and value through expansion to all ICUs and operating rooms at JHH, as well as for facilitating remote access for the care of COVID-19 patients in 2020.

Keywords

Neurocritical care · Multimodality neuromonitoring · Neurocritical care unit Big data · Data integration

P. H. Dziedzic
Division of Neurosciences Critical Care, Precision Medicine Center of Excellence for Neurocritical Care, Center of mHealth and Innovations, Department of Neurology, The Johns Hopkins University School of Medicine, Baltimore, MD, USA
e-mail: phd@jhu.edu

J. I. Suarez (✉)
Division of Neurosciences Critical Care, Precision Medicine Center of Excellence for Neurocritical Care, Departments of Anesthesiology and Critical Care Medicine, Neurology, and Neurosurgery, The Johns Hopkins University School of Medicine, Baltimore, MD, USA
e-mail: jsuarez5@jh.edu

Learning Objectives

After completing this chapter, readers should be able to:

- Characterize special clinical and data needs of patients in intensive/critical care and in neurocritical care

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- Describe how biological data (modes) from patients in NCC are captured and processed for use in clinical care and decision-making
- Define Multimodality Modeling and describe its central role and value in managing data in the intensive/critical care information ecosystem

16.1 Introduction

Intensive Care Medicine (ICM) is the clinical science and practice that focuses on treatment and life support of patients with acute life-threatening conditions, to prevent further deterioration and to achieve the best possible outcomes [1]. ICM is provided by integrated teams of specialized clinicians operating in a specialized environment that supports technology and data-intensive protocols for managing patients. This environment is called an intensive care or critical care unit (ICU/CCU).

16.2 Neurocritical Care (NCC)

Neuro-Critical Care (NCC) is ICM that focuses on the special needs of the brain and central nervous system (CNS) in acute and critical pathologic states, such as stroke, traumatic brain and spine injury, and after neurosurgical interventions, among others [2]. NCC also focuses on mitigating subtle secondary damage to which the brain and CNS may be susceptible during care. The brain and CNS consume the most oxygen in the body and are most vulnerable to delayed and long-term damage that may have high impact on the quality of life.

Special aspects of NCC include:

- The need for simultaneous and continuous measurement, awareness, and management of two separate but vitally connected physiology domains: the neurologic (brain and spinal cord) and the systemic (rest of the body)
- The need for special invasive and non-invasive techniques, technologies, and modalities, unique to NCC, to detect and measure neurologic function within the spatial constraints of the brain and CNS/spinal cord
- The need to alter brain function therapeutically (through pharmacologic and/or physical [hypothermic methods]) to mitigate primary and secondary brain damage.
- The need to recognize, detect, and manage the time between pathophysiologic signal and pathologic impact during which intervention may be most effective.

These special needs require even more specialized ICM resources, technology and expertise: the Neuro-Critical Care Unit (NCCU) [1].

16.3 The Neurocritical Care Unit (NCCU)

The NCCU, a dedicated physical inpatient location for managing patients with NCC needs, is distinguished from other types of ICU/CCU units in its alignment of resources and expertise in providing care for patients with the following pathologies:

- Stroke:
  - Intracranial hemorrhage
  - Subarachnoid hemorrhage
  - Intracranial thrombosis and cerebral ischemia
- Brain pathology
  - Injury
  - Seizures
  - Coma
  - Brain Inflammation
  - Elevated intracranial pressure
- Disorders of the spinal cord
  - Injury
  - Stroke
  - Compression of nerves and/or blood supply
  - Tumors

In addition, there are special tools and procedures that are carried out in the NCCU alone. These include:

- Perioperative (pre- and post-) neurosurgical care
- Management of intracranial pressure
  - Measurement/monitoring
  - Control
- Brain and systemic hypothermia
- Coma induction
- Continuous electroencephalographic (EEG) monitoring
- Ventricular (cerebrospinal) fluid drainage

The availability of specialized NCCUs and NCC provider teams has been shown to be associated with decreased mortality and better outcomes of patients with severe neurological conditions [3–5]. However, the need for specialized care of these patients may continue beyond discharge from the NCCU, and comprises a continuum of NCC care, and the NCCU as is connected to other units within the hospital that may provide other forms of high-level neurologic care to patients, such as other ICUs/CCUs and neurological step-down units, the emergency department, and neurological surgical suites and postoperative wards.

16.4 NCCU Stakeholders

16.4.1 The Neurocritical Patient

The patient is the central stakeholder and source of all real-time clinical data. NCC patients are usually admitted to the NCCU for three primary reasons: close neurological monitoring (88%), hemodynamic monitoring (90%), and respiratory monitoring (51%) [5]. Neurological monitoring usually requires a 1:1 or 1:2 nurse-patient ratio and entails frequent neurological examination to ensure stability or detect early changes that require further treatments. Hemodynamic monitoring requires a similar nurse-patient ratio with periodic assessment of continuous recorded blood pressure and heart rate. Respiratory monitoring comprises continuous recording of pulse oximetry (oxygen saturation), respiratory rate, and (where appropriate) respiratory support parameters (such as mechanical ventilator settings). NCC patients are cared for by a multi-professional team made up of physicians, nurse neuro-intensivists, advanced practice providers (APP), pharmacists, physical and occupational therapists, and nutritionists, among others. In addition to postoperative neurosurgical cases (about 40%), the most common diagnoses requiring admission to the NCCU include subarachnoid hemorrhage (13%), intracranial hemorrhage (12%), and severe traumatic brain injury (12%) [5].

16.4.2 The Neuro-Intensivist

The Neuro-Intensivist is a physician trained and certified in critical care medicine, with demonstrated competence in NCC and its cognitive and procedural domains [6] as specified by the United Council of Neurologic Specialties (UCNS) [7]. The neuro-intensivist has detailed knowledge of protocols and evidence-based practice, with skill in ICU management, critical care team leadership and communication/collaboration with patients/families, ICU team members, and telemedicine [3–5]. The neuro-intensivist is physically present in the unit [8].

16.4.3 The Neurocritical Care (NCC) Nurse

The Neurocritical Care Nurse has, in addition to formal training in critical care nursing, a coupled knowledge of and experience in neuroanatomy and neurologic assessment. This training, in addition to a broad skill set in patient management, including post-anesthesia, medical-surgical, trauma care, makes the NCC nurse a key member of the interprofessional NCC team. The NCC nurse provides frontline clinical contact to the patient and incoming data, has frontline comprehensive knowledge of patients' neurologic assessments and serves as a source of patient-centric information with team members and the patient/family. The NCC nurse, complementary to the neurocritical physician, has knowledge and experience in managing patient flow and teamwork [3–5, 9].

16.4.4 Neurocritical Care (NCC) Team Members

NCC Team members, in addition to neurointensivists and nurses, form a heterogeneous and multidisciplinary group of clinical, information technology and clinical engineering professionals with special training relevant to the care of patients in the NCCU. These include advance practice providers (physician assistants and nurse practitioners) [10], allied health professionals (pharmacists), imaging and testing personnel (ultrasound, electroencephalography, angiography/radiology) and the biomedical and clinical engineering professionals who develop and maintain the technology that collects and transforms neurologic signs into electronic data for subsequent management and presentation. Each of these professionals must work within the team of NCCU stakeholders and its patient workflows.

16.5 Clinical and Data Workflow in the NCCU

"Workflow" in the NCCU can be organized on two levels: Patient Throughput (i.e., movement of patients into and out of the NCCU) and Clinical Data Flow within the NCCU.

16.5.1 Patient Throughput: Pre and Post NCCU Care

The NCCU may admit patients from the Emergency Department, from other areas within the hospital or external facilities (other hospitals), and surgical (or other procedural) suites. Once patients are stabilized and no longer need NCCU-specific care, they are discharged to other non-NCC units in the hospital or to external long-term care or rehabilitation facilities.

- Pre-NCCU Care and Data
- The neuro-intensivist and NCC nurse work together to coordinate admissions and overall care to plan and organize a patient's clinical and data needs prior to and upon arrival to the NCCU. If the patient is being transferred from an ICU, emergency or surgical unit, reconciliation and coordination of care and ongoing data streams will be required through communicating physicians, nurses and other NCCU care and administrative teams.
- Post-NCCU Care and Data
- Once a decision has been made that a patient no longer requires NCCU-specific care, information about the care received in the NCCU is summarized for patient transfer to a receiving facility at the administrative, nursing, physician, and care coordination team levels. If the patient is transferred to another ICU, reconciliation and coordination of ongoing data streams between nursing and clinical technology staff/teams will be required.

16.5.2 Clinical Data Flow in the NCCU

Once a patient has been admitted to the NCCU, the specified clinical data modes (physiologic measures and signals from clinical devices for electronic data processing and presentation) are established (Fig. 16.1):

Pragmatic challenges in establishing standard data connections in ICUs include:

- Space and usability constraints—devices and monitors may block direct physical care (ergonomics)
- Non-interoperability—interfaces between devices and monitors may be incompatible due to proprietary issues
- Mismatches in signal handling—among devices and monitors, between care units and across the institution
- Other limitations in connectivity—availability of sufficient connection ports to the hospital IT network, etc.

Overcoming these challenges requires effective leadership, collaborative planning, thoughtful design and implementation to optimize capacity and extensibility while not disrupting ongoing clinical workflows.

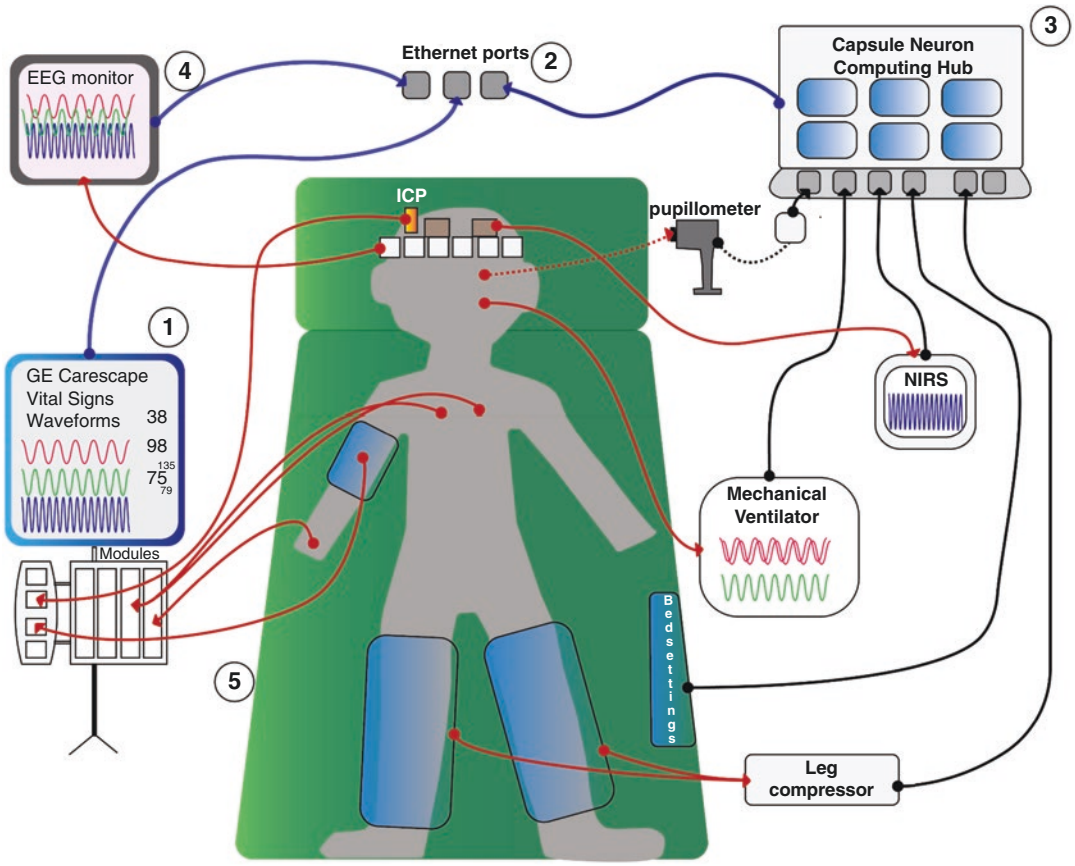

Fig. 16.1 Patient Connection to Modes in JH NCCU—Illustration of how biological data modes (Table 16.1) connect through sensors (via the hospital network) through Main Monitor (GE Carescape (1)) or Connectivity Interfaces (Capsule Neuron Computing Hub (3)) and further to the Multimodality system. (1) Main Monitor (GE Carescape (1)) in a JH NCCU patient room. It collects modes (Table 16.1: vital signs, waveforms) via sensors that connect through module bins. Sensors (invasive and noninvasive, Ex: ICP monitoring devices) must be compliant to work with the Main Monitor. (2) Ethernet Ports. These interface the Main Monitor to the Hospital Network and further to the Multimodality system. GE Carescape (1) and Capsule Neuron Computing Hub (3) are always connected to these Ports. (3) Connectivity Interface (Capsule Neuron Computing Hub (3)) provides connection for devices that are not compliant with GE Carescape (1), to send data through the Hospital Network. Devices include: mechanical ventilators, pupillometers, near-infrared spectroscopy (NIRS) for brain oxygenation, leg compressors sensors and bed settings. The Capsule Neuron Computing Hub (3) can also extend device/sensor capacity in hospital rooms. (4) Optional electroencephalogram (EEG) Monitor in a JH NCCU patient room. It collects modes associated with electrical brain activities. (5) Patient in a bed with all the devices connected via sensors

16.5.3 Multimodality Monitoring

Multimodality Monitoring is defined as:

> …the simultaneous collection of data from multiple diverse (and complementary) sources associated with a single patient when no one single method can provide complete information [11].

Multimodality Monitoring (MMM) is the process and technology for handling input signals (modes) that represent physiologic functions and states. Modes may be raw signals or combinations/transformations of signals of different types, discrete, continuous, waveforms, periodic (Table 16.1). The MMM system provides a technical platform on which these transfromations of data modes can be realized into meaningful clinical information.

To be useful to clinicians, output must be presented in an integrated, time-synchronized format

Table 16.1 List of modes via connected devices and monitors (Fig. 16.1)

Abbreviation	Physiologic measurement (mode)	Device/data source
ABP	Arterial blood pressure	Sphygmomanometer or intra-arterial line
SpO2	Oxygen saturation	Pulse oximeter
ICP	Intracranial pressure	Probe or non-invasive method
ECG	Electrocardiogram (cardiac rhythm)	Non-invasive continuous method
EEG	Electroencephalogram (brain activity)	Non-invasive intermittent/continuous measurement
Vital signs	BP, RR, Pulse, Temperature	Intermittent/continuous bedside measurement (nursing data entry)
LOC	Level of Consciousness	Intermittent direct bedside measurement

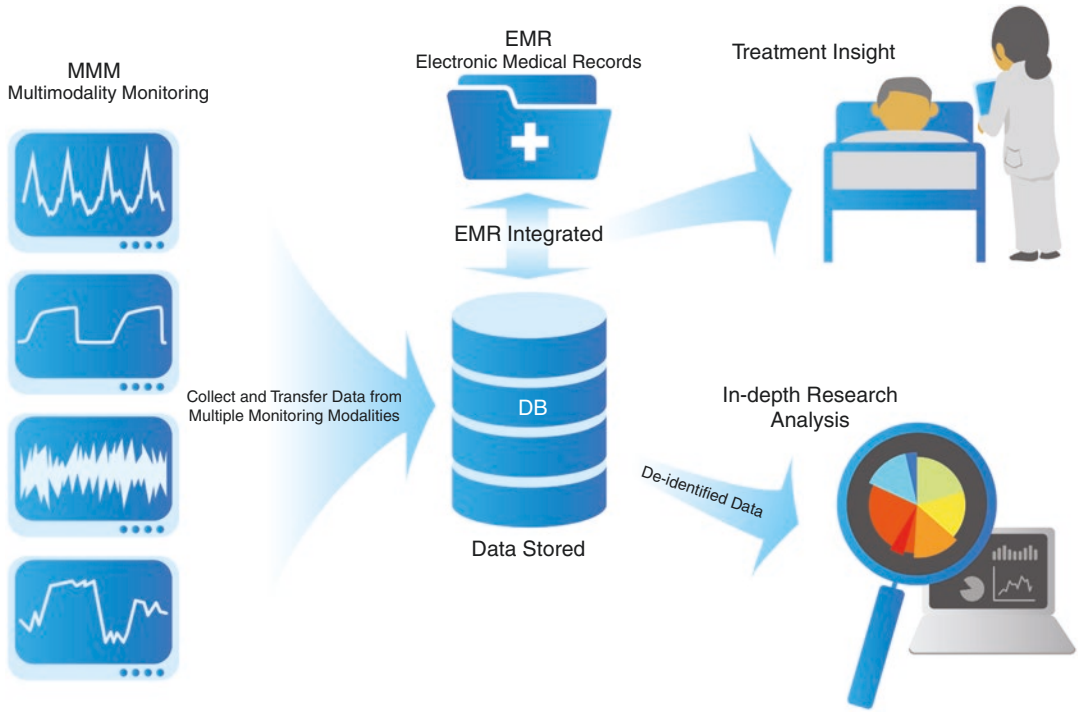

Fig. 16.2 The NCCU Data Ecosystem—Illustration of data creation and logical movement in the NCCU environment. Figure 16.3 shows the same layout from the perspective of the NCCU and hospital IT infrastructure. (1) MMM—Physiologic data from the patient (from Fig. 16.1) is collected by devices. (2) Data is organized and routed by MMM where it is needed (monitors, for calculation, for the EMR). (3) DB—Data is stored for use (clinical care, quality control, research) and linked to administrative data from the electronic medical record (EMR)

(Fig. 16.2) which reflects a shared mental model of clinical teams regarding a patient's neurologic and physiologic functions, hemodynamic, metabolic, and electrical subsystems, relevant to collective work and decision-making. Configurability of Multimodality Monitors/Displays is essential to providing a completely data-informed picture of a patient's clinical status.

Monitor and display interfaces can provide readily available quantitative, qualitative and/or trend data of physiologic parameters such as cerebral pressure, cerebral blood flow, brain tissue metabolism (oxygen use), and other functions. Neuro-intensivists are expected to understand the devices, sensors and technology involved in NCC MMM and how to interpret and use their outputs in clinical care [11].

As physiologic monitor displays become progressively complex, it becomes essential to understand their optimum deployment for multiple stakeholders [12] to optimize clinical usability [13] and patient safety [14].

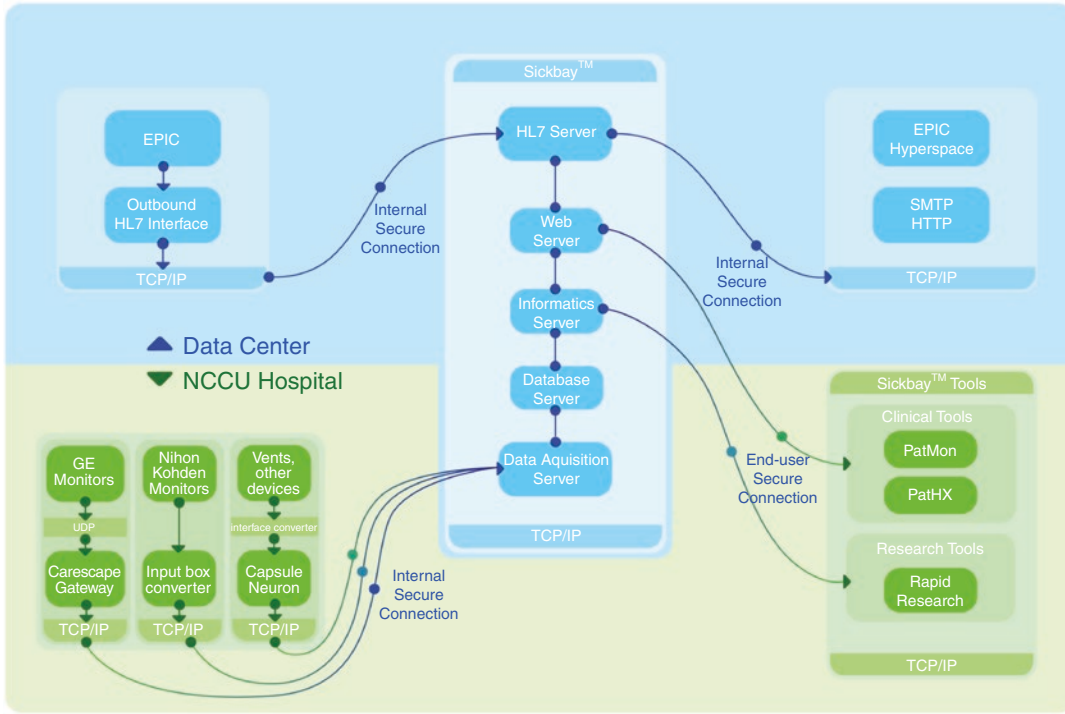

Fig. 16.3 Overview of JHH NCCU MultiModality data flow. Incoming patient data from NCCU bed monitors (lower left) is linked to patient-specific information from the hospital EMR (Epic, upper left) and combined in the MultiModality system (Sickbay™, center) for clinical use (Epic, upper right). Stored data is subsequently available from the hospital EMR (Epic) for clinical and research use through Sickbay™ tools (lower right)

In general, monitor displays can be classified according to the types of data they channel:

1. radiologic/imaging data (still and video)—high bandwidth with connection to picture archiving and communications systems (PACS), requires special rendering hardware/software
2. physiologic data - real time (continuous, intermittent and discrete), synchronous/asynchronous, trend data

16.5.4 Managing the NCCU Data Ecosystem

To control and direct available electronic patient data in the NCCU, it is necessary to assure accuracy/correctness, completeness, uniqueness, timeliness/relevance, validity and consistency of the data, as well as the integrity of its manipulation, presentation, and storage [15]. Clinical tools must be able to: (a) acquire and encode electronic data accurately and in real-time, (b) link/associated captured data to the correct patient metadata, (c) archive data for easy retrieval, (d) permit accurate (and timely) configuration of data transformations, groupings and displays for users, (e) allow users to control data manipulation and display for different uses (clinical, administrative, research), (f) detect and provide alerts of problems with respect to data flow/quality, and (g) connect to other data systems in an interoperable manner.

Historically, these functions were managed by "home-grown" applications built and maintained by dedicated clinical technology teams, and thereby NCCU data management systems were the province of large academic centers. More recently, integrated systems have been available commercially in service-based models (See Case Study) to streamline and simplify NCCU IT support.

16.6 Case Study: The Johns Hopkins Hospital NCCU

16.6.1 Introduction

The Johns Hopkins Hospital NCCU is a 24-bed ICU in a tertiary academic medical center in Baltimore, Maryland USA. It has been in continuous operation since 1983, providing comprehensive care for patients with neurologic injury and disease such as stroke, brain tumors and neuromuscular disease. The NCCU is one in a suite of ICUs that serves the Hospital, which is a Comprehensive Stroke Center and Center of Excellence in Neurocritical Care. It serves as a regional, national and international referral center for neurologic problems, with an accredited fellowship program in NCC. The NCCU provides care for 1500–2000 patients annually. The average length of stay (LOS) is 4 days; however, it is not unusual to encounter patients with over 100-day LOS. The overwhelming majority of NCCU patients (between 60% and 80%) are pre-operative and post-operative cases associated with an elective neurosurgery i.e., craniotomy. Another 20–40% of cases seen at NCCU are either Traumatic Brain Injuries (TBI) or cases related to Stroke. The JHH NCCU has a medical director, a nurse manager, clinical nurse specialists, and various levels of nursing staff seniority levels. Due to the academic nature of the JHH NCCU, physicians and nurses in training also are an integral part of the make-up of the NCC teams. Many nurses hold advanced certification in critical care and neuroscience nursing.

16.6.2 The Need for Multimodality NeuroMonitoring at Johns Hopkins

In 2017, a multidisciplinary team of medical, nursing, and engineering staff was tasked to design, implement, and deploy a data infrastructure to support and meet the needs of precision medicine in NCC, with overarching aims:

- To build an NCCU infrastructure for collecting high-resolution electronic clinical data
- To link incoming high-resolution-data with the institutional electronic health record (Epic)
- To create a workbench for advancing neurocritical care bioinformatics and research
- To establish a comprehensive, high-quality database of neuro-physiologic data from NCCU patients with respect to clinical outcomes
- To expand workforce, expertise and capacity in MultiModality NeuroMonitoring for development of tools and approaches for clinical care, prediction and research.
- To support research in clinical analytics to optimize neurocritical care:
  - To develop and implement algorithms and rules for predicting and preventing systemic and intracranial events
  - To construct analytic models of brain physiology and pathophysiology for developing new neurocritical therapies

16.6.3 Building the NCCU Electronic Infrastructure

The development of the NCCU data ecosystem began with the establishment of local standards for data.

collection (The NCCU Patient Bed [Fig. 16.1]) and a needs assessment (Problems Encountered and Approaches [Fig. 16.2]) to incorporate them into an architecture for control and archiving of collected data for multiple purposes.

16.6.4 The NCCU Patient Bed

The “patient bed” (Fig. 16.1) is the origin of electronic data (modes), collected through patient-connected sensors and devices. Each electronically controlled bed is equipped with a monitor GE Carescape (GEC) [16], a connectivity interface Capsule Neuron Computing Hub (CNCH) [17], used for sensor/devices not compatible with (GEC), and a clinical workstation linked to the JHH Clinical Intranet (including

EPIC [18]). Each patient room is designed to hold additional equipment as needed.

The GEC and CNCH receive data and signals from various sensors (intracranial pressure monitors, cerebral tissue oxygen and blood flow sensors, continuous EEG) and devices (targeted temperature management equipment, cardiac output estimation tools, mechanical ventilators, etc.). Captured data are grouped into streams that are transformed and forwarded to multiple displays via the hospital network and to (bedside and central) monitors, according to central patient identifier (via EMR).

16.6.5 Problems Encountered and Approaches Taken

An initial problem encountered was that the GEC, the preferred and established monitor in the NCCU, required GE-specific interfaces which were not universally supported by many sensors and devices. Issues such as synchronization of sampling frequencies, combinations of multiple non-compatible input signals, security requirements for connecting to the institutional network, and even an insufficient number of input ports per bed posed barriers.

First, to expand data input capacity and to bypass non-compatibility with GEC interfaces, a connectivity interface, the Capsule Neuron System (CNS, a commercial product) was employed, expanding capacity (to 6 devices per bed) and resolving some compatibility issues. Second, to address issues of compatibility due to synchronization, an agnostic FDA-approved, commercially available analytic platform, (Sickbay™, Medical Informatics Corporation [19]), was adopted (Fig. 16.3). This platform provided tools to integrate the streams of the NCCU data ecosystem from GEC and CNS with the institutional electronic health record (EPIC) (Fig. 16.3).

16.6.6 Timeline of JHH NCCU Multimodality System Implementation (Table 16.2)

Table 16.2 JH multimodality implementation timeline

2011–2016	Establishment of NCCU MMM goals. Assessment and testing of available multimodality systems, (for research purpose only)
2016–2017	Selection of MIC Sickbay™ as the JHH NCCU clinical MultiModality system
2017–2018	Incorporation and implementation (non-production) of Sickbay™ into the JHH NCCU
Oct 2018	Rollout (production) of Sickbay™ into the JHH NCCU (24 beds) for care and research
2019–2021	Integration of NCCU data input devices with Sickbay™
Early 2020	Establishment of NCCU research projects using the JHH NCCU Multimodality system
Summer 2020	Expansion of the MultiModality system to other ICUs at JHH: 260 beds
Summer 2020	JHH NCCU recognized as a Precision Medicine Center of Excellence
Early 2021	Extension of the MultiModality system to Operating Suites at five Johns Hopkins Hospitals

16.6.7 Ongoing Development and Cost/Benefits

Implementation of the MultiModality system for the JHH NCCU was undertaken with the goal of leveraging available electronic data to optimize NCC and to promote clinical NCC research. The costs of development of the system soon grew beyond those for maintenance and upgrading of the MultiModality system alone. Expanding data increased costs for integration of new devices, manpower (systems engineering/programming and administration/management) and storage. Two-thirds of the IT cost was associated with expansion and maintenance of data storage, systems engineering, administration, and hardware for device integration. Budgetary constraints limited initial work on the research component in favor of expanding the number of data elements collected from an ever-growing number of devices.

Some of the devices integrated into the system include:

- Mechanical ventilators from various manufacturers—May–July 2020
- Bispectral Index (BIS)—April 2020
- Near-infrared spectroscopy (NIRS)—Fall 2020
- Pupillometry device—Feb 2021
- Integrated electroencephalography (EEG)—Summer 2021.

During the 2020 COVID-19 pandemic, the described system was extended to other entities within the Johns Hopkins Health System, first to all ICUs (250 beds) and operating suites at the Johns Hopkins Hospital, and subsequently to connect the regional network of Hopkins hospitals. At the bedside level, the system helped mitigate COVID-19 exposure by limiting the need for direct contact between staff and equipment (via "plug-and-play" connections) and staff and patients (via remote patient monitoring).

16.6.8 Advancing NCC Research

The system provides a data-rich platform for NCC research. It collects 2GB of high-frequency binary data per patient per ICU day, managed by a central research data infrastructure—the Johns Hopkins Data Trust Committee. Access is controlled and managed by a central institutional review board and data oversight committee. Provisioned data brokers provide researchers raw data according to IRB approved protocols, in either de-identified or identified manner. Extracted data is provided to certified and trained researchers in a secure data environment for processing and storage.

Examples of NCCU research using data extracted from the MultiModality system include:

- Prospective Evaluation and Validation of a Non-invasive Sensor Device for Intracranial Pressure (ICP) Monitoring for Patients with Neurologic Disease
- Non-invasive Monitoring of Cerebral Autoregulation in Sepsis using Cerebral Oximetry
- Blood Pressure Variability in Patients with Intracranial Hemorrhage
- Cerebral Regional Oxygen Saturation in Comatose Patients Using (non-invasive) Near Infrared Spectroscopy (NIRS)
- Cerebral Regional Oxygen Saturation in Sepsis Using NIRS
- Validation of a Method to Measure Vital Signs With Contact-Free Video Biometrics
- Leveraging Invasive Neurophysiologic Monitoring for Endotype (Condition Subtype) Discovery in Neurocritical Care

16.7 Conclusions

Intensive Care Units and NCCUs (in particular) are data-rich environments that provide challenges and opportunities for using technology to improve the care and outcomes for critically ill patients. MultiModality Monitoring is technology that provides integration and organization to this high-volume, high-velocity, high-variety data environment to reduce information overload for clinical decision-making and to provide insights into patients' conditions at the point of care.

Questions and Answers

1. What is Multimodality Monitoring and what is its central importance in sharing information in Neuro (and other forms of) Critical Care Medicine?
   (a) Multimodality Monitoring (MMM) is the process and technology for handling electronic input signals that represent (neuro) physiologic functions and states. Modes may be raw, combined/transformed, discrete, continuous, periodic or waveform of signals of different types.

   The purpose and central importance of MMM is to reliably collect, organize and transform data into timely and meaningful clinical information. To be useful to clinicians and teams, MMM output must be presented in an integrated, time-synchronized format that represents a shared mental model of a patient's neuro-

logic and physiologic functions and state for collective work and decision-making.

2. What were the issues JH NCCU encountered while building the NCCU Electronic Infrastructure solutions for Multimodality Monitoring?
   (a) An initial problem encountered was that the GEC, the preferred and established monitor in the NCCU, required GE-specific interfaces which were not universally supported by many sensors and devices. Other issues linked to the project were: synchronization of sampling frequencies, combinations of multiple non-compatible input signals, security requirements for connecting to the institutional network, and even an insufficient number of input ports per bed posed barriers.

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Data-Driven Disease Progression Modeling

17

Kenney Ng, Mohamed Ghalwash, Prithwish Chakraborty, Daby M. Sow, Akira Koseki, Hiroki Yanagisawa, and Michiharu Kudo

Abstract

This chapter provides a comprehensive overview to data driven disease progression modeling techniques. It adopts a broad approach to disease progression, focusing on all computational methods able to model any temporal aspects of disease progression. Consequently, we have focused on three classes of analysis: staging and trajectory estimation analysis to better understand the course of a disease, predictive classification analysis for important disease related event prediction, and time to event analysis with survival models to estimate when clinically significant events are expected to occur during the progression of a disease. We describe the state of the art in each of these classes, together with discussions on challenges and opportunities for additional research.

Keywords

Disease progression modeling · Trajectory models · State-based models · Predictive modeling · Time-to-event modeling · Survival analysis · Censoring

Learning Objectives

On completion of this chapter, the reader should be able to:

- Define and describe Disease Progression Modeling (DPM) and reasons it is of importance and value in promoting the Quadruple Aim of improving health and health care
- Articulate the types of questions for which DPM may provide insights and solutions at the individual and population health levels
- Distinguish Trajectory and State-Based approaches to DPM and their application to predicting "time-to-event" and survival in disease

K. Ng (✉)
IBM Research, International Business Machines Corporation, Cambridge, MA, USA
e-mail: kenney.ng@us.ibm.com

M. Ghalwash · P. Chakraborty · D. M. Sow
IBM Research, International Business Machines Corporation, Yorktown Heights, NY, USA
e-mail: Mohamed.Ghalwash@ibm.com; Prithwish.Chakraborty@ibm.com; sowdaby@us.ibm.com

A. Koseki · H. Yanagisawa · M. Kudo
IBM Research, International Business Machines Corporation, Tokyo, Japan
e-mail: akoseki@jp.ibm.com; yanagis@jp.ibm.com; kudo@jp.ibm.com

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17.1 Introduction

Chronic diseases are becoming more prevalent across the globe and are known to drive rising costs of healthcare. Understanding the various stages and factors that drive the progression of these chronic conditions is of interests to many stakeholders within the healthcare ecosystem. From a patient and provider perspective, modeling the progression of chronic diseases opens the door for early diagnosis, more accurate assessment and improved personalized care with better decision support. From a payer perspective, such modeling could help improve population health management solutions through better patient segmentation, and lead to better informed value-based pricing. From a pharma perspective, understanding how diseases progress is critical to drug development: it can be used to develop trial simulation tools for enhanced trial design and trial enrichment tools to help target the right patient population at the right disease progression stage.

Disease Progression Modeling (DPM) refers broadly to efforts from the research community to develop computational models characterizing the progression of disease at both the population and individual levels. Such models are focusing on temporal aspects of the disease, how it evolves with time, how it leads to important clinical events, including hospital (re-)admissions, increased disease severity, and health complications including death. Following [1], these computational efforts can be classified in three groups: systems biology, empirical and semi-mechanistic. System biology models encapsulate mathematical models of biological, pathophysiological, and pharmacological processes characterizing the progression of diseases. They often make heavy use of sets of differential equations aiming to model diseases and patients as dynamical systems. Empirical models are completely data driven, derived using AI, Machine Learning, and statistical methods to characterize disease progression from various patient related observations. Semi-mechanistic models are essentially hybrid models leveraging both empirical and system biology approaches for the modeling of disease progression.

In this chapter, we focus exclusively on empirical, or data driven approaches to disease progression modeling. With the wide-spread use of electronic health records and proliferation of various ways to sense patient health (e.g., through Internet of Things (IoT) technologies or even through sources of social determinants of health), health informatics researchers have been developing a plethora of data driven ways to model disease progression. These techniques can be portioned into three groups. The first group called staging and trajectory analysis contains methods that attempt to derive meaningful representations (as trajectories or states) of the underlying disease progression characterizing how patients progress during disease. The second group called predictive modeling aims to develop innovative explainable AI modeling methods to predict future patient states and adverse events, including disease onset, hospital readmission, mortality, and onset of complications. The third group called time to event modeling aims at estimating the time of occurrence of various important events that relate to a disease, such as time to complications, time to hospital admissions or more generally, time to deterioration according to well defined disease states.

This chapter surveys all these empirical disease progression modeling techniques. After describing a taxonomy for these methods, we describe various analytical approaches that have shown some success in each of these groups, before closing the chapter with concluding remarks.

17.2 Taxonomy of DPM Solutions

The healthcare industry has adopted a quadruple aim framework [2] to drive overall improvements and help organizations be more effective. This framework consists of four aims seeking to:

1. Improve population health
2. Enhance patient experience
3. Reduce the cost of care
4. Improve the work life of providers

Solutions powered by disease progression models are helping institutions get closer to these aims. In this work, data driven disease progression modeling refers broadly to all AI techniques applied to clinical data to describe the time course of disease status to track and predict disease severity over time, including related adverse events associated with the disease progression. AI models describing progression along these lines can be categorized in three groups defined by the type of insights that they provide:

1. AI providing insight on the stages and trajectories defining disease progression
2. AI providing insight on the occurrence and prediction of disease related events
3. AI providing insight on the timing of disease related events

Clearly, improving the life cycle of drug development is having an impact on all these four aims. The COVID-19 pandemic has stressed the importance to develop drugs at increased speeds to urgently address this population health crisis, while enhancing patient experience, reducing the cost of care (e.g., with less hospital admissions and ICU stays) while improving the work life of providers with less stress on the health system. To shorten the drug development cycle, pharmaceutical institutions have been researching disease progression models to inform their decisions in this cycle. In fact, one can argue the attribution of the genesis of research in this area to the pharmaceutical industry as researchers have been developing and integrating staging disease models with pharmacokinetics-pharmacodynamic models for at least three decades for drug development [1]. For these institutions, disease progression models can be used in many ways during the drug development process. Data driven models are particularly well suited for clinical trial design and enrichment, to help identify cohorts of patients at the right stage in the progression to evaluate the efficacy of experimental treatments. The use of such models in the pharmaceutical industry has been recognized as an important step towards modern drug development by the US FDA, prompting them to introduce in 2004 the Critical Path Initiative [3].

From a payer perspective, disease progression modeling promises to help health insurance companies provide better patient care management services and optimize their ROI. The COVID-19 pandemic has underlined the importance for payers to provide enhanced care management capabilities to their members to reduce stress on the health system and reduce costs [4]. From a disease progression standpoint, better understanding of patient risk forecasts through predictive and time to event analysis and patient trajectories may lead to early interventions aimed at improving health outcomes and avoiding costly situations with the management of patients in advanced disease stages. Capturing and characterizing homogeneous trajectories of patients is desired. Furthermore, understanding factors and actionable levers that can be used to control or even alter disease progression is also sought.

Providers see a lot of value in disease progression modeling mostly at the individual patient level. Looking back at the healthcare quadruple aims, disease progression modeling may help in building provider solutions able to not only enhance overall patient satisfaction through better outcomes but also boost provider's productivity and reduce burn out. Decision support tools driven by progression models able to ingest the large amount of clinical data to provide staging, predictive risk scores and time to event insights may reduce data overload problems suffered by providers by distilling these data sets into actionable insights delivered effectively at the point of care. These tools are allowing providers to better understand their patients thus enhancing the patient doctor relationship, driving better outcome and overall satisfaction.

17.3 Staging and Trajectory Estimation

In this section, we review data-driven disease progression modeling approaches that facilitate disease staging and disease trajectory analysis. At a high level, these methods model observed disease dynamics and attempt to derive meaning-

ful representations of the underlying disease progression as it evolves over time. The models are usually trained in an unsupervised manner since there are no ground truth labels of the actual underlying disease stages or trajectories in the observational data. Indeed, the primary goal of fitting these models is to discover underlying disease progression patterns captured in the data. Once trained, these models can help answer a number of useful questions at both the population level and the individual patient level. Population level questions that can be addressed include:

- What are the different trajectories for the disease?
- What are the most/least common trajectories?
- What are the underlying progression states for the disease?
- What clinical and biomarker characteristics are associated with each state?
- What are the possible state transitions?
- How much time do patients spend in each state?
- What are the most/least common progression pathways?

Individual patient level questions that can be addressed include:

- What is the patient's most likely trajectory?
- What is the patient's most likely trajectory value in the future?
- What is the patient's most likely historical/past disease progression pathway?
- What is the current disease state for the patient?
- What is the most likely next disease state for the patient?
- What is the patient's most likely future disease progression pathway?

The remainder of this section is organized as follows. First, we begin with a description of the data used to train these types of disease progression models. Next, we review the different modeling approaches that have been developed (Fig. 17.1) and highlight some representative studies of each (Table 17.1). Then we summarize the applications in terms of disease focus and the clinical tasks addressed. Finally, we discuss some open challenges and possible future directions.

17.3.1 Data

Many types of healthcare related data can be used to fit and train data driven trajectory and staging based disease progression models. The data can range from sensor signals measured on individual patients, to longitudinal clinical measurements collected over a sequence of clinical visits for a specific cohort of patients, to aggregate summary statistics from multiple studies on different patient

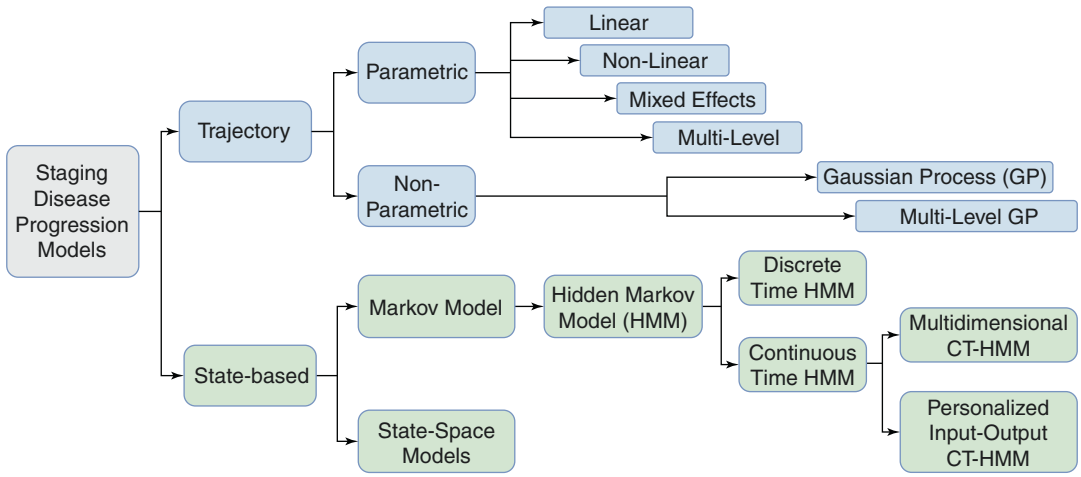

Fig. 17.1 Taxonomy of data driven trajectory and staging based disease progression modeling methods

Table 17.1 Summary of the applications of the trajectory and state-based disease progression models in terms of disease areas, methods, and the clinical tasks addressed

Disease area	Method	Clinical tasks	Reference
Alzheimer's Disease (AD)	Trajectory (nonlinear mixed effects)	Predict future ADAS-Cog scores	[5–7]
	State-based (DT-HMM)	Characterize disease progression patterns from observed biomarker values	[8]
	State-based (3D CT-HMM)	Characterize disease progression patterns from observed biomarker values	[9]
Huntington's Disease (HD)	Trajectory (linear, quadratic)	Predict future UHDRS scores	[10]
	State-based (CT-HMM)	Characterize disease progression patterns from observed UHDRS scores	[11]
Parkinson's Disease (PD)	State-based (PIO-HMM)	Characterize disease progression patterns from observed UPDRS scores	[12]
Amyotrophic Lateral Sclerosis (ALS)	Trajectory (clustering)	Predict future ALSFRS-R scores	[13]
	Trajectory (sequence mining)	Identify deterioration change patterns	[14]
Type 1 Diabetes (T1D)	State-based (CT-HMM)	Characterize disease progression patterns from observed islet autoantibody measurements	[15, 16]
Chronic Kidney Disease (CKD)	Trajectory (GP)	Predict future disease biomarker values	[17]
Chronic Obstructive Pulmonary Disease (COPD)	State-based (CT-HMM)	Characterize disease progression patterns from observed comorbidities	[18]
	State-based (CT-HMM)	Characterize disease progression patterns from observed facility utilization data	[19]
Glaucoma	State-based (2D CT-HMM)	Characterize disease progression patterns from observed biomarker values	[9, 20]
Multiple Sclerosis (MS)	Trajectory (Multilevel)	Estimate the EDSS trajectory over time	[21]
Scleroderma	Trajectory (GP)	Predict future disease biomarker values	[22]
Physiological data	Trajectory (multitask GP)	Impute and forecast physiological time series data	[23, 24]
Cystic Fibrosis (CF)	State-based	Characterize disease progression patterns from observed biomarker values	[25]

populations. Here we focus on longitudinal clinical measurements which can include biomarkers and laboratory test results (e.g., estimated glomerular filtration rate (eGFR) for chronic kidney disease (CKD) [17], predicted forced vital capacity (PFVC) for interstitial lung disease [22], islet autoantibody positivity for type 1 diabetes (T1D) [16]), treatment drug usage (e.g., Levodopa for Parkinson's Disease [26]), and disease severity assessment scores (e.g., Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) [27], Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) [28], Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS) [29], Unified Huntington's Disease Rating Scale (UHDRS) [30], Expanded Disability Status Scale (EDSS) [31]).

These longitudinal measurements are collected from a cohort of patients that are observed over a defined follow-up time. Depending on the disease condition of interest, the duration of the follow-up time can range from hours to years. For each patient, multiple measurements are collected, typically at irregular intervals, over the course of the follow-up. Even clinical studies with well-defined visit schedules will likely have delays or missed visits, and observational data from electronic health records will only capture events when the patient has an encounter with the health system. In addition, missing values or

errors in the recorded values are not uncommon in this kind of data [32]. Another challenge is that the data for any particular patient is not complete in the sense of only covering a portion of the entire disease progression trajectory. Data from many different patients would need to be "stitched together" to obtain a comprehensive characterization of the whole disease progression process. In addition to longitudinal clinical measurements, other patient characteristics, such as genetic, demographic, and social-economic information, may also be available to be incorporated into the modeling. Some example data sets that have been used for disease progression modeling include:

- Alzheimer's Disease Neuroimaging Initiative (ADNI) [33]
- Parkinson's Progression Markers Initiative (PPMI) [34]
- Pooled Resource Open-Access ALS Clinical Trials (PRO-ACT) [35]
- Answer ALS [36]
- Medical Information Mart for Intensive Care (MIMIC) [37]
- Type 1 Data Intelligence (T1DI) [16]
- Electronic Health Records (EHR) [18]

17.3.2 Methods

As previously mentioned, the primary goal of data driven trajectory and staging based disease progression modeling is to discover underlying disease progression patterns captured in the data. This is typically done by specifying a model form with a set of parameters that are learned by fitting the model to observed temporal data related to the disease dynamics and progression (e.g., known relevant biomarkers or validated disease severity assessment scores) from a population of patients. Once trained, the model can then be used to gain insight into disease progression and can be used to answer some of the population and patient level questions listed earlier. Many different model forms have been used in disease progression modeling. At a high level, as illustrated in Fig. 17.1, they can be divided into two categories: trajectory models and state-based models.

Trajectory models focus on fitting a functional form to the observed data to obtain a model that can describe the data well. Disease progression is then characterized as the "shape," "path," or "trajectory" of the observations over time. State-based models focus on learning meaningful underlying disease states and transitions between the states that can describe the observed data well. Disease progression is then characterized by sequences of the states over time. For both trajectory and state-based models, several variations in the model form have been proposed in attempts to better account for heterogeneity in terms of the observed symptom manifestations and disease progression as well as the effects of interventions (i.e., drugs).

17.3.2.1 Trajectory Models

Among the simplest trajectory models are ones where the functional form is linear:

$$y_{ij} = \beta_0 + \beta_1 * t_{ij} \tag{17.1}$$

where y_{ij} and t_{ij} are the disease status score and the time variable, respectively, for individual i at time point j, β_0 is the baseline (at time 0) disease status score, and $\beta_1$is the slope of the disease status score over time (i.e., the rate of disease progression). A separate regression model can be fit to the temporal observations for each individual to produce patient specific models. The estimated values of the model coefficients (β_0 and β_1) can then be used to characterize the trajectory of the patient's disease progression (e.g., started mildly and then declined rapidly or started severely and then declined slowly, etc.). For example, linear and quadratic regression models were used to predict the two-year progression of Huntington's disease (HD) in individual patients with good accuracy [10]. The models can also be fit to data from multiple patients instead of a single patient to capture the average trajectory of a specific patient population.

Multi-level trajectory models attempt to model both the population and individual levels simultaneously using the following functional form:

$$y_{ij} = \beta_0 + u_{0i} + (\beta_1 + u_{1i}) * t_{ij} + e_{ij}$$

where y_{ij} and t_{ij} are the disease status score and the time variable, respectively, for individual i at time point j, β_0 is the mean baseline disease status score and $\beta_0 + u_{0i}$ is the i^{th} individual's baseline disease status score, and β_1 is the mean slope over time and $\beta_1 + u_{1i}$ is the i^{th} individual's slope over time. The $\beta_k (k = 0, 1)$ are known as the fixed effects and are estimated over the entire patient population. The $u_{ki} (k = 0, 1)$ are the individual-level random effects and assumed to be normally distributed with mean zero and an unstructured covariance matrix D_u. They measure the deviation of the individual-specific line from the population mean line. The e_{ij} are the observation-level random effects and assumed to be normally distributed with mean zero and variance σ^2. They measure the deviation of observations about the individual-specific line. These additional components in the functional form allow the model to better capture heterogeneity in the observations at the individual patient level. A multi-level model of this form was used to estimate the EDSS trajectory over time for patients with multiple sclerosis [21].

More complex trajectory models can include nonlinear functional forms. For example, generalized logistic functions of the following form:

$$y_j = \frac{\beta_0 * N}{\left[\beta_0^{\alpha} + \left(N^{\alpha} - \beta_0^{\alpha}\right) * e^{-\alpha r t_j}\right]^{1/\alpha}}$$

have been used to characterize a sigmoidal progression of ADAS-Cog scores in Alzheimer's patients [5, 7]. Here, y_j is the disease status score at time point j, β_0 is the baseline disease status score, N is the maximum possible observed disease status score, r is the intrinsic rate of disease progression, t_j is time point j, and α is the shape factor allowing for a non-central inflection point of disease progression. This function describes an asymmetric, S-shaped curve with a nonlinear rate of disease progression that increases when y_j is below the inflection point and decreases when y_j is above the inflection point.

Mixed-effects nonlinear regression models that incorporate terms to account for treatment effects have also been used to model the ADAS-Cog score in Alzheimer's disease progression [6]. In this case, the trajectory functional form looks like:

$$y_j = \beta_0 + \beta_1 * t_j + E_d(t_j) + E_p(t_j)$$

where y_j and t_j are the disease status score and the time variable, respectively, at time point j, β_0 is the baseline disease status score, β_1 is the rate of disease progression, and $E_d(t_j)$ and $E_p(t_j)$ are nonlinear functions incorporating the drug and placebo effects, respectively, at time point j. In this model, the drug treatment effects can be temporary (e.g., symptom relief) or can be permanent (e.g., alter disease progression).

There are other ways to handle heterogeneity in disease progression trajectories. One approach is to first partition the patients into clusters that are more homogeneous and then to train different models on each of these patient clusters separately. For example, in [13], ALS patients were first split into groups of fast and slow progression based on the difference in ALSFRS-R values between the first and last visit divided by the time between them. Then two separate non-linear Weibull models were trained, one for the slow progression group and another for the fast progression group. Another example is a two-step approach used to discover deterioration patterns in ALS patients [14]. First, sequence clustering was performed based on multi-dimensional dynamic time warping (DTW) to handle variable length observations and variable time intervals between observations (i.e., the number of and timing between visits) and hierarchical clustering to group patients with similar sequences. Second, within each cluster of similar patients, sequential pattern mining (SPADE) was performed to discover common deterioration change patterns and a classifier was trained to predict the next value in the sequence.

All the functional forms described above have a finite number of unknown parameters (in the linear regression example, these are the β coeffi-

cients of the model) that need to be estimated as part of the data fitting process. Such models are called parametric. As one can imagine, there is an infinite number of possible mathematical formulas to choose from. Prior domain knowledge is typically needed to help select the appropriate formula or family of formulas to use. However, there are many situations where there is little, or no, prior domain knowledge regarding appropriate parametric models to use. In these scenarios, Bayesian non-parametric modeling approaches can be used. Conceptually, these non-parametric approaches allow one to work mathematically with the infinite space of all functions that have a specified set of characteristics (e.g., smoothness, continuity, time scale, value range, etc.) but do not have an explicit set of parameters to be inferred (although they do have hyper-parameters that have to be learned). There are probability distributions over this function space and the goal of fitting the model to the data is to refine these distributions to focus on regions of the function space that are best able to model the observed data. These models can handle irregularly sampled observations and missing data.

One of the most popular non-parametric models is Gaussian Processes (GPs) and it has been used extensively for time-series data analysis [38] and has been applied to model disease progression. For example, multivariate longitudinal clinical data from vital signs [23] and from the Intensive Care Unit [24] were modeled using multitask GPs to enable accurate imputation and forecasting of the time series data.

Multi-level (hierarchical) extensions to GPs have also been developed and applied to model disease progression. In one study, a hierarchical GP model with three levels (population, subpopulation, and individual) was developed to directly address common sources of heterogeneity observed in complex chronic diseases [22]. It was used to model the disease activity trajectory of the predicted forced vital capacity (PFVC) measure for interstitial lung disease in scleroderma patients. This multi-level GP model was extended to support multi-task outputs by using a highly structured mean function to model each longitudinal variable for each individual patient [17]. The means were made dependent through shared latent variables. It was used to model the trajectories of six biomarkers (estimated glomerular filtration rate (eGFR), serum albumin, serum bicarbonate, serum calcium, serum phosphorus, urine albumin to creatinine ratio (ACR)) for chronic kidney disease (CKD) patients and used to make predictions about the future trajectory of their disease severity.

17.3.2.2 State-Based Models

State-based models focus on discovering and characterizing stages of disease progression by learning meaningful underlying disease states, the observations associated with each state, and the transitions between the states that describe the observed longitudinal data well. Disease progression can then be characterized by sequences of the discrete states over time. The most popular probabilistic state-based model is the Markov model which can be used to model data for which (1) the probability density function generating the observation depends on the state, and (2) the states follow a Markov process, i.e., future states depend only on the current state and not on the events that occurred before it. If the data observations can completely determine the state of the system (i.e., the states are "fully observable"), we have a Markov Chain model. If, on the other hand, the data observations are related to the state of the system but are insufficient to precisely determine the state (i.e., the states are "partially observable"), we have a probabilistic hidden Markov model (HMM) [39]. HMM models are well suited for modeling disease progression from observational data. They have a flexible framework that can accommodate different possible progression pathways. Prior domain knowledge and constraints can easily be incorporated into the model. They include probabilistic models that can describe the stochastic variability in the individual observations and in the sequence of observations. From the data perspective, HMMs can be trained from data with no ground truth labels (i.e., unsupervised). They also provide natural handling for noisy measurements and missing data. In addition, no explicit data alignment is needed. The model will automati-

cally determine which states are best associated with the data. This means that data from a subject regardless of where they are in the disease progression journey can be used to train the model. The model can "stitch together" data from many different patients to obtain a characterization of the longitudinal disease progression process. The HMM describes sequential data through a series of transitions between hidden (or latent) states, with each state describing distinct characteristics of the observed data instances. As shown in Fig. 17.2, An HMM has the following components: (1) a set of hidden states, (2) a transition model which specifies the possible transitions between those states and the probability of those transitions which governs how the states evolve in time, and (3) an observation model which is a probability density function of multiple measures that describes the manifestation of each state in the observed space.

The number of hidden states in an HMM model, M, is a hyper-parameter that needs to be specified and depends on the specific application. For diseases that have widely accepted staging definitions, M can be determined based on prior clinical domain knowledge. However, for many diseases where the staging is less well understood, data-driven approaches can be used to determine the appropriate number of hidden states. Model selection via cross validation based on fitness measures is commonly used. For example, the development dataset is first split into a training set and a testing set. Next, a series of HMM models with various values of M are built on the training set. Each model is then applied to the test set to calculate the fitness measure. The model with the best fitness measure provides the best fit for the data, and its corresponding M is chosen as the optimal M Different fitness measures have been used. These can include the predictive log-likelihood on a held-out test set or penalized-likelihood criteria such as the Akaike Information Criteria (AIC) or Bayesian Information Criteria (BIC) that combine log-likelihood and model complexity measures [40].

The transition model, Q, is an $M \times M$ matrix that specifies the probability of transitioning between the hidden states. Different types of disease progression can be specified by imposing various constraints on the structure of this matrix, as illustrated in Fig. 17.3. For example, a completely unconstrained Q specifies a "full progression model" where a patient in any disease state can progress/recover to any other state. A Q with all the lower triangular elements equal to 0 specifies a "forward progression model" where the disease can only get worse, and the progression cannot be reversed. A Q with only the diagonal elements and the first L upper off-diagonal elements not equal to 0 specifies an "L-th order forward chain progression model" where the disease can only progress forward to the next L states at any time. When $L = 1$, it is referred to as a "forward chain progression model." The most appropriate transition model needs to be determined based on prior domain knowledge or pragmatic assumptions about the target disease.

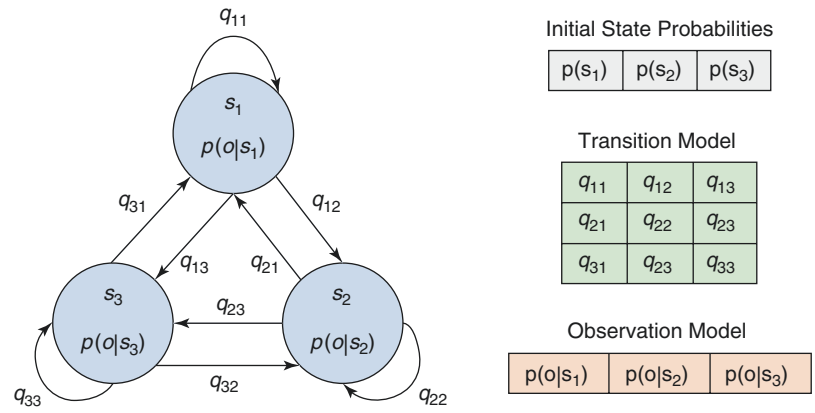

Fig. 17.2 A probabilistic hidden Markov model (HMM) with three hidden states, initial state probabilities, a transition model, and an observation model

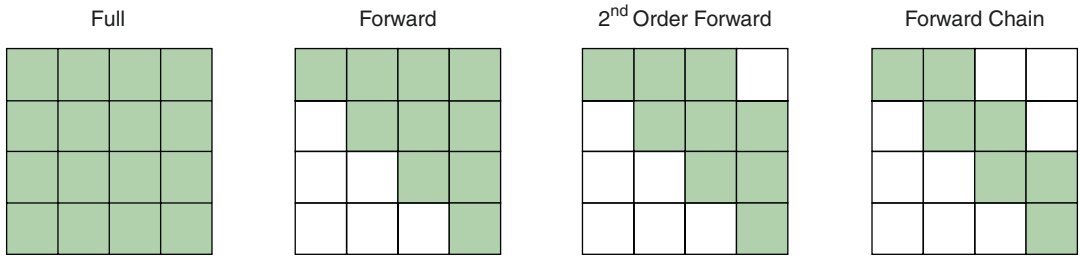

Fig. 17.3 Illustrative HMM transition models Q: full progression, forward progression, second order forward chain progression, and forward chain progression. The green shaded q_{ij} matrix entries are non-zero; the white entries are zero

The observation model in each state is a multi-dimensional probability density function that describes the observed data associated with that state. It specifies the probability of the observation given the hidden state. The choice of the probability distribution will depend on the characteristics of the observed data. For example, if the observations are continuous, then Gaussian distributions are appropriate. However, if the observations are Boolean or categorical, then Bernoulli or multinomial distributions may be more appropriate.

The parameters of the HMM model (which includes the transition model, the observation model, and the initial state probabilities) can be efficiently estimated by fitting it to the longitudinal training data by maximizing the data likelihood using the iterative Expectation-Maximization (EM) algorithm [41].

Once the HMM disease progression model is trained, it can be used to help answer questions and draw useful insights at both the population level and the individual patient level. First, the trained HMM can be introspected to obtain population level insights. For example, the states can be examined to answer the question "What are the underlying progression states for the disease?" The observation model for each state can be examined to help answer the question "What clinical and biomarker characteristics are associated with each state?" The transition model can be examined to help answer the questions: "What are the possible state transitions?", "How much time do patients spend in each state?" and "What are the possible progression pathways?" Next, patient data can be processed by the trained HMM to obtain both population level and patient level insights. Given the longitudinal observations for a patient, the HMM can associate a state to each observation to produce the most likely temporal state sequence for each patient. This sequence can then be analyzed to provide patient level insights such as "What is the patient's (past) disease progression pathway?" and "What is the patient's current disease state?" Analyzing the state sequences for a population of patients can help answer the population level questions "What are the most common progression pathways?" and "What are the least common progression pathways?" The state sequences can also be clustered to quantify the variability and heterogeneity in the observed progression pathways. In addition to state sequences, posterior probabilities of state assignment can be computed for each observation which can be used to quantify the uncertainty of the state assignments. Finally, predictions of future disease states and future observation values can be made by leveraging intermediate results from the model to help answer the questions "What is the most likely next disease state for the patient?", "What is the patient's most likely future disease progression pathway?", and "What will the patient's disease status score be one year from now?"

Several different types of HMMs have been developed and applied to model disease progression. One is the discrete time HMM (DT-HMM) which assumes that the observed data is sampled at fixed, regular, discrete time intervals and that each observation is associated with an instantiated hidden state variable (Fig. 17.4a). The transition model Q for a DT-HMM contains the state

transition probabilities at each time step. A six state DT-HMM model was trained on the ADNI data set to develop a disease progression model for Alzheimer's Disease [8]. The transition model only permitted single step forward, single step backward, and self-loops, and the observation model consisted of continuous Gaussian mixture distributions to model biomarkers derived from brain MRI images.The fixed sampling rate assumptions that underlie the DT-HMM make it a sub-optimal model choice for data that is distributed irregularly in time, such as data collected from observational studies or extracted from electronic health records. In these data, observations are only recorded when the patient has an encounter with the health system. To better handle irregularly sampled temporal data, continuous time HMM (CT-HMM) models have been developed [16, 18]. The CT-HMM is an HMM in which both the transitions between the hidden states and the arrival of the observations can occur at arbitrary times (Fig. 17.4b). In other words, not only are the hidden states unobserved, but the transition times of the hidden states are also unobserved. In the CT-HMM, the transition model Q specifies a transition generator matrix. The $(i,j)^{th}$ element of Q, denoted as Q_{ij} characterizes the intensity of instantaneous transition from disease state i to disease state j, for $i \neq j$. The ith diagonal element $Q_{ii} = -\sum_{i \neq j} Q_{ij}$ and the row sums of Q equal to 0. The transition probability matrix with time parameter t is denoted as $P(t)$ and is computed by taking the matrix exponential of Q: $P(t) = expm(t * Q)$. The $(i,j)^{th}$entry of $P(t)$, denoted as $P_{ij}(t)$, is the probability of being in state j at time $t\_0 + t$) in the future, given that the state at time t_0 is i.

A CT-HMM disease progression model for Chronic Obstructive Pulmonary Disease (COPD) with 6 states, a forward progression transition model, and a bipartite noisy-or Bayesian network observation model was trained on electronic health record data [18]. The goal was to understand the progression trajectory of COPD through the onsets of associated comorbidities. Another study tried to understand the progression of COPD via healthcare facility utilization events [19]. In this case, a 4 state CT-HMM with a forward chain transition model and a multinomial observation model was trained on healthcare administration data. A 9 state CT-HMM with a second order forward chain transition model and a Gaussian observation model was trained on prospective observational study data to characterize disease progression patterns for Huntington's Disease (HD) from observed UHDRS scores [11].

An 11 state CT-HMM with a forward chain transition model and a Bernoulli observation model was trained on prospective observational study data to identify characteristics of type 1 diabetes (T1D) progression based on islet autoantibody biomarkers [16]. An interactive visualization tool was developed to help facilitate understanding and analyzing the HMM based disease progression model [15]. The study was able to classify children into three independent

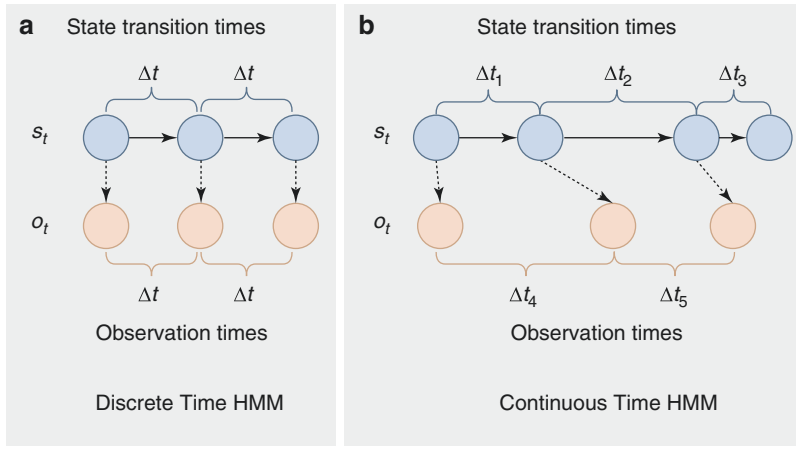

Fig. 17.4 (**a**) Discrete Time HMM. The state transitions s_t and observations o_t occur at fixed time intervals Δt. (**b**) Continuous Time HMM. Both the state transitions s_t and observations o_t occur at irregular time intervals Δt_i and can be asynchronous

biomarker-based progression trajectories and found associations between these trajectories and speed of progression to T1D, genetic background, and demographic profiles.

CT-HMMs have been extended in several directions. Multi-dimensional CT-HMMs have been developed to allow the simultaneous modeling of disease progression along several different dimensions (e.g., structural, and functional). This is especially useful if the time courses of progression in the various dimensions are different. For example, 2D CT-HMMs were used for glaucoma progression modeling given longitudinal structural and functional measurements [9]. In this case, many states (105) with Gaussian observation models were used to represent a 2D-grid state space defined by successive value bands of functional and structural severity. Since the glaucomatous damage is typically irreversible, the transition model only allowed a state to transition to another state with increased degeneration in either or both dimensions. A 3D CT-HMM with 277 states was used to model disease progression for Alzheimer's Disease along clinical, imaging, and biochemical dimensions using the ADNI data set [20]. The goal of this study was to quantify the multi-dimensional temporal interactions between the three types of biomarkers as the disease progressed over time.

To improve the modeling of heterogeneity in the disease population, CT-HMMs have been extended to be able to learn personalized and medication aware disease progression models. This personalized input-output CT-HMM (PIO-HMM) model can account for personalized state effects, personalized medication effects, state-based medication effects, or any combination thereof [12]. An 8 state PIO-HMM with Gaussian observation models and a forward progression transition model was used to model the progression of Parkinson's Disease (PD) from observed UPDRS scores and records of non-disease modifying medication use (e.g., Levodopa) from the PPMI data set.

More complex probabilistic models that relax the first-order Markovian assumption have also been developed. One "attentive state-space model" method explicitly considers information from the past (e.g., via attention mechanisms) to influence future disease states [25]. This would allow personalization of the progression dynamics across patients unlike in conventional HMMs where all patients in the same current disease state will have identical predicted future disease states. Such a model with 3 states, Bernoulli and Gaussian observation models, and a non-Markovian attention mechanism driven transition model was used to model the progression of Cystic Fibrosis (CF) based on lung function biomarker data from the UK Cystic Fibrosis Trust [42].

We note that there has been much related work on models that just predict future disease status (e.g., a future ALSFRS-R score or a future eGFR laboratory test value) without attempting to characterize the trajectory or states of the disease qualitatively or quantitatively as it progresses. These include models that leverage machine learning [43], multi-task [44, 45], and deep learning [46] methods. Prediction-focused disease progression models are covered in Sect. 17.4 of this chapter.

Table 17.1 summarizes the applications of the trajectory and state-based disease progression models discussed in this Section in terms of disease areas, methods (trajectory or state-based), and the clinical tasks addressed. Again, these are representative studies of the different modeling methods and not intended to be a comprehensive survey of all studies that have used these methods.

17.3.3 Challenges and Future Directions

Although there has been much progress in the development of data-driven disease progression modeling approaches to facilitate disease staging and disease trajectory analysis, many challenges remain. The computational time and cost needed to appropriately train some of the current models is already very high. As the models become more complex and the amount of available data continues to grow, the computational requirements will only increase. Algorithmic advances to improve model convergence, to improve model parameter

efficiency (i.e., using fewer parameters), and to make smarter use of the available data (e.g., selecting the most useful data subsets for model training) will be needed to address these computational issues.

On the data front, many different sources and types of data ranging from clinical trial data, observational studies, registry data, electronic health record data, administrative claims data, and intensive care unit data have been used for disease progression modeling. It is very encouraging to see that there is useful signal in so many different types of healthcare related data. There are opportunities to combine the different types of data to potentially detect even stronger signals for disease progression modeling. However, more work to standardize data models and improve data sharing will be needed. Progress in data standardization and sharing can also facilitate the validation of developed models on independent data sets.

The ability to quantitatively evaluate the performance of developed disease progression models for many diseases is currently very difficult mainly due to the lack of proper gold standards. For many conditions, existing measurements of disease progression either only cover limited portions of the disease progression journey or suffer from measurement and/or ascertainment bias and noise. More complete and accurate gold standard disease status measurements are needed to help drive data-driven disease progression modeling.

For the state-based disease progression models, it is typically very challenging to interpret the hidden states and to clearly map them to disease "stages." Some approaches simply interpret each state in the model as a stage in the disease progression [8]. Others approaches aggregate several states into a disease stage [16] or anchor some states with specific observations that map to accepted disease stages and allow other states to fill in progressions in between [18]. Each approach has pros and cons and there is no right or wrong approach. Much of this is due the probabilistic nature of the models where the added model flexibility unfortunately increases the complexity of model understanding. Building transparent and interpretable models is a broad challenge in machine learning. As progress is made in this area, the new methods and tools should be leveraged to improve disease progression model understanding.

In addition to addressing the challenges described above, there are other possible directions for future work. One is the development of more sophisticated models to better account for the heterogeneity in the observed data. Some possibilities include more sophisticated models of individual variation and more sophisticated models to account for medication effects that are not linear and that may not affect all disease measures but only a subset. Other possibilities include the use of patient-specific global variables that can influence various components of the model. For example, age, gender, family history could be used to determine the initial disease state distribution in an HMM model. The transition model could depend on patient behavior factors (e.g., medication, smoking, alcohol use, etc.) that may increase or decrease the rate of disease progression. Finally, the observation model could depend on characteristics of the provider to account for any differences in treatment or documentation behavior that may affect the observations captured in the data.

Another direction is to leverage the outputs and results of the disease progression model (i.e., the disease progression phenotypes) in other downstream analyses or models. This can include novel integration of disease progression modeling with cost effectiveness analysis or genomics data analysis. Finally, models incorporating additional outcomes such as medical costs, hospitalizations, and patient quality of life are of significant practical interest and may help in the translation and adoption of disease progression models into clinical practice.

17.4 Predictive Modeling for Disease Progression

Understanding the progression of a disease often calls for models able to predict the occurrence of any interesting events that are tied to the progression of the disease. For instance, many clinicians

are quite interested in estimating the risk of developing complications from T2DM within a fixed period of time, once a patient has been diagnosed with the disease.

Predicting the occurrence or risk of such events in a data driven way requires the development of classification techniques trained on an open set of data types meant to capture as much information as possible on the patient and the disease. One crucial characteristic of this problem is the importance to capture meaningful patterns in the temporal dimension. This problem has received a great deal of attention in the scientific community and has been approached in various ways that we describe in this section.

The literature in this area is extremely broad. Our intent here is to illustrate the main approaches instead of performing a comprehensive survey of all the work that has been done. In what follows, we review state of the art in machine learning methods able to cope with such temporal classification problems to shed light on the occurrence of important events that relate to specific diseases. We start with a discussion on the data sets commonly used, followed by descriptions of methods before ending with a discussion of challenges that remain to be addressed to further the adoption of such methods in clinical settings.

17.4.1 Data and Pre-processing

Data requirement for the development of predictive models for disease progression are more stringent than the ones needed for proper disease staging analysis. Broadly speaking, any data sets capturing any observed aspects of patients of interests can be candidates for analysis. Such data sets are required to contain various features about patients together with ground truth labels used for classification. Electronic Health Records and clinical claims data sets have been used successfully for the classification of several adverse events such as mortality, hospital re-admission [47] and various complications from chronic conditions [48]. These data sets span a rich set of data types, including diagnosis, procedures, lab tests, demographics, and patient family histories. Additional studies have made use of additional data modalities not commonly present in EHR and claims databases. For instance, in [49], authors discussed how researchers have been able to successfully analyze genomic data with machine learning to model the risk of complex diseases. Others are complementing these data sets with IoT sensor data providing important insight on patients [50, 51].

Regardless of the source and modality used, these datasets tend to be extremely sparse as patients are often associated only to small set of diseases, diagnoses and procedures. They also tend to be incomplete as the healthcare system overall is still figuring out how to resolve interoperability questions that will enable a complete 360-degree view of all health-related data for all patients. As with many real-world data sets, they also tend to have many missing entries, prompting the academic community to research effective ways to impute missing data to improve modeling in general.

17.4.2 Methods

The digitization of clinical data has sparked AI researchers to develop novel computational methods for various analytical tasks, including the sequential prediction of various clinically meaningful events related to disease progression. In a nutshell, these methods aim at learning from data functions able to map patient historical data typically represented as a vector X_t^i into a risk score y_t^i representing the probability of observing the predicted event. Here, the superscript i indexes a specific patient while the subscript t represent time.

17.4.2.1 Classical and Deep Learning Models

Most of these modern methods are inherited from the relatively recent popularity of deep learning in general. In [48], the authors provide a comprehensive survey of deep learning methods that have been used in this field, including Convolutional Neural Networks (CNN) and their temporal extensions, recurrent architectures such

as Long Short-Term Memory (LSTM) and Gated Recurrent Units (GRU). With their growing popularity, attention schemes are also making their way to this list. Recurrent architectures are particularly well suited for sequential problems and when applied to disease progression modeling, they essentially track the state of a given patient with a context vector h_t^i from which they learn how to predict or estimate the risk of events of interests. They implicitly learn how to summarize patient histories into this context vector h_t^i that could be interpreted as patient i's disease states at time t. Memory networks have expanded on this approach by allowing neural architectures to enrich their way of encoding patient histories with access to memory banks trained to retain important aspects of patient histories. The work presented in [52] illustrates such efforts with the successful design of a memory network architecture inspired from human mental memory models and able to model clinical data for the prediction of various adverse events.

Despite all the success of these deep learning approaches, conventional machine learning techniques ranging from simple logistic regression models to more complex tree and rule learning techniques (e.g., Gradient Boosted Trees, Random Forest) or even support vector machines have also been applied quite successfully to similar problems. While these simpler machine learning models may have limited capacity and make certain assumptions about the data distribution (e.g., linear assumptions) compared to the non-parametric and extremely high-capacity deep learning models, these classical methods can perform quite well in the limited and sparse nature of medical data - especially when significant effort has been applied to handcraft the features. These are also important as these are sometimes readily interpretable and transparent to the end user. In fact, in [53], it is reported that deep learning approaches are unable to outperform such conventional methods to predict hospital readmissions. Furthermore, prominent researchers have also guarded the community from overusing deep approaches that tend to be more difficult to interpret when more conventional rule learning methods could be applied [54]. Conventional Machine Learning techniques are typically unable to estimate and track context vectors h_t^i. They rely heavily on domain knowledge provided by data scientists able to transform X_t^i vectors into features summarizing the patient state. Consequently, these models tend to be limited in their ability to capture complex temporal patterns that relate to disease progression. However, this limitation does not restrain these models from being effectively applied in practice.

17.4.2.2 Model Explanations

To promote trust and facilitate the consumption of the output of such predictive models, several approaches have been designed to explain a predictive risk score value by showing the effects of input features that led the AI model to its conclusion. Data scientists commonly perform feature importance analysis to quantify how valuable each feature is for the trained AI classification models. Feature Importance is commonly estimated in two ways: (1) at the model level, which is the value a feature provides globally in the model training process; and (2) at the instance level, which is the value a feature provides locally in generating a specific prediction based on that data instance.

At the model level, some classical machine learning models are learned in a form that enable humans to readily understand what is being inferred. Examples include logistic regression, tree, and rule learning schemes such as XGBoost. For instance, an XGBoost learned model consists of a set of human readable rules describing how the model processed its inputs to produce the outputs. Similarly, the values of β coefficients learned during the training of a logistic regression model provide valuable insight into the model operations. Being obtained at the model level, these forms of explanations are *the same for all instances, for all patients*. Algorithms providing feature importance at the instance level can provide dynamic rationales on the predictions made for an individual patient, offering insights into how a specific prediction is generated. The instance level explainability algorithms can either be inferred during training or in a post-

hoc way. Schemes capable of inferring feature importance at training is dominated by attention schemes typically applied to recurrent neural network architectures (e.g., GRU and LSTM) or more recently to transformer architectures. Other attention scheme approaches worth mentioning here include the RETAIN algorithm initially designed for the prediction of clinical events from clinical data sets and the more recently developed Self Attention or Transformer models presented in [55].

Schemes inferring feature importance in a post-hoc way have also gained a lot of attention. These schemes tend to be quite flexible and completely model agnostic. The most popular techniques include the LIME [56] and SHAP algorithms [57] able to fit local models to each instance to approximate the behavior of a complex AI model locally with a simple and interpretable model. The Contrastive Explanation Method (CEM) [58] is also providing an interesting post-hoc explanation way to characterize the behavior of an AI model. The CEM allows data scientists to identify the reasons that an event was predicted relative to other possible events. It can be used to identify pertinent negative and pertinent positive reasons for a classification output for an AI model following common approaches in medicine [58].

17.4.3 Challenges and Future Directions

While classification techniques used for predictive disease progression modeling are quite pervasive and well understood, their adoption in the clinical settings remains hindered by three main challenges.

The first challenge relates to the nature of clinical data sets and the difficulty of extracting proper cohorts for predictive modeling. While this problem is not specific to this form of disease progression modeling, it has certainly had a negative impact on the development of predictive models. Health data scientists often spend 3/4 of their time to extract cohorts from complex EHR and claims data sets and pre-process the data for proper modeling. Unfortunately, cohort construction is not a perfect science. Establishing the right inclusion and exclusion criteria for patient selection may vary across institutions. This problem may result in the generation of models that cannot be ported across institutions. This limits the reproducibility of AI results across institutions.

The second challenge relates to the consumability of predictive models by health practitioners. Quite often, there is a significant gap between how data scientists consume and interpret the output of AI models with how practitioners interact with such models. Data scientists tend to evaluate the quality of these models using well defined metrics such as precision, recall, area under the ROC curve, F1 score and calibration to name just a few. However, translating these rather low-level metrics into higher level key performance indicators (KPIs) of interest for health practitioners such as patient outcomes and cost remains quite challenging. In general, optimizing for these KPIs during model training remains an open research problem.

The third challenge relates to the explanation of predictive model outputs. Most health practitioners consume the output of predictive models to better inform their clinical decision-making process. They seek explanations from AI models with the intent to be able to identify actionable knobs to control disease progression. However, most predictive AI models do not establish causal relations between input features and prediction outputs. While the explanation techniques described above provide insights on how an AI model is producing its outputs, they do not model explicitly how the input features may be causally related to the predicted events. More research on causal explanations and causal machine learning [59] is needed to address this problem.

17.5 Time to Event Modeling for Disease Progression

In this section, we describe time-to-event modeling for disease progression that uses statistical methods for estimating the amount of time that elapses before the occurrence of a particular event of interest, such as time to complications,

time to hospital admissions, and time to deterioration according to well defined disease states. Since the term survival analysis is commonly used as time-to-event modeling, particularly in the context of medical and healthcare literature, we use the term *survival analysis* hereafter.

Survival analysis attempts to answer certain questions, such as "what is the proportion of a population expected to experience a specific disease related event?" and "when will they experience that event?" In a clinical context, any predictions with respect to the occurrence of such events are particularly significant for providers and payers wishing to make treatment plan and care management decisions.

Classification techniques described in Sect. 17.4 are not well equipped to answer such time-to-event questions. They are limited in their ability to handle censoring problems that occur when the event of interest has not been observed within the data set used for analysis due to various reasons. For instance, while modeling the time to neuropathy from the onset of type 2 diabetes, the data set used is inevitably bounded in time within an observation window and some patients present in this data set may have experienced neuropathy after the end of this observation window. While classification techniques do not factor in censoring, survival analysis techniques are designed to cope with it.

Classical statistical approaches such as Kaplan-Meier estimation [60] and Cox regression [61] have been developed to overcome this censoring issue. Several books provide great overviews of these techniques [62, 63]. A survey paper [64] holistically summarizes survival analysis techniques from traditional methods to more modern machine learning approaches. In this section, we provide a structured review specifically focusing on machine learning techniques including emerging neural network methods published recently within the survival analysis research community.

17.5.1 Data and Censoring

Data sets created from real-world clinical research and experiments on patients usually have censoring issues. Figure 17.5 shows some examples of censoring and contrasts normal and censored cases. Subject A started observation at Month 0 and event "X" is observed at Month 4. Therefore, the survival time T is 4 (months) and the data is not censored. Subject B started observation at Month 1 and event "X" occurs at Month 3. After that, the next observation starts at Month 5 and the second event "X" occurs at Month 9. Subject B shows a recurrent event. Since both subjects A and B have event "X" before the end of the monitoring period (Month 10), these data are not censored. Subject C started the study at Month 0 but event "X" does not occur within the monitoring period, so that data is censored. Thus, the accurate survival time is not known but we observe that Subject C survives at least 10 months. Likewise, subject D data is also censored. Subject E started the study at Month 0 but withdrew on Month 4, so is censored. Subject F is lost to follow-up on Month 8 and is censored. Subjects C, D, E, and F are all examples of censoring, in particular right-censoring examples as defined below. Here we summarize terminology often used in the survival analysis literature:

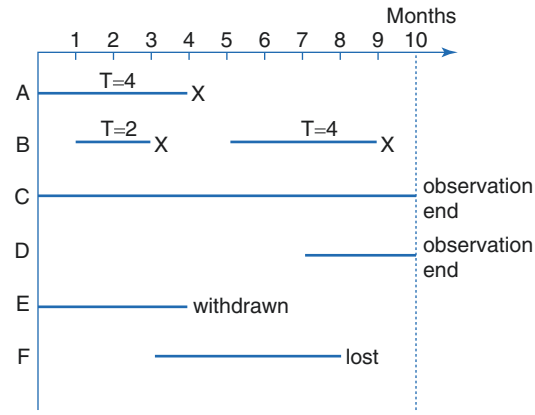

Fig. 17.5 Examples of censoring

- **Time**: Length in days, weeks, months, or years used to measure gaps between events.
- **Event**: Any incident of interest such as death or the onset of a disease. Events are always associated with a timestamp. Events are also quite often called *failures* as they often relate to negative outcomes, such as death and disease onset or re-hospitalization.

- **Survival time**: Elapsed time from a predefined index to the occurrence of a target event or until censoring.
- **Censoring**: The state of incomplete observation of survival times. Subjects in that state are referred to as censored. When censoring occurs in survival analysis, it means that only partial information regarding survival time can be obtained but accurate survival time is not known. For example, suppose that we investigate the survival time of the onset of retinopathy from the onset of the type 2 diabetes mellitus in a 3-year observational study. Some patients may not develop retinopathy within that observation period but develop retinopathy in 5 years. In this case, the event does not occur, and survival time is censored. In this case, survival time is right-censored because true survival time is greater than the observed survival time. There are three types of censoring:
  - **Right-censoring**: true survival time is equal to or greater than observed survival time. There are three types of right-censoring: (1) no event observed during the study period, (2) a person withdraws during the study period, and (3) a person had another event that prevented further tracking of the primary event.
  - **Left-censoring**: true survival time is less than or equal to the observed survival time.
  - **Interval-censoring**: true survival time is within a known time interval.

Figure 17.5 shows four right-censored cases of Subjects C, D, E, and F. The typical data format used in survival analysis is called Counting Process [63]. The Counting Process table provides flexible expressiveness for supporting cases like a time-dependent variable, a recurrence of the target event, and missing gaps during the follow-up period. Table 17.2 shows the Counting Process format for the subjects represented in Fig. 17.5. The table consists of six columns: subject, instance, event indicator, start time, end time, and group ID. The subject column identifies the participant in the study. The instance column indicates the sequential order of the record if the subject has suffered from the target event multiple times during the study period. When the same subject encounters two or more separate target events, this table will have two or more rows for separate events for the same subject, e.g., Subject B. The event indicator will be "1" if the subject has the event, and "0" if the subject is censored. The start time and end time indicate the start and end time of each survival instance. The group ID is used for identifying the group to which the subject belongs in the study, e.g., group ID is "1" for experiment group and "0" for control group.

17.5.2 Methods

As previously mentioned, the goal of survival analysis is to estimate the amount of time that elapses before the occurrence of a particular event of interest, denoted as the survival time T. In Table 17.2, the survival time T is observed as "End time" - "Start time" for the subject whose event indicator is "1". Specifically, survival anal-

Table 17.2 Example of counting process table format

Subject	Instance	Event indicator	Start time	End time	Group ID
A	1	1	0	4	1
B	1	1	1	3	1
B	2	1	5	9	1
C	1	0	0	10	1
D	1	0	7	10	1
E	1	0	0	4	1
F	1	0	3	8	1

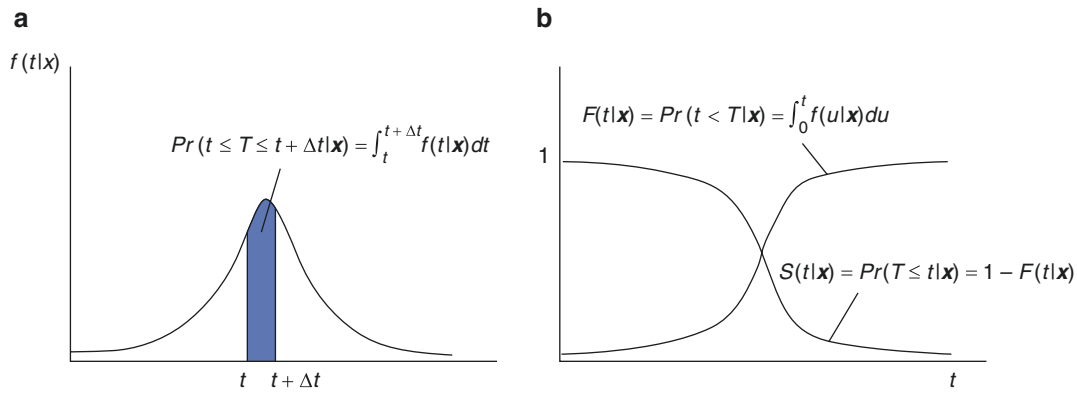

Fig. 17.6 (**a**, **b**) Distribution of survival time

ysis models the event distribution of T as a function of time. This translates to modeling the probability density function of event time $f(t|x)$ and its cumulative distribution function $F(t|\boldsymbol{x})$ which is the probability that the patient suffers from an event before time t, where t is measured from a certain reference time point such as the "Start time" in Table 17.2. Note that we discuss the conditional probability given covariates $\boldsymbol{x}$ to consider the interaction with the input covariates, where $\boldsymbol{x}$ are the characteristics of the subject. Figure 17.6a shows $f(t|\boldsymbol{x})$ which describes the distribution of survival time T for a given $\boldsymbol{x}$. Such distributional information resides in the counting process table (Table 17.2). For example, Subject A, with covariates $\boldsymbol{x}$, has a survival time of 4. If such a value is typical for $\boldsymbol{x}$, the distribution $f(t|\boldsymbol{x})$ would have greater values near $t = 4$. In the case of Subject B, there are two events possibly with different covariates $\boldsymbol{x}$; survival times of 2 and 4 are separately observed and contribute to forming the distribution of $f(t|\boldsymbol{x})$ separately. Subject C is a censored sample; in this case only the fact that T is at least equal to or greater than 10 is known. Even in such a case, this helps to infer that $f(t|\boldsymbol{x})$ would have larger values for $t \geq 10$. Utilizing those censored data to estimate the distributions are discussed further in the following subsections.

Rather than $f(t|\boldsymbol{x})$ and $F(t|\boldsymbol{x})$, the survival function or survival rate function $S(t|x)$, which is the probability that the patient *survives* up to time t, can also be modeled. The survival function is the opposite of $F(t|\boldsymbol{x})$, thus $S(t|\boldsymbol{x})$ is computed by $1 - F(t|\boldsymbol{x})$ as illustrated in Fig. 17.6b.

In addition to $S(t|\boldsymbol{x})$, the hazard function $h(t|\boldsymbol{x})$, which gives the instantaneous potential probability of the event at time t, can also be modeled. In some cases, such as population data analysis, the quantitative characteristics of the hazard function is known. For those cases, modeling can be done based on the hazard function. Its cumulative distribution function $H(t|\boldsymbol{x})$ can also be used for deriving the survival function $S(t|\boldsymbol{x})$.

Current research has focused on modeling the distributions of $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, or $f(t|\boldsymbol{x})$ more accurately by handling complex interactions with the input covariates $\boldsymbol{x}$. In this section we describe modern approaches of modeling $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, and $f(t|\boldsymbol{x})$ that leverage advanced machine learning technologies. We use the following notations according to the literature:

T: A non-negative random variable denoting the survival time, or the time that an event occurs.

$\boldsymbol{x}$: The covariates of the patient.

$f(t|\boldsymbol{x})$: The probability distribution, or probability density function, of survival time $t = T$ with covariate $\boldsymbol{x}$:

$$f\left(t|\boldsymbol{x}\right)=\lim_{\Delta t\to 0}\frac{\Pr\left(t\le T<t+\Delta t|\boldsymbol{x}\right)}{\Delta t}$$

$F(t|\boldsymbol{x})$: The cumulative distribution function of survival time $t = T$, or the probability that the event has occurred by time t:

$$F\left(t|x\right)=\Pr\left(T<t|\boldsymbol{x}\right)=\int_0^t f\left(u|\boldsymbol{x}\right)du$$

S(t|**x**): The survival function—the probability of not observing the event up to time t:

$$S\left(t|\boldsymbol{x}\right)=\Pr\left(T\ge t|\boldsymbol{x}\right)=1-F\left(t|\boldsymbol{x}\right)=1-\int_0^t f\left(u|\boldsymbol{x}\right)du$$

$h(t|\boldsymbol{x})$: The hazard function—the instantaneous potential probability of the event at time t:

$$h\left(t|\boldsymbol{x}\right)=\lim_{\Delta t\to 0}\frac{\Pr\left(t\le T<t+\Delta t|T\ge t,\boldsymbol{x}\right)}{\Delta t}$$

H(t|**x**): The cumulative hazard function—accumulation of instantaneous hazard function to time t:

$$H\left(t|\boldsymbol{x}\right)=\int_0^t h\left(u|\boldsymbol{x}\right)du$$

The hazard function $h(t|\boldsymbol{x})$ is related to the survival function $S(t|\boldsymbol{x})$ as follows:

$$\begin{aligned}h\left(t|\boldsymbol{x}\right)&=\lim_{\Delta t\to 0}\frac{Pr\left(t\le T<t+\Delta t|T\ge t,\boldsymbol{x}\right)}{\Delta t}\\&=\lim_{\Delta t\to 0}\frac{Pr\left(t\le T<t+\Delta t,T\ge t|\boldsymbol{x}\right)}{Pr\left(T\ge t|\boldsymbol{x}\right)\cdot\Delta t}\\&=\lim_{\Delta t\to 0}\frac{Pr\left(t\le T<t+\Delta t|\boldsymbol{x}\right)}{Pr\left(T\ge t|\boldsymbol{x}\right)\cdot\Delta t}\\&=\lim_{\Delta t\to 0}\frac{f\left(t|\boldsymbol{x}\right)\cdot\Delta t}{S\left(t|\boldsymbol{x}\right)\cdot\Delta t}=\frac{f\left(t|\boldsymbol{x}\right)}{S\left(t|\boldsymbol{x}\right)}\\&=-\frac{\frac{d}{dt}S\left(t|\boldsymbol{x}\right)}{S\left(t|\boldsymbol{x}\right)}=-\frac{d}{dt}\log S\left(t|\boldsymbol{x}\right).\end{aligned}$$

Solving the differential equation also results in:

$$S\left(t|\boldsymbol{x}\right)=\exp\left[-\int_0^t h\left(u|\boldsymbol{x}\right)du\right]=\exp\left(-H\left(t|\boldsymbol{x}\right)\right).$$

We then see when one of $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, and $f(t|\boldsymbol{x})$ is known, the others can be derived from it.

To better estimate $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, or $f(t|\boldsymbol{x})$ using a counting process table as training data, many advanced approaches have been studied exploiting modern machine leaning techniques. As illustrated in Fig. 17.7, advanced survival analysis methods can be divided into two groups: Distribution Regression and Standard Regression. Distribution Regression focuses on predicting the distribution to model $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, or $f(t|\boldsymbol{x})$ with interaction with the covariates $\boldsymbol{x}$. According to distribution modeling approaches, these methods

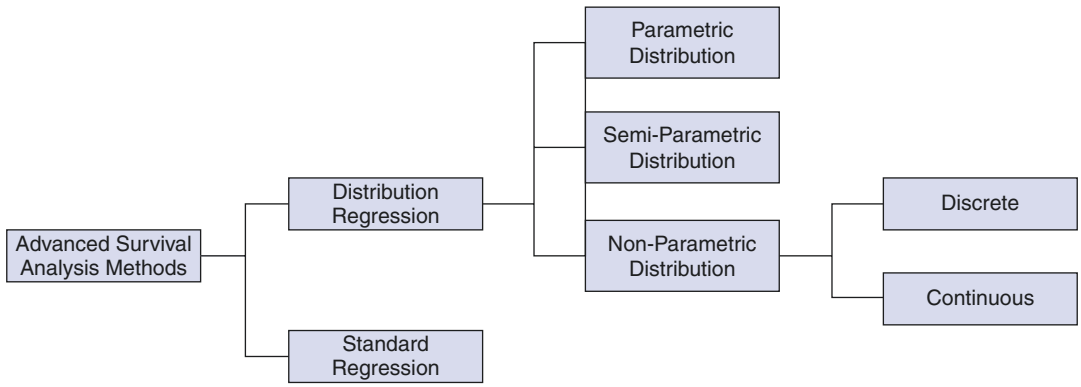

Fig. 17.7 Advanced survival analysis methods and taxonomy

can be further categorized as parametric, semi-parametric, and non-parametric; there are discrete and continuous versions of the non-parametric approaches. Different from distribution prediction approaches, Standard Regression focuses on predicting the survival time T itself, modeling it using a function of the covariates $T(x)$ by optimizing its parameters to minimize the prediction error as well as the concordance amongst pairs of observations.

Figure 17.8 illustrates (*a*) parametric, (*b*) semi-parametric, and (*c*, *d*) non-parametric approaches; the following subsections explain those respectively. Note that non-parametric approaches do not use the parameters of well-known "parametric" distributions but make use of a set of parameters (of a neural network or a kernel function) which are optimized to obtain the resultant distribution.

17.5.2.1 Parametric Distribution

Parametric approaches model the survival function $S(t|\boldsymbol{x})$ or the hazard function $h(t|\boldsymbol{x})$ using well-known distributions including exponential, log-normal, Weibull distributions and others. Figure 17.8a shows an example of modeling a survival function using the Weibull distribution:

$$S\left(t|\boldsymbol{x}\right) = e^{-\left(\frac{t}{\beta}\right)^{\eta}} \tag{17.2}$$

where η and β are distribution parameters. Note that $f(t|\boldsymbol{x})$ can be derived from $S(t|\boldsymbol{x})$ as described above. Traditional analysis is conducted by fitting the distribution's parameters using training data.

In training, as discussed before, even censored data have information that the survival time T is at least more than the censored time. Uncensored data also indicate that the survival time equals the event time. Getting all that information together, the joint probability can be described as follows:

$$\prod_{(x,t)\in D_{uncensored}} \Pr\left(T = t|\boldsymbol{x}\right) \prod_{(x,t)\in D_{censored}} \Pr\left(T > t|\boldsymbol{x}\right) \tag{17.3}$$

where $D_{uncensored}$ and $D_{censored}$ are the sets of data points that are uncensored and censored, respectively. Using notations of survival analysis, the above joint probability gives a likelihood function to be maximized as follows:

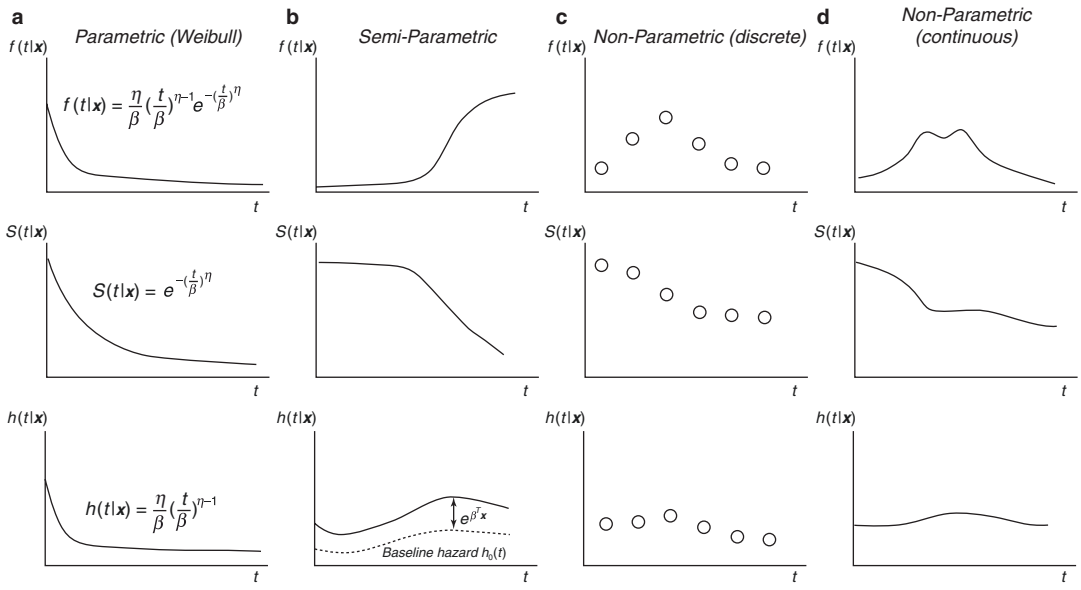

Fig. 17.8 (**a**–**d**) Parametric, semi-parametric, and non-parametric approaches

$$L = \prod_{(x,t)\in D_{uncensored}} f(t|\boldsymbol{x}) \prod_{(x,t)\in D_{censored}} S(t|\boldsymbol{x}). \quad (17.4)$$

Note that this formulation of joint probability and likelihood is general so will be often mentioned in the following subsections.

Especially with modern machine learning techniques, it is possible to capture more complex dependencies between the covariates $\boldsymbol{x}$ and the survival times by expressing the distribution's parameters as non-linear functions of the covariates. Such approaches can be found in [65, 66]. For example, techniques are discussed in [65], where the parameters of Weibull distribution η and β in Eq. (17.2) are expressed taking advantage of deep neural networks.

17.5.2.2 Semi-Parametric Distribution

Semi-parametric approaches are approaches that, in a certain way, separates the survival or hazard function into parametric and non-parametric parts. The Cox model [61] is the most common semi-parametric approach which is widely used and researched so this section mostly discusses this. Cox's insight is that one's hazard is proportional to another depending on his risk regardless of time. Cox thus separates the hazard function $h(t|\boldsymbol{x})$ into two parts: a non-parametric part and a "parametric" part:

$$h(t|\boldsymbol{x}) = h_0(t)\exp\left(\boldsymbol{\beta}^T\boldsymbol{x}\right) \quad (17.5)$$

where $h_0(t)$ is the non-parametric part and defines the basic hazard distribution over time. This term only represents a time development of the hazard, and it is called a baseline hazard since it is common to all subjects. This can be regarded as the hazard when $\boldsymbol{\beta}\mathrm{T}\boldsymbol{x} = 0$ and is typically obtained by estimation. The remaining $\exp(\boldsymbol{\beta}^T\boldsymbol{x})$ term is the "parametric" part ($\boldsymbol{\beta}$ are the learned parameters) because the shape of the function is predetermined, which describes the effects of covariates $\boldsymbol{x}$ as a time-independent proportional factor to the baseline hazard. Since the parametric part is a multiplicative factor on the non-parametric (baseline) part, this model is also referred to as the proportional hazard model. Figure 17.8b shows a semi-parametric Cox model with a non-parametric baseline hazard function and a parametric hazard function that is proportional to the baseline hazard.

As discussed above, data including censored samples are used for training. Traditionally in a Cox model, a partial likelihood is used, which can be derived from the "full" joint probability (17.3) and Cox argued most of the information of $\boldsymbol{\beta}$ is included in it. Intuitively, the partial likelihood is interpreted as the product over each observed events of conditional probabilities, of observing an event of the subject i, given the set of subjects still surviving at the time of the event of i. Such a set is called a risk set $R(i)$ for a given subject i. Note that $R(i)$ includes censored and uncensored subjects. The contribution of i to the likelihood is written as follows:

$$\begin{aligned} Pr\left(i\ has\ an\ event\ at\ T_i | one\ of\ the\ R(i)\ has\ an\ event\ at\ T_i\right) &= \frac{Pr\left(i\ has\ an\ event\ at\ T_i\right)}{\sum_{j\in R(i)} Pr\left(j\ has\ an\ event\ at\ T_i\right)} \\ &= \frac{h_0(T_i)exp\left(\boldsymbol{\beta}^T\boldsymbol{x}_i\right)}{\sum_{j\in \boldsymbol{R}(i)} h_0(T_i)exp\left(\boldsymbol{\beta}^T\boldsymbol{x}_j\right)} \\ &= \frac{exp\left(\boldsymbol{\beta}^T\boldsymbol{x}_i\right)}{\sum_{j\in R(i)} exp\left(\boldsymbol{\beta}^T\boldsymbol{x}_j\right)}. \end{aligned} \quad (17.6)$$

Training is done by maximizing this likelihood to optimize the concordance amongst pairs of observations, namely, the subject i and an uncensored or censored subject in $R(i)$. To measure the concordance, the C-index [67] is commonly used; it estimates the probability that, for

a random pair of subjects, the predicted survival times of the two subjects have the same ordering as their actual survival times. We note that Cox and its extended models thus mostly focus on concordance, not on directly predicting the survival function $S(t|\boldsymbol{x})$.

After model training, the survival function can be obtained using:

$$S\left(t|\boldsymbol{x}\right)=\exp\left(-\widehat{H_0}\left(t\right)\exp\left(\widehat{\beta}^{T}\boldsymbol{x}\right)\right) \quad (17.7)$$

where $\widehat{\beta}$ is an estimated parameter and $\widehat{H_0}\left(t\right)$ is an estimated cumulative hazard function which can be calculated also using training data by the Breslow estimator [68] or Kalbfleisch/Prentice estimator [69].

Advanced semi-parametric distribution modeling has focused on replacing the linear function $\boldsymbol{\beta}^{T}\boldsymbol{x}$ in the hazard function by non-linear functions $g(\boldsymbol{x}|\boldsymbol{\theta})$, typically estimated using neural networks [70–73] with model parameters $\boldsymbol{\theta}$:

$$h\left(t|\boldsymbol{x}\right)=h_0\left(t\right)\exp\left(g\left(\boldsymbol{x}|\boldsymbol{\theta}\right)\right) \quad (17.8)$$

These non-linear functions have more representational power and can capture more complex relationships between the covariates and the survival times and have led to improved risk estimation performance. We also see other semi-parametric approaches intriguingly discussed in [74–76]. In [76] and [70], Cox model with non-proportional hazards, which captures time-dependent interaction of covariates using $\exp(g(t,\boldsymbol{x}|\boldsymbol{\theta}))$ in the parametric part, is studied. To measure the concordance when using non-proportional hazard, time-dependent C-index by Antolini et al. [77] is used. Time-dependent C-index is calculated based on such ordering that a subject who developed the event should have a less predicted probability of surviving at event time than any subject in the risk set. This scheme is general so we can also notice that time-dependent C-index is used to measure the concordance for models discussed in other subsections.

17.5.2.3 Non-parametric Distribution

Non-parametric approaches do not assume any predetermined distribution for $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, or $f(t|\boldsymbol{x})$. Traditionally Kaplan-Meier method [60] is used which estimates the survival function $S(t|\boldsymbol{x})$ in the case of having no covariates. Recent approaches that try to model the complex empirical distributions directly in the presence of covariates have been intensively studied. Although these models do not use known "parametric" distributions, they do have model parameters and hyperparameters that must be learned during training. In modeling the distribution, discrete or continuous time approaches are possible. In the discrete time approach, as illustrated in Fig. 17.8c, the hazard or survival probability at each discrete time step are directly predicted using neural networks such as neural networks [78–80] or state-space generative models [81]. In the continuous time approach, as illustrated in Fig. 17.8d, continuous-time models such as Deep Gaussian Processes [82] and Generative Adversarial Networks [83] have been used to model temporal trajectories. Survival trees [84] including Random Survival Forests [85] can also estimate $S(t|\boldsymbol{x})$ as a mixture of continuous but step functions in a non-parametric manner.

17.5.2.4 Discrete Distribution Regression

An example of discrete modeling of non-parametric survival time distribution is the neural network model, DeepHit [78]. In this discrete model, we assume that the time horizon is finite and discretized and is expressed as a set $\{0,1,2,\ldots,\Omega\}$, and that any event occurs before time Ω. Let $p_{t,}$ x, a discrete form of $\int f(t|\boldsymbol{x})dt$, be the probability that an event occurs at time t for patient $\boldsymbol{x}$:

$$p_{t,\boldsymbol{x}}=S\left(t-1|\boldsymbol{x}\right)-S\left(t|\boldsymbol{x}\right)\text{for}t=1,2,\ldots,\Omega. \quad (17.9)$$

Then the survival function $S(t|\boldsymbol{x})$ for discrete time can be expressed as:

$$S\left(t|\boldsymbol{x}\right)=1-\sum_{\tau=1}^{t}p_{\tau,\boldsymbol{x}}. \quad (17.10)$$

In DeepHit, a neural network is designed to estimate a set of event probabilities (at each of Ω time points): $\left\{p_{t,\boldsymbol{x}}\right\}_{t=1}^{\Omega}$. Since $\sum_{t=1}^{\Omega}p_{t,\boldsymbol{x}}=1$, a SoftMax function is used in the last layer of the neural network. Any type of layer can be used for

the other layers. Figure 17.9 shows an example network with three fully connected layers.

This neural network uses a loss function L which is designed to handle censored data. This loss function minimizes the negative log-likelihood of the joint distribution of the event time:

$$L = -\sum_{(\boldsymbol{x},t)\in D_{uncensored}} \log p_{t,\boldsymbol{x}} + \sum_{(\boldsymbol{x},t)\in D_{censored}} \log S\left(t|\boldsymbol{x}\right), \tag{17.11}$$

where $D_{uncensored}$ and $D_{censored}$ are the sets of data points that are uncensored and censored, respectively. The first term of L corresponds to improving the estimation of the event probability $p_{t,}$ x for uncensored data. The second term of L corresponds to improving the survival rate $S(t|\boldsymbol{x})$ for censored data. Note that this equation corresponds to a discrete form of likelihood (17.3).

After the publication of DeepHit [78], more advanced neural network models have been proposed [79, 80, 86]. Two of them [79, 80] are recurrent neural networks (RNNs), which are trained to learn hazard rates rather than the event probabilities to improve prediction performance. The other one [86] proposes a new technique to model the event probability $p_{t,}$ x in a hierarchical manner.

17.5.2.5 Continuous Distribution Regression

An example of continuous modeling of non-parametric survival time distribution is the Deep Gaussian Processes, as studied in [82], which is a multi-layer cascade of Gaussian processes, generally yielding non-Gaussian distributions as continuous survival time distributions with complex covariate interactions. To model the probability density function $f(t|\boldsymbol{x})$, for example, a two-layer Gaussian process can be formed as follows:

$$\boldsymbol{Z} = f_Z\left(\boldsymbol{X}\right) + \epsilon_Z, \epsilon_Z \sim \mathcal{N}\left(0, \sigma_Z^2\right), f_Z \sim \mathcal{GP}\left(0, \boldsymbol{K}_{\boldsymbol{\theta}_Z}\right)$$

$$\boldsymbol{T} = f_T\left(\boldsymbol{Z}\right) + \epsilon_T, \epsilon_T \sim \mathcal{N}\left(0, \sigma_T^2\right), f_T \sim \mathcal{GP}\left(0, \boldsymbol{K}_{\boldsymbol{\theta}_T}\right) \tag{17.12}$$

where $\boldsymbol{T}$ is a set of the survival time of the subjects $\{T_1, T_2, T_3, \ldots\}$, $\boldsymbol{X}$ is a set of such covariates $\{\boldsymbol{x}_1, \boldsymbol{x}_2, \boldsymbol{x}_3, \ldots\}$, $\boldsymbol{Z}$ represents a latent variable, and ϵ_Z and ϵ_T are noises generated from zero-mean Gaussian distributions with variances σ_Z^2 and σ_T^2. The latent functions f_Z and f_T are generated from zero-mean Gaussian processes with kernels $\boldsymbol{K}_{\boldsymbol{\theta}_Z}$ and $\boldsymbol{K}_{\boldsymbol{\theta}_T}$ with hyperparameters $\boldsymbol{\theta}_Z$ and $\boldsymbol{\theta}_T$. Kernels are responsible to express the correlation between inputs, $\boldsymbol{X}$ and $\boldsymbol{Z}$, respectively; and thus to generate complex but smooth functions of the inputs. For example, correlation between $\boldsymbol{x}_i$ and $\boldsymbol{x}_j$ is expressed by matrix element of $\boldsymbol{K}_{\boldsymbol{\theta}_Z} = (\boldsymbol{x}_i, \boldsymbol{x}_j|\boldsymbol{\theta}_Z)$.

Seeing a generation of complex shaped distributions, as shown in Fig. 17.10, the generative model of T_i $|\boldsymbol{x}_i$ for the subject i is illustrated as follows. At first $\boldsymbol{f}_Z = \{f_Z(\boldsymbol{x}_1), f_Z(\boldsymbol{x}_2), f_Z(\boldsymbol{x}_3), \ldots\}$ is generated as an infinite-dimensional Gaussian distribution from the Gaussian Process with the kernel $\boldsymbol{K}_{\boldsymbol{\theta}_Z}$. Considering ϵ_Z as a noise, a latent variable Z_i for $\boldsymbol{x}_i$ is generated from $\mathcal{N}\left(f_Z\left(\boldsymbol{x}_1\right), \sigma_Z^2\right)$. From such a distribution of Z_i, we assume $\{Z_{i\_1}, Z_{i\_2}, Z_{i\_3}, \ldots\}$ are generated. For taking Z_{i_j} as an example, T_{i_j} is also generated from $\mathcal{N}\left(f_T\left(Z_{i\_j}\right), \sigma_T^2\right)$. Notice that $\boldsymbol{f}_T = \{f_T(Z_1), f_T(Z_2), f_T(Z_3), \ldots\}$, an infinite-dimensional Gaussian distribution, is also generated from the Gaussian Process with the kernel $\boldsymbol{K}_{\boldsymbol{\theta}_T}$. Finally, the distribution of T_i $|\boldsymbol{x}_i$, expressing $f(t|\boldsymbol{x}_i)$, is thus obtained by integrating over the distributions of Z_i, $\boldsymbol{f}_Z$ and $\boldsymbol{f}_T$.

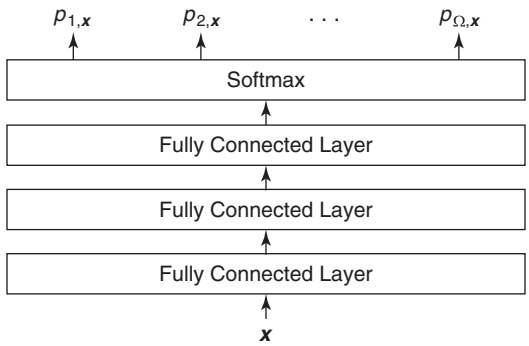

Fig. 17.9 Example of neural network model

Loss functions to learn hyperparameters $\boldsymbol{\theta}_Z$ and $\boldsymbol{\theta}_T$ are defined for maximizing the likelihood to explain the training data. The marginal likelihood is obtained by marginalizing out $\boldsymbol{Z}, \boldsymbol{f}_Z$ and $\boldsymbol{f}_T$ from the joint probability (17.3). Because such integration is analytically intractable, in [82], a variational Bayesian approximation method is discussed to optimize $\boldsymbol{\theta}_Z$ and $\boldsymbol{\theta}_T$. The approximation of the posterior distributions of $\boldsymbol{Z}$ is also obtained by optimization; and thus the posterior distributions of $\boldsymbol{f}_Z$ and $\boldsymbol{f}_T$ are estimated to fit the training data. We notice that the approximation of the posterior distributions of $\boldsymbol{Z}$ is related to Gaussian Process Latent Variable Models [87]. Intuitively, making use of those optimized results, hyperparameters $\boldsymbol{\theta}_Z$ and $\boldsymbol{\theta}_T$, and the posterior distributions of $\boldsymbol{Z}, \boldsymbol{f}_Z$ and $\boldsymbol{f}_T$, the density function for an unknown covariates $\boldsymbol{x}_*$, $f(t|\boldsymbol{x}_*)$, can be obtained using the generative process illustrated in Fig. 17.10. Note that the predictive distributions of $\boldsymbol{f}_Z$ and $\boldsymbol{f}_T$ for $\boldsymbol{x}_*$ are obtained by Gaussian Process Regression.

17.5.2.6 Standard Regression Approaches

Previous sections have described approaches that model the distributions of for $S(t|\boldsymbol{x})$, $h(t|\boldsymbol{x})$, or $f(t|\boldsymbol{x})$. A different approach is to train models to directly predict the time of the event, $\boldsymbol{T}$, as a function of the covariates, namely $T(\boldsymbol{x})$. Standard regression models focus on predicting the actual time-to-event with minimal error for the uncensored patients. Cox and its extended models, on the other hand, mainly focus on correctly estimating concordance (relative ranking) among survival time among patients including right-censored ones. An interesting approach is to try to achieve both goals at the same time.

RankSvx [88] intriguingly developed a model to optimize both concordance and survival time prediction simultaneously using an objective function of the following form:

$$\alpha \, \mathrm{L}_{uncensored}\left(t_i, T\left(\boldsymbol{x}_i|\boldsymbol{\theta}\right)\right) + \left(1-\alpha\right)\mathrm{L}_{censored}\left(t_i, T\left(\boldsymbol{x}_i|\boldsymbol{\theta}\right)\right) + g\left(\boldsymbol{\theta}\right) \tag{17.13}$$

where t_i is the time of an event for the subject i, $\boldsymbol{x}_i$ represents the covariates for the subject i, $T(\boldsymbol{x}_i|\boldsymbol{\theta})$ is a regression function to predict the actual time of disease onset with parameter $\boldsymbol{\theta}$, and α is a hyper-parameter to weight the contribution of each term.

In RankSvx, $T(\boldsymbol{x})$ effectively works for obtaining both goals. The first term, $\mathrm{L}_{uncensored}$, aims to minimize the prediction error of $T(\boldsymbol{x}_i|\boldsymbol{\theta})$ over the event time t_i. The second term, $\mathrm{L}_{censored}$, aims to correctly rank the relative risks of two subjects, which is equal to maximizing the probability of

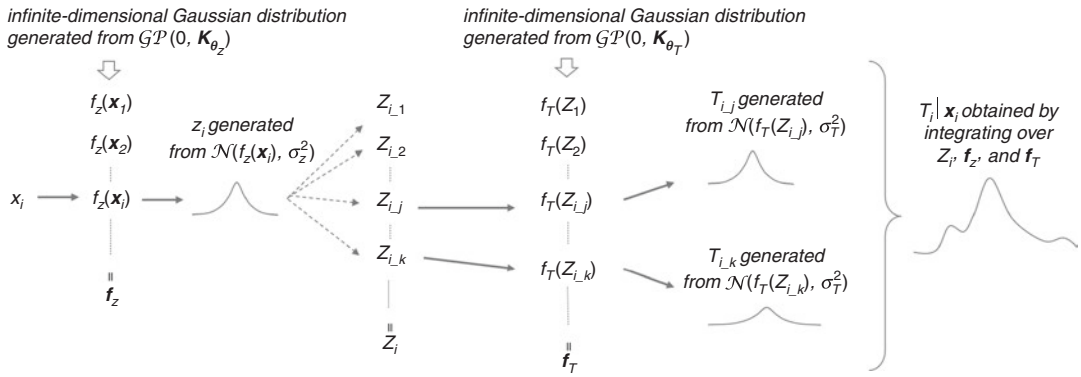

Fig. 17.10 Modeling with 2-layer Gaussian process

all pairs of subjects whose predicted event times are correctly ordered among all subjects that can be ordered, including the censored events. This is modeled by for each subject j in in the risk set $R(i)$ for the observed subject i, namely $t_j > t_i$, maximizing the probability to observe $T(\boldsymbol{x}_j|\boldsymbol{\theta}) > T(\boldsymbol{x}_i|\boldsymbol{\theta})$. Finally, the regularization term $g(\boldsymbol{\theta})$ is an L_2 norm to penalize the model complexity to prevent over-fitting. On a diabetes complication prediction task, this model was able to outperform the Cox and regression models alone, giving higher mean absolute errors of predicted times and C-indices.

17.5.3 Challenges and Future Directions

One of the challenges of survival analysis is related to the connection of survival model output to clinical decision making. Can the performance improvement measured by the concordance index of the survival model quantitatively lead to better clinical treatment? Translating low level metrics into more real-world key performance indicators (KPIs) of interest for health practitioners and insurance companies remains challenging.

Some areas of ongoing and future research of machine learning technologies include feature engineering, survival rate distribution modeling, and model interpretation.

First, the information captured in electronic health records data, which include images, clinical notes, laboratory tests, and other rich data can be further exploited. Recent achievements in deep learning technology such as CNN [89], LSTM [90], Transformer [55] and others can be used to extract non-linear data representations from these multi-modal data types to potentially improve downstream modeling.

Second, the design of the loss function and metrics for survival analysis has also been an area of research focus. Rather than using naive objective likelihood derived from the Eq. (17.3), Survival CRPS was proposed in [91], which is a generalization of the continuous ranked probability score (CRPS) for right-censored and interval-censored data, yielding sharper and calibrated distributions. Another metric X-Cal was proposed in [92]. Very recently, an improvement over the Survival CRPS was proposed in [93]. These loss functions were designed to be a well-calibrated metric. In other words, the loss functions were designed to equalize the estimated event probability and the actual event probability. Further exploration of better metrics for survival analysis continues to be an active area of research.

Next, several general advancements in modern machine learning have proven to be beneficial to survival analysis in general, independent of the specific modeling method. For example, multi-task and competing risk treatments have been successfully added to survival analysis models [79, 88, 94]. In addition, covariate selection and representation learning have enabled effective transfer learning from the source domain to the target domain for survival analysis [73, 95]. Non-parametric methods have been used to express survival rate distributions and further research on both discrete and continuous approaches will exploit state-of-the-art deep learning and other approaches. Recently approaches have proposed to virtually make RNN continuous using ordinary differential equations [96–99]. ODE-based RNN encoders [97, 98] have successfully demonstrated the ability to generate complex continuous trajectories. It is expected that these approaches can bridge continuous RNN research achievements to continuous survival curve modeling.

Finally, more work needs to be done to better understand how more complex machine learning models work. Cox models are widely used in clinical research because they can nicely show the hazard ratios and associated confidence intervals of covariates. Currently, more complex survival models, especially deep learning models, do not have such transparency and interpretability. However, the recent development and use of algorithms such as LIME [56] and SHAP [57] to better understand complex machine learning models can be expected to also help improve understanding of advanced survival models.

Survival analysis with modern machine learning is thus an active area of research. Many topics have been proposed and discussed in specific symposia such as AAAI-SPACA 2021 [100].

17.6 Concluding Remarks

In this chapter, we reviewed data driven approaches to disease progression modeling, focusing on trajectory and staging, predictive, and time to event analysis through survival modeling. While research has come a long way to provide robust machine learning methods for each of these modeling approaches, several open challenges remain, as discussed in each section. Beyond these challenges, we believe that progress on disease progression modeling may benefit from more attempts to couple data driven approaches with system biology models. This will offer opportunities to develop models that can benefit from both the centuries of medical knowledge behind system biology models and the large amounts of observational data collected by health institutions in recent years. We believe that such a hybrid approach may help us further understand complex diseases while also providing a natural way to explain the behavior of data driven models in terms that are understood by health practitioners.

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Virtual Health in Patient Care and Clinical Research

18

Tianna M. Umann, Molly McCarthy, Clifford Goldsmith, Paul Slater, and Christopher Regan

Abstract

In this chapter we will introduce core concepts both benefits and challenges in a modern understanding and approach to implementing quality, patient-centric care in a virtual health environment. We will provide context for a standard definition of virtual health and application of this definition within industry enterprise. Specifically, we will focus on two healthcare industry sub-verticals; Virtual health in enterprise healthcare and the patient-provider experience and virtual health in pharmaceutical industry decentralized clinical trials and the study staff and patient experience. Further, we will describe the approach to defining a high value high impact implementable virtual health solution within these industry sub-verticals including technology considerations, maturity models in virtual health solutions and an approach to the science and rigor for measuring these solutions. We will close the chapter with some thoughts on the future of virtual health and a use case study that extends a patient—provider virtual health solution to decentralized clinical trials management.

Keywords

Virtual healthcare · Decentralized clinical trials · Virtual health maturity model Clinical research as a care option (CRAACO) Diversity and inclusion · Virtual clinical trials platform · Virtual health prioritization framework

T. M. Umann (✉)
Microsoft Corporation, Office of the CTO, Technology Strategy, New York, NY, USA
e-mail: tianna.umann@microsoft.com

M. McCarthy
Microsoft Corporation, US Health and Life Sciences, Redmond, WA, USA
e-mail: molly.mccarthy@microsoft.com

C. Goldsmith
Microsoft Corporation, Health and Life Sciences, Redmond, WA, USA
e-mail: clifgold@microsoft.com

P. Slater
BillionMinds, Woodinville, WA, USA
e-mail: paul@billionminds.com

C. Regan
Microsoft Corporation, Office of the CTO, Health and Life Sciences, Redmond, WA, USA
e-mail: chris.regan@microsoft.com

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Learning Objectives

- You will be able to describe the challenges and opportunities in virtual care encounters as well as business and technical solutions.
- You will be able to describe specific high impact use cases in virtual care and the business and societal impact of virtual care.
- You will be able to describe the approach for building a business solution and technical framework for virtual care use cases.
- You will be able to describe the multiple dimensions of the maturity model for Virtual Health and understand how it can be used to plan and effectively enable the various capabilities of Virtual Health with an organization

18.1 Introduction

Care coordination and collaboration are critical to deliver the highest levels of patient centric care. The healthcare delivery paradigm is shifting to a more seamless, connected and most importantly, a diverse and inclusive patient journey. Patient care facing industry verticals such as enterprise healthcare and the pharmaceutical clinical trials recognize the need for a more patient-centric approach to the delivery of care that refocuses the patient at the center of the care team focusing on the unique needs of each individual. At the core of a seamless patient journey is enabling the broad definition of the 'care team' to collaborate and coordinate in real-time. In fact, from a care provider perspective payors and clinical trials are two sides of the same coin. In the former case, care is supported and funded through a public or private payor, and in the latter, care is resourced through a clinical trial supported by research funding. Virtual care is one example of this duality of care funding.

As new, innovative technologies emerge and are incorporated into best practices for care delivery a personalized coordinated and collaborative care model is moving from aspirational to standard of care [1].

18.2 Can We (or How Do We) Define Virtual Health?

Virtual health connotes different meaning, concepts, and experiences to different people. To define virtual health is really to ask the question, "What problem are you trying to solve and for whom?" Initially, one may construe virtual health simply as a synchronous video visit between and patient and provider. However, virtual health encompasses much more than just a video visit. According to the American Telemedicine Association (ATA) Telehealth Taxonomy, *"Telehealth effectively connects individuals and their healthcare providers when an in-person interaction is not clinically necessary and facilitates physician-to-physician consultation. Using telehealth services, patients can receive care, consult with a provider, get information about a condition or treatment, arrange for prescriptions, and receive a diagnosis."*

The ATA explains that the most common approaches to telehealth include live, synchronous video visits; chat-based interactions such as asynchronous messaging with a provider; remote-patient monitoring such as the collection and transmission of vital signs from a patient at home to their provider; and finally, technology enabled solutions such as provider consultation, patient education, digital diagnostics, and therapeutics. The ATA Taxonomy also acknowledges multiple benefits including increased access to care for patients and providers in rural areas, seniors, and marginalized or vulnerable populations. However, such benefits must assume the availability of both device and Wi-Fi connection, as well as a favourable comfort level and knowledge base of the patient or family technology user.

McKinsey and Company's article "Virtual health: A look at the next frontier of care delivery" attempts to categorize, subcategorize, and define major aspects of virtual health in a slightly different and broader approach. McKinsey proposes three major categories for its definition of virtual health including telehealth, digital therapeutics, and care navigation. These three groups

also encompass many of the points the ATA discussed but is more expansive with its digital therapeutics' definition including replacement therapies and treatment optimization, hinting at personalized medicine.

These authors (or do we say 'We') argue that virtual health is best defined as a means to *connect clinicians, patients, families, care teams and health professionals to provide health services, promote professional collaboration, support self-management, and coordinate care across the care continuum*. This definition is more comprehensive and more inclusive of the various touch points throughout a patient's journey and considers both synchronous and asynchronous activities. The diagram below best illustrates how we conceptualize virtual health in today's complex world.

Illustrated in Image 18.1, a connected care ecosystem is the north star for quality, patient-centric coordinated and collaborative care. While this lens depicts the entryway as a "digital front door", it leads to a robust and diverse set of connected systems and tools that enable a secure, collaborative, and seamless experience. These tools provide secure, scalable solutions that enable internal enterprise communication channel across care management teams as well as other entities within and outside of the organization with a shared comprehensive view of the patient. Moreover, for a truly seamless, comprehensive coordinated care across the healthcare continuum we need to think of the enterprise, be that the healthcare enterprise or pharmaceutical all as part of the ecosystem of care with the patient in the center of that ecosystem.

18.3 Virtual Health in the Context of Clinical Care

A common thread across clinical care in both enterprise healthcare and the clinical trials industry are siloed, inefficient legacy infrastructure, data and communication systems that result in a disconnect within internal organizations and between patients and care teams. Outdated legacy systems and siloed communication tools a restrict collaboration across teams resulting in disconnected patient care delivery in enterprise healthcare, disconnected collaboration across enterprise healthcare and their patients participat-

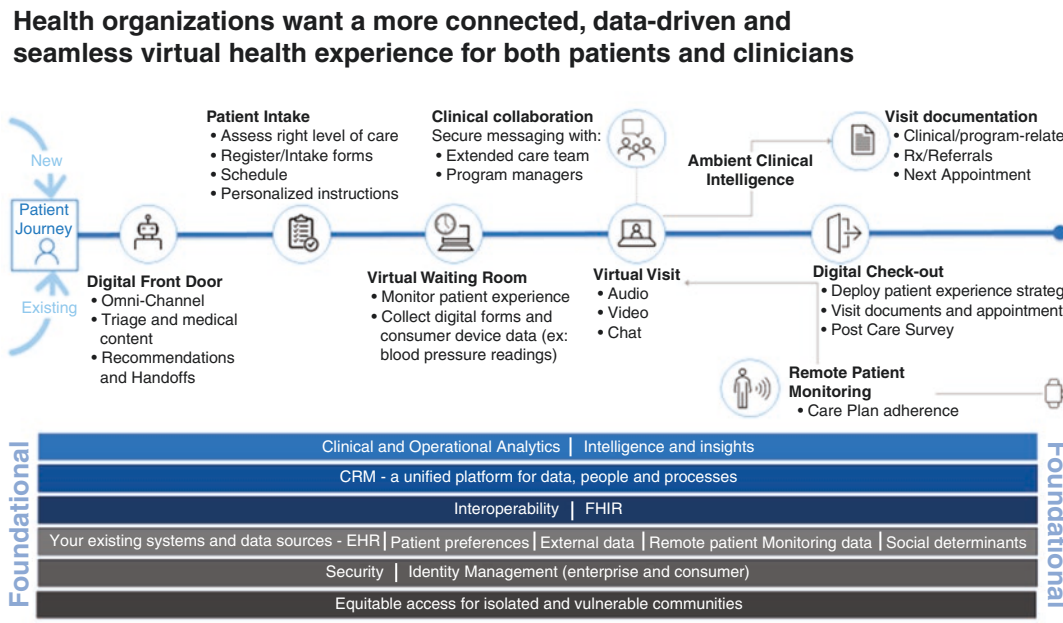

Image 18.1 Connected care ecosystem (credit Shawn Remacle, Microsoft Corporation)

ing in clinical trials. This hampers the care providers to deliver the highest standard of care to their patients as well as delays the time to market for life saving therapies delivered through clinical trials research.

18.4 The Virtual Care Visit

At its core, a virtual care visit experience is about replacing the usual in person interaction between a patient and a care giver with a video call supported by a robust infrastructure of connected systems as seen in Image 18.2, enabling both the provider and the patient a comprehensive view of the patients care journey.

There are many aspects of the virtual care visit that move healthcare to a state of more coordinated, collaborative patient-centric state of quality care.

As our use of electronic health records has become pervasive our in person provider to patient interaction has also changed. Historically this face to face interaction was a discussion between provider and patient with the provider taking handwritten notes. In the era of electronic medical records providers and supporting staff often find themselves working through unintuitive patient data capture workflows facing a computer while talking with a patient and entering information via a keyboard.

In virtual care visits supported by an integrated communication and collaboration platform, the virtual visit enables a return to face to face discussions between providers and patients. Modern communication and collaboration platforms powered through AI solutions built specifically to understand the language, disease and care workflows enable secure and private voice-enabled data capture platforms to capture patient conversations. This alongside integration of siloed data and care team collaboration systems that provide a holistic view of the patient care journey are key to enabling providers to focus on patient care and spend less time on administrative tasks that distract from both parties ability to communicate the visual and vocal cues such as those of empathy, concern and presence we all look for when communicating.

An additional benefit of the virtual visit, is the impact of diversity and inclusion in patient care. Examples in clinical care inequity across diverse populations and socio-economic groups are stark in many areas such as mental health and psychia-

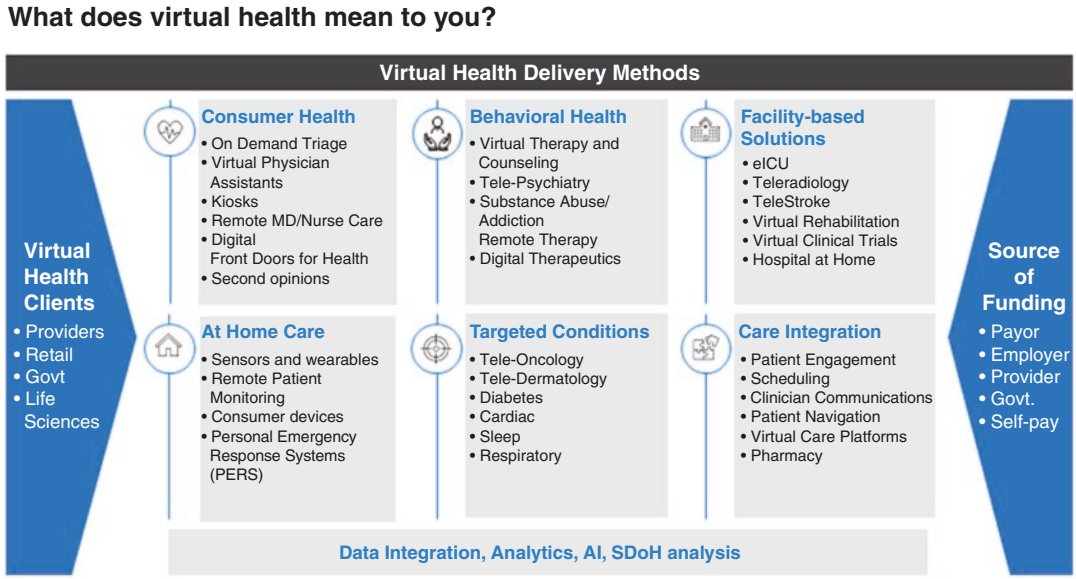

Image 18.2 Virtual health delivery methods (credit Shawn Remacle, Microsoft Corporation)

try but also extends to chronic care disease management and population health as a whole. Many socio-economic and cultural factors limit access to care. Diversity and Inclusion has been an important element, recognized by the industry, missing from the clinical research landscape for decades. [add info regarding inequity and access to cloud—Airband] A detailed discussion on diversity and inclusion in clinical trials follows later in this chapter. At the same time, access to video virtual care through the internet is a source of inequity that needs to be addressed by governments in much the same way as we addressed ubiquitous access to landline phones.

While most aspects of the in-person interaction can be replicated and in many aspects enhanced through a virtual visit it is important to acknowledge that one of the highest held diagnostic and human interactions—touching the patient, is lost in a virtual visit and thus should not seen as a replacement of the in person provider and patient visit but an extension of it.

One of my first experiences out of medical school was working with a seasoned and deeply loved physician in a rural community treating patients with advanced chronic diseases. Our time was divided between the 40 to 60 patients seen in our clinic every day, nursing home visits and critical care rounds at the hospital. Most of our patients were alone and unable to engage in the usual social and community interactions most of us enjoy. I remember very early in my work with him we saw a patient together and he made a point to tell me that many of our patients live alone, and this man's monthly visit is likely the only time he is touched by another person and as busy as we are taking the time to touch someone is an honor and privilege as a clinician.

18.5 Virtual Care in Enterprise Healthcare

Referring back to our definition of Virtual care of as a set of agile connected systems that enable an entire ecosystem of seamless, connected and coordinated care and our approach for defining enterprise solutions to reach this north star, lets examine some of the universal pain points, challenges and opportunities that are pervasive in the enterprise healthcare.

As we walk through these examples we will adhere to the approach of focusing on defining a solution in terms of the people and process. Once we understand the challenge, problem statement and desired outcome the technology is the enabler. Later in this chapter we will address technology considerations in defining a virtual health platform in detail but ultimately, the technical implementation of the "optimal outcome" of your virtual care solution will be dependent on multiple factors such as your existing infrastructure your near, mid and long term digital transformation roadmap and other factors that your trusted business advisor representing your technology partner will provide support and guidance on.

Disconnected care teams, poor care plan execution and limited patient insights are three common challenges limiting the delivery of quality, patient-centric care [2].

When thinking in terms of creating enterprise solution from a single or set of defined use cases we can organize the above concepts in terms of:

1. Collaboration across care teams
   (a) **Challenge**: Disconnected care teams waste time, money, contribute to patient data gaps and disrupt patient care.
   (b) **Problem statement**: care teams within health systems lack a shared, comprehensive view of their patients. This extends beyond the care teams to fragmented communication channels that make it difficult for care team members from different parts of the health system to collaborate across a patients health journey. Additionally, having multiple siloed communication applications across care teams and the organization produce opportunities for inconsistent security and enforcement of enforcing rules and regulations related to the protection of sensitive patient information.
   (c) **Optimal outcome**: Care teams across the organizations ecosystem share a single

enterprise-wide secure and compliant communication and collaboration hub with integrated access to patient data systems and workflow coordination tools accessible to both internal and external teams to provide quality, patient-centric coordinated care.

2. Patient engagement in care execution
   (a) **Challenge**: Poor care plan execution due to lack of resources and systems necessary for coordinating care across multiple locations and providers
   (b) **Problem statement**: outdated legacy care management systems and siloed communication tools inhibit providers and patients to build strong relationships. Providers have a hard time establishing a clear view of their patients care plan which leads to ineffective care plan management, patient outreach and care coordination. Additionally, legacy systems can be unintuitive for both providers and patients making it harder to even technically savvy patients to engage in adherence to their care plan.
   (c) **Optimal Outcome**: Create a unified view of patient and institutional data to streamline care coordination across care locations and providers.
3. Shared holistic view of the patient
   (a) **Challenge:** Limited and siloed patient insights; providers struggle to monitor patients outside of clinical setting; siloed systems contribute to uncoordinated workflows and siloed tasks.
   (b) **Problem Statement**: Providers and patients struggle to navigate siloed data systems leading to both providers and patients with an incomplete view of the patients health information. This makes it harder from providers to provide informed recommendations to the patient and weakens the relationship between provider and patient inhibiting quality, patient-centric care.
   (c) Optimal outcome: Unify disparate data systems to create a shared, intuitive comprehensive view of the patient and tailor care to their unique needs. Extend patient care beyond the hospital and clinic walls through remote monitoring and actionable real time insights.

18.5.1 Hub and Spoke Model for Inpatient Consults for Telestroke and Psychiatry Example

Telestroke and Telepsychiatry are two of the most rapidly adopted applications in virtual health. Telestroke for rapid consulting and therapeutic care delivery and Telepsychiatry for both inpatient and outpatient care delivery.

In 2016, as part of team within a large enterprise healthcare organization in the US, we deployed both a telestroke program across 16 of our academic and community hospitals and a telepsychiatry program in the emergency departments of the same group of academic and community hospitals. The state of technology collaboration and data integration platform capabilities were in the early stages but the results were impressive. We were able to significantly decrease the time to diagnosis and therapeutic drug delivery of Tpa for nonhemorrhagic stroke in many cases under 30 min.

Our telepsychiatry program was able to reduce the average time to psychiatry consult in our emergency departments from eight hours to 30 min.

A recent publication reporting on a multicenter hub and spoke pilot for telepsychiatry between 2018 and 2019 on 557 consults found the average patient wait time from consult request to face to face evaluation was reduced from >24 h to 92 min [3].

18.5.2 Enterprise Patient-Provider Engagement Example

Leveraging a secure unified communication and collaboration platform accessible to both internal enterprise care teams and external consultants and patients, providers and patients have easy

access to patient information through multiple communication channels including encrypted messaging, voice and video calling and virtual meetings.

Virtual Health for internal provider to provider consults and internal learning and training of staff.

Virtual Health for external provider to patient virtual visits, call center management and electronic medical record sharing.

Virtual Health in a Patient-centric approach enables patients to remain engaged in their health and care plan outside of their visits with their healthcare provider. Modern solutions such as virtual scheduling and consults enable patients to connect and engage with care teams and providers wherever and whenever is convenient.

Innovations such as virtual health bots help reduce the burden of live agents by managing common questions and request as well as escalating to live support if the patient need additional help.

Coronavirus Self Checker 'CDC launches Covid-19 bot to help you decide if you need to see a doctor' [4].

18.6 Virtual Care in Decentralized Clinical Trials

The tenants of virtual care as a set of agile connected systems that enable an entire ecosystem of seamless, connected and coordinated care and the use cases, challenges and optimal outcomes identified in the previous section together create the foundation for extending virtual care solutions to decentralized clinical trials. Decentralized clinical trials is a term that has evolved over time and represents a continuum of virtual health components that may be incorporated into the clinical trial. Importantly, the term allows for flexibility within the industry managing multiple clinical trials at any given time to leverage the appropriate set of applications and platform tools fit for purpose to the specific clinical trial and the preference of engagement of each patient participating in a clinical trial.

18.7 Virtual Health in the Context of Clinical Research

Rather like virtual health itself, the terminology used to define virtual elements of clinical research is not that well defined, and varies between institutions. In reality, there is a continuum of clinical research needed that varies from fully observational to fully interventional, alongside a continuum from fully centralized to fully decentralized. Regardless of where a clinical trial lies on this continuum, the clinical research process as a whole benefits from the core elements of decentralized clinical trials that are designed in this context to include the appropriate amount of virtual components for the study, illustrated in Image 18.3.

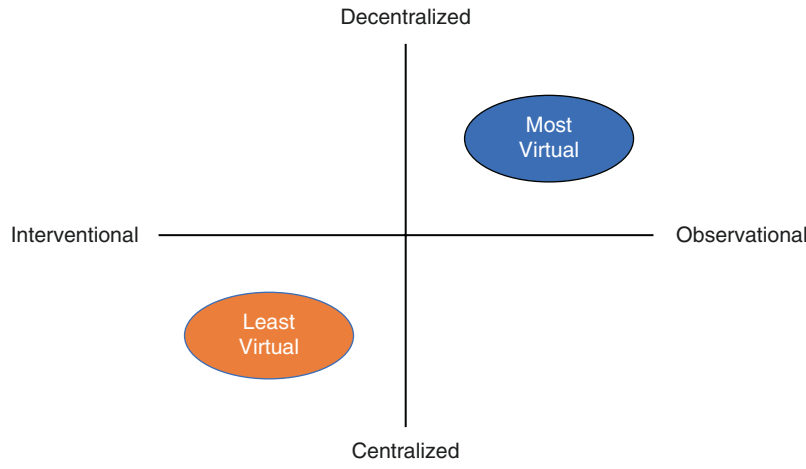

Image 18.3 Continuum virtualization in clinical research trials

As in a clinical care setting, there are a number of reasons for using virtual elements in a clinical research setting, including:

- Efficiency (Can make trials faster contributing to accelerated onboarding of participants and reduced cost)
- Improved assurance of safety, efficacy, equity, diversity and inclusion ("better" trials)
- Improved experience for patients

For well over a decade, the industry has been steadily introducing virtual elements into clinical research in some cases. This is a trend that has been dramatically exacerbated by the COVID-19 pandemic, with many protocol amendments being issued to allow for more virtual elements. While it is likely that there will be some reversion to the mean that occurs post-pandemic, many organizations have now observed firsthand the benefits of increased virtual elements in clinical research and are using the opportunity to restructure their overall approach.

18.8 Diversity and Inclusion in Virtual Health and Clinical Trials

Two and half years ago a Clinical Innovation Research Hub took on the societal problem to save lives through accelerating time to market for life saving therapies. We examined both the societal and industry problems of why it takes 12 to 15 years at an average cost of $2.6 Billion dollars to bring a new life-saving drug to market, delaying access to best available treatments for patients around the globe. These stark numbers elicit diverse commentary and opinion across the spectrum of science, research, government and the public. Diving deeper into the "why" we find some indisputable reasons that we can agree upon as driving factors for the cost and length of time for life saving therapies to reach those in need.

We reached out to hundreds of industry thought leaders, citizens, public, government and private organizations looking to understand "why". What we learned from those involved in clinical research and clinical trials in both the private and public sector were the common rate limiting factors are inefficiencies in drug development, a 10,000% rise in drug development cost since the 1950s and as part of the drug development roadmap, patient participation in the clinical trials process. Specific to the clinical trial process CRO's are unable to provide efficient research services and find their business model threatened. 50% of medical centers (sites) enroll one zero patients in any given clinical trial. 97% of patients do not have access to clinical trials despite the fact that it produces better health outcomes. Looking even closer we see that at the center of the challenge of patient participation in clinical research trials are two primary factors—Diversity and Inclusion in clinical trials. Below are some key resources related to Diversity, Inclusion and Equity data in clinical research are:

- Multi Regional Clinical Trials the MRCT Center of Brigham and Women's Hospital and Harvard
- National Academies of Science, Engineering, Medicine
- NIH Revitalization Act of 1993 Public Law 103-43
- NIH task force on Black and Minority Health
- FDA Drug Trials Snapshots

18.9 Examples of Virtual Elements in Clinical Research

As described above, a clinical trial does not have to be "fully traditional" or "fully virtual", rather it likely to have virtual components in it. These include:

- Virtual Visits
- Virtual Placebo Arms
- Virtual Populations for simulation
- Real World Data (RWD), Real World Evidence (RWE) and Synthetic Data (trial control arms)
  - RWD can inform trial design, eligibility, and synthetic trials
  - RWD is complex due to its fragmented nature

  - FDA has already implemented guidance on the use of RWD for RWE
  - Researchers have proven that RWD can be used to test new treatments
  - Cures Act also encourages the use of RWD to generate RWE for regulatory decision-making.
- Regulatory Agencies (FDA) guidance includes RWD data that is fit-for-purpose [5, 6]

18.10 A Maturity Model for Virtual Health

The maturity of Virtual Health is a helpful concept in envisioning and planning the enablement of virtual capabilities within an organization. As we will see, virtual health has a breadth and depth of capabilities developed to achieve a wide variety of business and clinical goals. Understanding the elemental components of virtual health will help plan investments and set appropriate expectations, allowing organizations to start the potential uncertain journey with a framework to achieve success.

Virtual Health Maturity is a portfolio of capabilities that enable and enhance the delivery of care when a patient, administrator or caregiver are not physically together. The term Virtual Health has been used to describe a wide variety of capabilities and interactions between clinicians and patients. When surveyed, most healthcare and health IT leaders commonly offer different descriptions of what Virtual Health is and, surprisingly, all be right. What makes all these descriptions correct is that they are all Virtual Health. In general, the different definitions are just describing different maturity levels along the virtual care continuum. Adding to the diversity in definitions is that there are multiple dimensions of maturity of Virtual Health. There is a vertical maturity and a horizonal maturity model. Vertical maturity is the completeness of a specific virtual health capability illustrated in Fig. 18.1. For example, a single Virtual Health capability is Virtual Triage. A **Basic** capability for this would be for a patient to synchronously chat with a clinician, describing a condition and being given advice on what to do next. An **Intelligent** level version of Virtual Triage would be the ability for a patient to asynchronously send a medical selfie (video/still image) in a mobile app that "pre-reads" the image and directs the

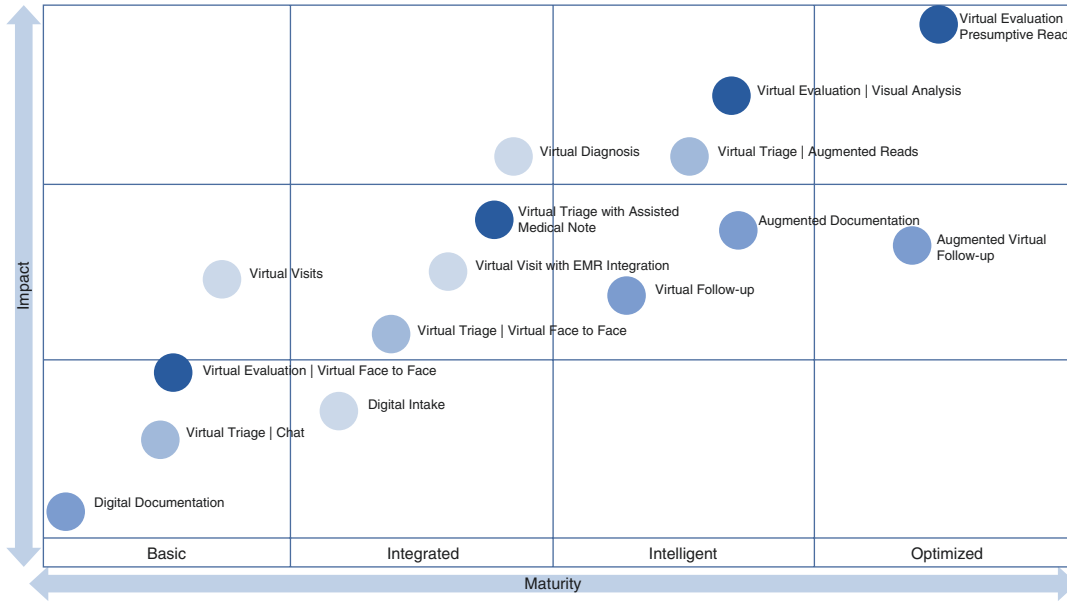

Fig. 18.1 Virtual health vertical maturity model

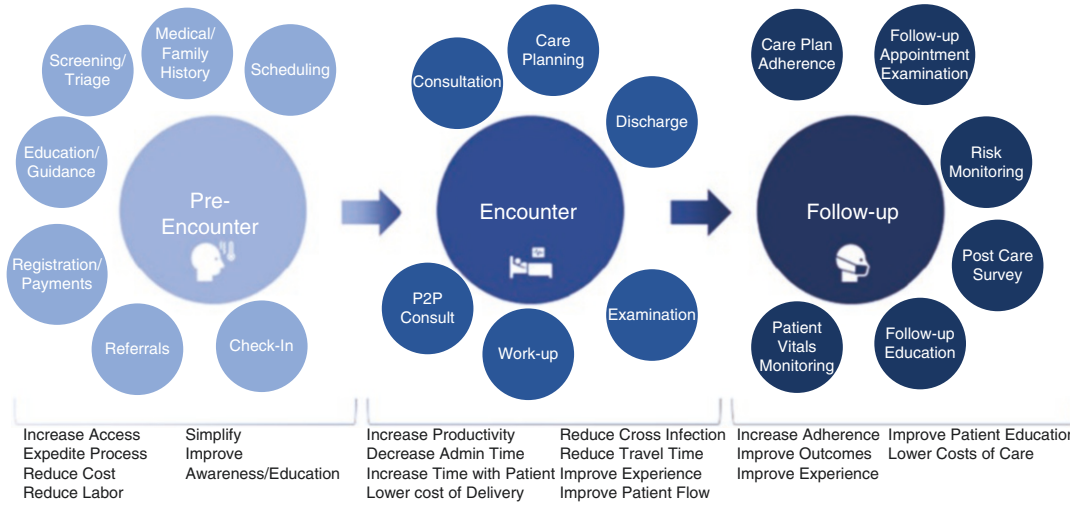

Fig. 18.2 Virtual health horizonal maturity model

requestor to an appropriate clinician queue to review the pre-read and respond back to the patient with a recommendation.

The second dimension of maturity is horizonal illustrated in Fig. 18.2. Horizonal or longitudinal maturity is the completeness of virtual experience across the lifecycle of a medical issue from pre-, during and -post events. In the example of **Integrated** virtual triage, the recommendation could come with a link to schedule an appointment with the appropriate caregiver for the diagnosis or establish a follow-up care tracking model to help the patient return to health.

It is more important to recognize that there is a maturity model of capabilities with Virtual Health rather than the specific definitions or criteria of each level. Having that awareness will help establish that there is also a maturity model for Key Performance indicators (KPIs) or Objectives and Key Results (OKRs).

To ensure appropriate investments and to set the correct expectations, the virtual health leadership team should establish time-series of the KPI milestones over time. This plan for the evolution of benefits both helps account for the adoption of innovative technologies and processes but is also useful for validating the enabled capability as appropriate for fit. If interim milestones are not met, corrective actions can be applied before full investment has been committed.

Establishing clear goals and success criteria for each level of a virtual health program is critical to balancing the investments and priorities when establishing a Virtual Health program. When defining these goals and timelines, it is important to be specific and inclusive of the whole impact.

KPI/OKR Examples:
Too Narrow/Too Capability Focused

- Initiate 30% of Low Accuity Encounters through Virtual Triage
- Improve pre-encounter patient experiences.
  - 10% reduction in labor requirements
  - 10% reduction in delivery costs
  - 5% increase in new patients
  - 5% increase in Net Promotor Score
  - 75% adherence to referral/treatment
- From a well-defined set of business KPI/OKRs as illustrated in Fig. 18.3, you will then need to add specific adoption numbers to the virtual health capabilities and apply the
  - 50% increase medical education with health chatbot.
  - Initiate 30% of Low Accuity Encounters through Virtual Triage

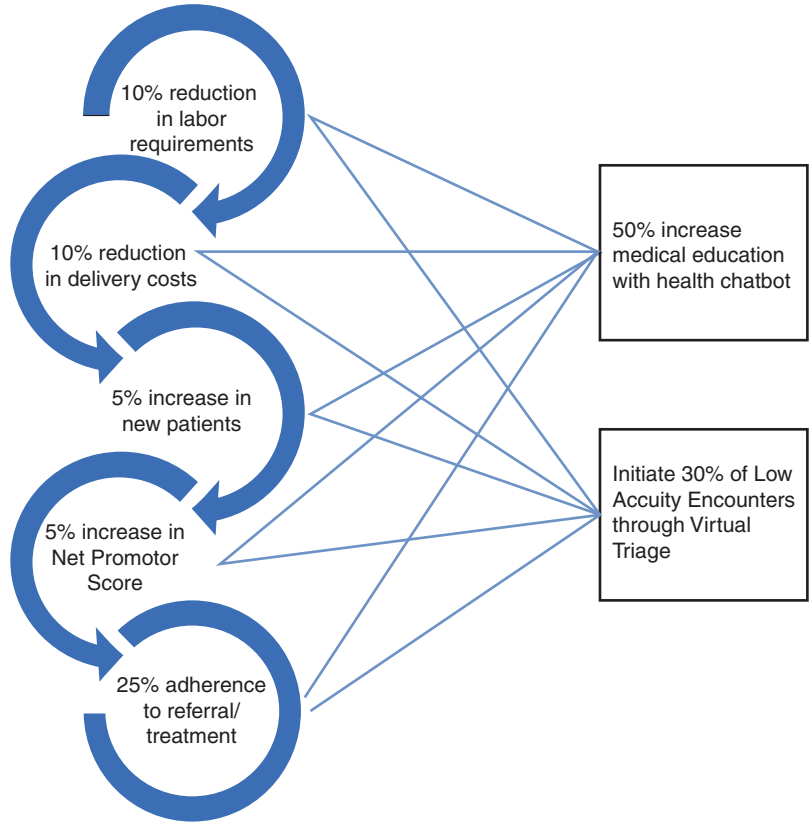

Fig. 18.3 Defining virtual health KPIs

Considering that Virtual Health is a large portfolio of capabilities enabling a wide breadth of outcomes, it can become challenging to decide where to start. There is not a universally right starting point, but there are good practices that help find a good starting process as illustrated below in Fig. 18.4.

By prioritizing the KPIs or OKR with their associated capabilities, planning teams can align the Priorities and Cost/Complexities in a 2 × 2 matrix. From that, you can identify a starting point and journey thought the horizonal and vertical maturity evolution.

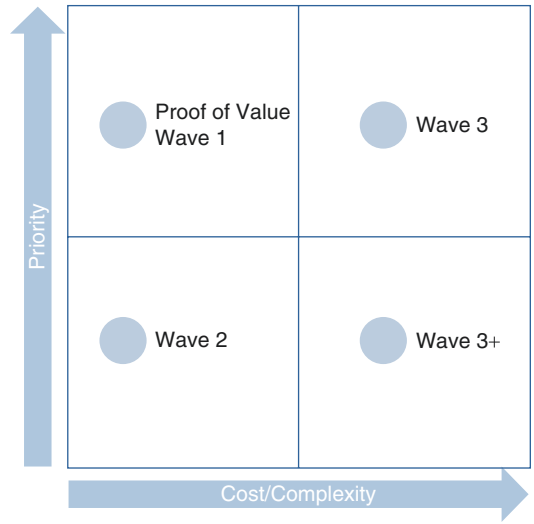

Fig. 18.4 Virtual health prioritization framework

18.10.1 Know the Vision but Prioritize Starting the Journey

By following a structured data driven approach to plan for Virtual Health, a clear vision and roadmap for enabling Virtual Health and a timeline for measurable benefits for patients, caregivers, and administration and be used for the complete

lifecycle of the Virtual Health Program. It is especially important to balance the time and completeness of the planning phase at the beginning of the journey. It needs to be clear with program sponsors that starting the deployment of Virtual Health with potentially incomplete information, or more commonly, non-unanimous prioritization, is more important that waiting for the sometimes-impossible tasks of either having complete context or unanimous agreement. The key to ultimate program success is to regularly verify the performance and the openness to reprioritization the program based on the feedback from the project as it is being delivered.

18.11 Approach to Defining Virtual Health Digital Transformation Solutions

People, process, and technology; the approach to establishing a dynamic and scalable program for enabling collaborative, connected and seamless care for inpatient and outpatient virtual care and decentralized clinical trials starts with understanding the People involved in delivering and receiving care, then the Process for delivering and receiving care and lastly the Technology involved in enabling the people and process in care delivery.

Following a structured process for defining the approach to delivering a virtual health platform within multiple healthcare delivery scenarios such as enterprise healthcare and clinical research trials provides the best probability of delivering a high value, high impact, and implementable virtual care program within your organization.

Although there may be some variation on the approach the following description encompasses the components you should document as part of a well-defined virtual care or decentralized clinical trials solution.

The virtual care solutioning team should represent a diverse set of individuals within your organization and a trusted business advisor that represents a technology partner with a strong change management and technical team with experience delivering enterprise level production virtual healthcare solutions across various industry scenarios. Specifically, your internal team working with your technology partner should include business decision makers, technology decision makers, administrators, change management, operations and patient facing care providers. This list is not inclusive, many organizations also choose to engage additional resources such as patients and others that are part of the virtual care experience. A diverse team brings deeper insights and experience to the defining of the scenarios, use cases and workflows of the solution resulting in a more mature, high value, high impact, and implementable solution.

The Scenario Envisioning and Architectural Design definition process: (the title of workshops and process for defining a solution will vary between technology partners).

Notes on technical terminology commonly used in defining a business and technical solution:

- Scenarios and Personas: A scenario involves a situation or challenge that involve a single or multiple personas that follow a path to create a resolution to the scenario. Personas represent the kind of person who would interact with a system; they define a typical user of a system.
- Use Case and Actors: In software and engineering, a Use Case is a list of steps or actions that define interactions between an Actor and a system to achieve a goal. Note, an Actor can be a person or other external system.

Reference Architecture: provides a template for modelling a technical solution to express a business outcome based on a common terminology. It shows the structure, relationships and integrations between the technical systems that form a business solution.

Scenario Envisioning—Identification of a high value, high impact, and implementable solution.

Scenario Envisioning: "A scenario is a story told from the protagonist's point of view that explains their situation and what they want to achieve" [7].

Core elements of a scenario: Important note, technology is not the focus here. The resolution of the challenge is described as the resolution of the challenge through achieving a desired outcome; instead of naming a technology solution we say some "magic happens" and the desired outcome is achieved.

- Describe the Protagonist; who is the scenario about? What is their background, mindset, and technical affinity?
- Summary of the challenge/opportunity; a summary of the main problem the scenario needs to address. What are some of the details that make this a problem/opportunity/challenge?
- Desired outcome: what is the best outcome and what objective, or subjective measures can be used for success metrics?
- Give the scenario a name.
- Tell a story from the protagonist point of view that is implementation free (free of technology implementation description) that relates to the business environment.
- The current state, the challenge, the "magic happens" and there is a desired future state outcome.
  - Describe the:
    Scenario
    Situation
    Problem statement
    Desired outcome
    Success metrics
- Identify the challenges, pain points and desired outcomes across multiple scenarios and personas (people) (scenario envisioning)
- From the documented scenarios, identify the key challenges, pain points and the desired outcomes the team agrees represents a use case resulting in a high value high impact solution.
- Define the Actors involved in the use case that represent the high value solution.
- Define the use case current state workflow(s) that encompass the identified challenges.
- Define the use case future state workflow that represent a resolution of the identified challenges.
- Identify the future state actors for the use case.
- Identify the use case current state technology environment.
- Identify future state use case technology environment.
- Assess if the future state environment can be implemented in the near term.
- If yes, then proceed to reference architecture if no, re-evaluate the future state workflow and use case to accommodate a phased approach. The near-term use case should be high impact, high value and implementable in the current environment.
- Create a reference architecture that embodies the future state high value, high impact, implementable use case as well as other core elements of a secure, dynamic, and scalable solution.

18.12 Technology Considerations for Virtual Health

Three core focus areas driving technology considerations in defining an architecture to enable virtual health solutions are:

1. Digitize the Data: Establish an end to end flow of data
   (a) For enterprise healthcare delivery this represents the dynamic holistic view of the patient care journey
   (b) For Clinical Research this is represented in an end to end flow of data from study objectives through study reporting
2. Maximize the value of data: Enhance access to high quality data and enrich data quality through artificial intelligence
3. Meet patient need as healthcare industries Modernize:
   (a) For enterprise healthcare delivery, reduce provider and patient burden in participation in care delivery, improve benefits to patients from modern healthcare delivery and expand access to quality care.
   (b) For clinical research this is represented by reducing patient participation burden, improved benefits to patients from research and expanding access to clinical trials

18.12.1 In the Context of Enterprise Healthcare

Your virtual health technology platform should include capabilities that support three key areas of patient centricity and capabilities:

1. Enhanced patient engagement: personalize care, patient insights and virtual health
2. Empower health team collaboration: care team collaboration, care coordination and continuous patient monitoring
3. Improve clinical and operational insights; clinical analytics, operational analytics and data interoperability

Technology applications and tools support these capabilities through health care apps, virtual health bots, open standards, custom and pre-configured workflows, AI/ML models, connectors (Apps, EHR connectors, APIs), templates, customized configurations and User interfaces, and common data models.

Technology applications and tools

- Compliant data handling
- Patient CRM
- Data Visualization & Reporting
- Clinician Portals
- Patient Portals
- Virtual Visits
- Data Storage
- Advanced Analytics
- IoMT (internet of Medical Things)
- FHIR API

18.12.2 In the Context of Clinical Care

Putting patient's first. Delivering quality patient-centric care also applies to our patients participating in clinical trials enabled through a holistic clinical trials experience. Core to achieving this holistic experience is enabling innovation and transformation in clinical trials management operations.

Successfully implementing new technology requires interoperability across multiple platforms and devices that can be integrated into existing workflows in accordance with standards.

One of the limiting factors that has historically prevented widespread adoption of virtual components into clinical trials, has been the lack of a common technology approach. This generally means that once a trial is designed to use virtual elements, a series of technology decisions need to be made for that trial, and technology needs to be deployed from scratch to support those technology decisions. The cost and time associated with this often eliminates many of the benefits that the virtual approach was supposed to provide.

As we move into an era where virtual elements will be used much more frequently, many organizations are moving towards a platform for virtual research, with components that can be used and reused across multiple trials as illustrated in Image 18.4. The backbone for such a platform should be a common data layer, designed to ingest, maintain and enrich data from traditional and non-traditional sources (including but not limited to clinical care). The platform should also interface with medical and consumer based devices, as both are frequently used in a virtual setting.

In addition to the three key areas of a virtual care platform; enhanced patient engagement, empower team collaboration and improve clinical and operational insights and their associated capabilities enabling a quality, patient-centric care, a decentralized clinical trials platform should also include the capabilities outlined below: [5, 6].

Clinical Trial Management Systems that enable:

- ePro (electronically patient reported outcomes)
- eConsent (electronic consent) supported by a dynamic and scalable consent management platform accommodating multiple configurations of consents to meet global geographical regulatory and compliance standards.
- eCOA (electronic clinical outcome assessments)

Connected people and devices

- IoMT/FHIR/Devices
  - Challenge of sensor or other device validation prior to introduction to a study.

Image 18.4 Key Personas and supporting technology systems in virtualized clinical research trials

Patient Clinical Trial Participant	Study Investigator & Coordinator	Trial Study Support Staff	IT Clinical Specialist Support Technician
Patient Apps & Devices		**Systems**	**Data**
Custom Trial App Security Connectivity Wearables monitoring Phone/video conferencing		CTMS EMR Telemedicine platform Patient App scheduling system	Medication monitoring Patient-reported health Study Visit results IoMT

- Regulator variability in sensor/device data in clinical research
- Home health and virtual technology training challenges

As shown in Image 18.5 below, an important component to the development of a production solution for decentralized clinical trials is the Proof of Technology or feasibility testing. The engagement approach described below represents an agile approach to product development thus enabling the lessons learned to be incorporated, inform and iterate on the backlog of development tasks created from the Sprint 0 prior to the Proof of Technology phase development. The Proof of Technology development phase is critical for informing the final approach for development and deployment of a successful production solution in decentralized clinical trials.

18.12.2.1 Patient Clinical Trial Participation Considerations

It is worth noting that in cases where patients are interacting directly with virtual health elements in trials, the patient experience is typically different to that of traditional clinical trials. It is incumbent upon trial designers to understand these differences, and understand that a patient responses to them may be quite individual. As an example, if a trial design is changed to include more home visits and less hospital visits, some patients will welcome this change and others will fear it. Similarly if technology such as an Apple Watch or Alexa is introduced into the patient experience, this will likely invoke different responses.

One area that deserves specific attention in this regard is inclusive design. Trials with virtual elements can often include a much more diverse group of participants, which is almost always a benefit overall. However, the greater the diversity of the participant pool, the more individualized their needs are likely to be. To help with this, we recommend that at the time of trial design, targets are set for diversity and inclusion and an inclusive design technology team is enlisted to ensure the right technology decisions are made for the trial's participant facing components.

18.12.2.2 Clinical Trial Sponsor and Trial Staff Considerations

- Unique aspects of decentralized clinical trial development and core elements of the protocol related to virtual communication, collaboration, patient monitoring and data integration.
- Direct to Patient Delivery of Study Drugs, Devices and Therapeutics

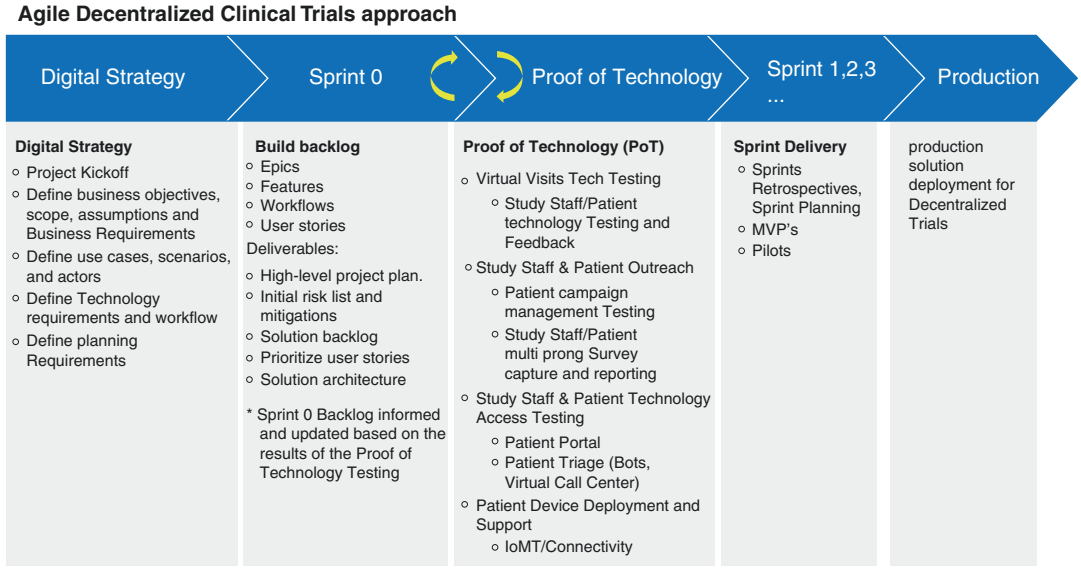

Image 18.5 Engagement approach for defining a decentralized clinical trial platform

- A new era for the Visiting Nurse and Home Healthcare industry
- Device configuration, compliance and security during and after the trial
- Training and support
- Feedback loop (surveys) for all staff and patients

18.12.2.3 Patients as Participants in Decentralized Clinical Trials Considerations

- Technology affinity—clinical trial participants and study staff
- Connectivity and access
- Training and support—a new era of clinical IT support in pharma and enterprise healthcare

18.13 Virtual Visits, Virtual Health and Clinical Outcomes

This chapter was written during the second wave of the coronavirus pandemic late in 2020. Even now you cannot discuss virtual health without acknowledging the impact that this pandemic has had on its adoption. As mass vaccination looms on the horizon, the "new normal" will undoubtedly include a significant role for virtual health molded by the pandemic. What can we glean already about the state of virtual health in the near future?

18.14 Pre-pandemic State of Virtual Care

Prior to March 2020 less than 0.01% of visits were virtual (Commonwealth Fund below) and only 24% of healthcare programs in the US Health systems had an existing virtual health care program. The primary factor keeping the rates of telemedicine low was reimbursement by payors. For example, Medicare only paid for care if the patient was in one of the designated, underserved, rural areas and the visit was performed with the patient in person at a local health facility and using specialized equipment. Other barriers to telemedicine included economic disparity, ability to use equipment, it runs counter to the healers' tradition of "laying hands on the patient" and the unproven belief that in person visits produce better outcomes. This point is especially true for telephonic visits (10% of Americans do not have internet access, Pew research Trust) which are thought to be sub-optimal when compared to video visits.

18.15 Virtual Visits During the First Wave of the Pandemic

At the onset of the pandemic with the imperative to reduce spread by staying home CMS rapid loosened regulations to allow Medicare to reimburse for a larger range of telehealth services (CARES Act). Changes include:

- More than doubling the number of allowable telemedicine services.
- Allowing all health care providers that are eligible to bill Medicare to provide telemedicine, including first-time professionals such as physical therapists, occupational therapists, and speech language pathologists.
- Waiving geographic restrictions that limited telemedicine to Medicare beneficiaries residing in rural areas designated as professional shortage areas;
- Permitting telemedicine to be delivered to Medicare beneficiaries in their homes rather than requiring them to come into physician offices, hospitals, and other health care facilities;
- And allowing telemedicine to be delivered over an audio-only phone in addition to video.

States (Medicaid) and private payors followed suit.

The number of telemedicine visits increased rapidly, while it decreased the spread of the coronavirus and protect vulnerable citizens and spared PPE that was in short demand for frontline workers, it did not offset completely the dramatic decline in in-person visits. The Commonwealth Fund reports a peak in virtual visits of about 14% in late April and May as illustrated in Fig. 18.5. Other estimates are higher with CMS reporting that 33% of visits being virtual. Forrester says we are on track to do over 1 billion virtual visits in 2020, 90% of which are COVID-19-related.

The number of telemedicine visits has been declining slowly from its peak as covid-19 cases slowed and stabilized at around 8% of visits from July to November. This is still considerably higher than pre-pandemic numbers. It is yet to be seen what the impact of the second surge and the vaccines that are on the horizon will have on telemedicine visits. We already know that many of the temporary regulations and reimbursement waivers are being rolled back which is likely to drive the numbers down. In addition, private insurers who had waived co-pays are now shifting some of the costs to consumers.

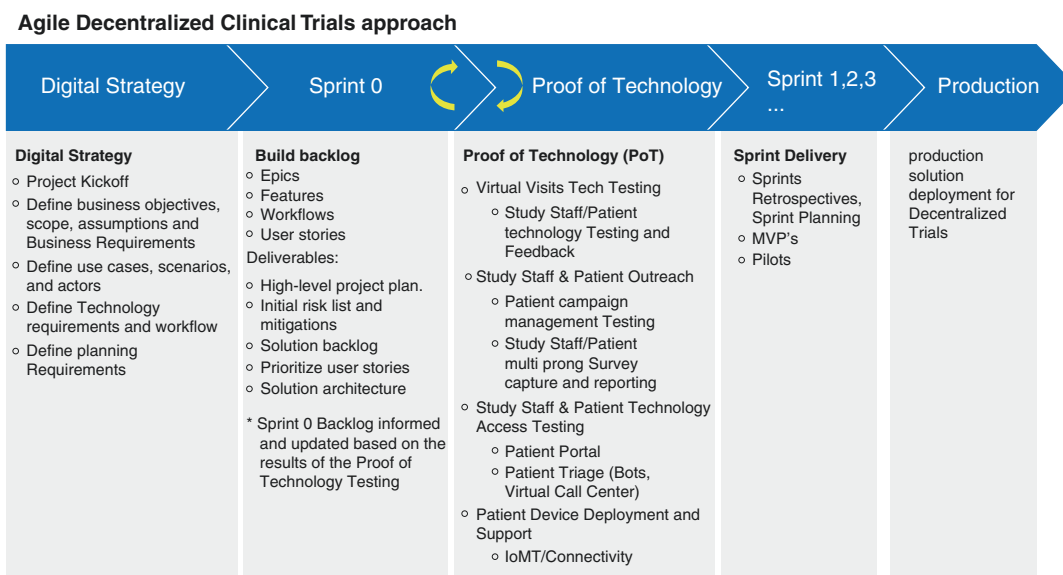

Fig. 18.5 Seamless virtual health experience

18.16 Virtual Health Post Pandemic

The healthcare system has adapted seamlessly to telemedicine visits and there is wide recognition that many of the temporary rules need to be made permanent. A final rule released by the Centers for Medicare and Medicaid Services December third, 2020 making 9 of the 140 telemedicine services permanent and extending coverage for 59 service temporarily. Permanent telemedicine services include psychotherapy, cognitive assessments, and certain home visits. Legislation will also be needed to make the changes permanent in urban and suburban areas. This is a cutback from the temporary measures that fueled the growth of telemedicine in March and April and several organizations have already expressed concern at these changes especially the lack of support for remote patient monitoring. Many providers are, understandably, hesitant to invest further in telehealth, waiting to see what CMS and other payers do regarding telehealth visit rules and reimbursement standards post-pandemic.

We will need to monitor several factors over the next 2–3 years including:

- Will the demand for Virtual Health grow? Frost and Sullivan predict a sevenfold increase by 2025.
- Will virtual Health become a revenue stream?
- Will reimbursement remain at parity with in-person visits beyond the pandemic?
- Will new virtual health technology that protects PHI be cost-effective?
- Can we build new processes into our existing workflow for telemedicine?

Underpinning all of this will be the need to demonstrate an ROI through the quadruple aim—better health, better care outcomes, lower cost and improved patient and provider satisfaction. We need to compare the ROI of a telephonic visit to a video visit to a virtual health experience that includes remote patient monitoring with the visit. We also need to demonstrate at a national level the variation in virtual care in different socioeconomic circumstances and where inequities are present, we need to make strong suggestions on how to correct them e.g., broadband access.

We have the data! The pandemic has provided this for us. The onus is on researchers to elucidate the value of virtual health and to show that at a national level that virtual health can be delivered in.

- Bringing data to the visit—360 view of patient
  - Patient self-reporting
  - Personal\consumer devices
  - Medical grade devices
- Qualitative measures
  - Patient satisfaction
  - Clinician satisfaction
- Quantitative measures
  - Cost effectiveness
  - Compliance with appointments
  - Quality of care—NQF quality framework
  - long term outcomes
  - Reduced admissions and readmissions
  - Diagnosis and SDOH

Use the ATA Telehealth guidelines

- Virtual Clinical Trials (separate section)
- The future. Conclusions. Despite cost savings and improved patient satisfaction it remains to be seen whether telehealth finds a secure foothold in the post-COVID-19 world.

18.17 Conclusions and Future Outlook

18.17.1 Connected Data Everywhere; The New Ecosystem of Patient Care and Clinical Research

One aspect of patient centricity is ensuring that patients who can benefit from clinical research have the option to participate in it. There's an increasing consensus in the research community that clinical research is not only essential to advancing medical science but is also associated with better health outcomes for many study par-

ticipants. This has led to the emergence of Clinical Research as a Care Option (CRAACO) as a serious topic of discussion among researchers and healthcare professionals. As technology is used to facilitate more effective recruitment, it is vital that the right patients are being matched to studies, balancing the need for a diverse patient population with the requirement for patients to make an informed choice on whether participating is the right choice for them.

Ultimately, we can use technology to ensure that every patient who will benefit from research has the option to participate, and every patient is making a fully informed choice on the risks and benefits to themselves and society.

Decentralized clinical trials present their own challenges. These trials may present fewer burdens in terms of participation, but in many cases, patients still have interests that need to be represented, particularly in terms of how their data is used and reused. Technology systems will need to be designed that are highly user-centric, giving participants a clear understanding of the intended primary and secondary uses of their data, alongside the risks of misuse (including reidentification of deidentified data). This will need to be provided both ahead of time and in real time, allowing patients to provide truly informed consent.

The real-world evidence (RWE) and Clinical Research as a Care Option (CRAACO) trends, when considered together, reveal that the lines between clinical research and clinical care are becoming increasingly blurred. Trial designs are emerging that may combine claims data, EMR data, and data from wearables. New operating models are emerging that are increasingly direct-to-patient, or where much of the research is being performed in a clinical care setting. In addition, data from (for example) off-label prescribing, could be of huge benefit to clinical research if captured consistently. These changes can make it more difficult to represent the needs of patients in all circumstances.

The goal is to make it possible for patients to aid in clinical research simply by participating in healthcare, and to ensure that the benefits of clinical research flow to clinical care much more efficiently than is currently the case. But as we facilitate this change, we must ensure that patients participating in all aspects of the healthcare system are fully informed of the downstream effects of their participation.

18.18 Technology Advances That Can Help the Patient Experience in Virtual Health

As more physician-patient interactions happen virtually, health systems should ensure clinicians are trained to focus on the patient during a virtual visit. They should convey empathy and compassion and communicate with the patient even while looking at data or notes and not making eye contact. (deloitte article).

In clinical research, there are many ways in which advances in technology can virtualize more elements of the clinical trials process for the benefit of the research itself and for participants. Three examples include:

- Data Analytics
- Robotics
- Artificial Intelligence

18.18.1 Data Analytics

At the time of writing, we have a richer collection of data about patients than at any time in our history, but in many ways, we are just at the beginning in terms of creating an accurate picture in data of a patient history. In addition to the information commonly stored in an EMR that could affect a patient's health include (but are by no means limited to), demographic, socioeconomic changes, job role, environmental factors, diet, and social interactions. Advances in how we maintain and manage data will allow us gain a much deeper understanding of how these factors combine to create highly realistic models of patient populations. This will allow some clinical research to happen largely without the direct involvement of patients, which in turn can dramatically increase its efficiency.

18.18.2 Robotics

One of the limiting factors in conducting clinical research is the need for roles that can only be conducted by skilled humans (from pre-clinical studies to remote site monitoring to direct patient interactions). In the near future, we will be able to use robotics for these purposes. As we move towards increased use of robotics for direct patient interactions, we must be particularly mindful of inclusive design, and carefully evaluate each use case. For example, patients are likely to respond differently to a robot that is used to record patient outcomes, to one that is doing a blood draw.

18.18.3 Artificial Intelligence

AI is already being used fairly extensively in the field of clinical research to get answers to research questions more efficiently. Before clinical trials begin, there are many uses of AI.

Today, AI can help us identify candidate molecules and drug targets. We can successfully predict gene-disease association, and can use AI to help us understand if inconsistencies in the pre-clinical phases are the result of human error. At this point we are moving towards being able to replicate large amounts of in vitro research in silico, in some cases taking substantial costs and years of time out of pre-clinical research.

In the clinical phases of research, we use AI insights from historical data to guide us towards important questions to ask (hypothesis generation), and as we are gathering information from patients, we use Natural Language Processing (or NLP) to automate the collection of unstructured data and put it in forms that can be more easily analyzed. There is real potential to develop novel digital biomarkers, reliant upon smart medical devices or even consumer wearables, combined with use of AI to enrich or validate the data. Increasingly clinical research will rely upon non-traditional data sources, from EMR to demographics data, and even social media feeds. AI can look for signals in those data, help us understand where data appears to be inaccurate, where data is missing, and even plug the gaps in some cases. And as data gathered in the context of a trial is compared to existing data, AI can perform predictive modeling, providing insights into likely future avenues of study.

Of course researchers conduct their activities in the context of other research that has happened before, and this is another area where AI can be enormously helpful. The full body of knowledge is not standardized, is often unstructured and in some cases is not even digitized. Around 4000 papers are published every day in biomedical journals. We can use machine reading to not only ingest this information, but to also help clinical researchers and biostatisticians be directed towards the most relevant content.

There are many opportunities for AI to optimize study operations. AI is used to evaluate study protocols and identify barriers to their successful completion. It is used to determine the best site candidates, to find target patient populations, and identify patients that are likely to match a desired phenotype. Given the persistent challenges that remain in site selection, patient enrollment and patient retention, these benefits are not to be sniffed at.

Other aspects of study operations provide real opportunities for AI as well. AI can be used to automate elements of endpoint adjudication, reduce errors associated with human data collection, provide automated assessment of safety signals, and increase the efficiency of risk-based monitoring approaches.

AI also has a significant role to play in terms of making trials more patient centric. We can use AI to direct patients to studies they may be best suited for, based on analysis of inclusion and exclusion criteria across thousands of protocols. We can predict which patients are most likely to enroll in studies, those most likely to adhere to the treatment protocol and those most likely to remain in the study. But there is also the opportunity to use technologies powered by AI that reduce the burden on patients participating in studies. We can use wearables to reduce data entry for patients and we can use personal assistants such as Alexa to collect patient recorded outcomes seamlessly, to establish ongoing patient engagement and to ensure that participating in the study continues to be fulfilling to the patient.

At some point in the future, it is likely that no trial will begin with real patients until it has been simulated using AI models. Properly deployed, AI has the potential to be the most important partner in clinical research for the study sponsor, co-ordinator and participant.

18.19 Case Study: Decentralized Clinical Trial Platform

Joseph, a 75-year-old grandfather from upstate New York who likes to walk along the lake with his dog, Spot.

- Diagnosed with prostate cancer with minimal symptoms in July 2018.
- Nearest academic hospital 1-hour drive away, he is aware the hospital is very active in clinical trials but opts not to be enrolled in a clinical trial due to the distance from his home.

What does a decentralized clinical trial have to look like to ensure Joseph can participate *and* successfully complete a clinical trial?

How can we ensure that both Joseph and the clinical trial team have a positive experience?

What services, tools and technology infrastructure are needed to deliver a delightful experience for both the clinical trial research team and Joseph?

Nurse Dan, Clinical Research Coordinator at the New York academic hospital, identifies a clinical trial as a possible viable option for Joseph.

Nurse Dan calls & invites Joseph in April 2020 to consider participating in a new Virtual Clinical Research Trial comparing two doses of a new prostate cancer drug.

Joseph agrees to schedule a virtual visit with the Study Coordinator, Judy, to be evaluated and review the trial logistics.

Joseph meets virtually with Judy over secure video conferencing software, gets and overview of the trial and decides it is a good fit. He completes his eConsent during the visit.

Joseph needs to have a biopsy and baseline labs drawn prior to confirm he meets eligibility criteria for the study. He has the option of going to a local lab or having a Mobile nurse visit him in his home to collect his vital signs, PSA, and other labs for his baseline screening visit. Joseph opts to have the mobile nurse come to his home.

As part of the clinical trial Joseph must have a biopsy of his prostate. The clinical trial sponsor has contracted with local community hospitals as part of the study initiation, so Joseph only has to travel 15 min to get a biopsy at his local community medical center to confirm prostate cancer diagnosis.

18.19.1 Joseph Is Officially Enrolled in the Virtual Clinical Trial!

Joseph receives "welcome kit": investigational drugs, drug information leaflets, pre-configured tablet, and wearable device to monitor his vital signs via Fed Ex.

Joseph has a virtual visit with one of the technical support team members on the clinical trial who walks him through the apps on his tablet, orients him to the trial bot "Liz," shows him how to schedule appointments, access his data and support 24/7. The tech support team member also orients Joseph to his new wearable device. Joseph also opts to download the app for the clinical trial on his mobile device.

Joseph regularly receives his investigational drugs in the mail through a delivery service contracted by the Pharma Sponsor.

Joseph takes his investigational drugs daily.

Joseph logs his symptoms as well as other activity on the telemedicine portal on his tablet (pain status, how often he walks spot, etc.)

The mobile nurse visits Joseph in his home every 2 weeks to check in and collect blood for his labs.

18.19.2 Throughout the Course of the VCT

Joseph's wearable device collects data 24/7 throughout the trial.

The Clinical research Team sends "push notifications" assessing QOL to Joseph: "How is your pain today?" "How far did you walk Spot today?" "Did you take your red pill yet?"

If pain is progressing, etc., team will proactively send the mobile nurse unit to assess.

He also is asked to assess his experience with the clinical trial staff, mobile nurse and technology on a regular basis.

18.19.3 Use Case Discussion Topics

Below are important questions to consider related to both the clinical trial site staff and Joseph's experience and ability to complete the clinical research trial:

- How do we help Joseph use his new devices and apps?
- How we create a feedback loop that informs both the clinical study sponsor, study staff and Joseph?
- How do we make sure the technical devices and virtual experience portal are aligned to Joseph's physical and mental abilities?
- How will we assess if the technology needed to be used by Joseph will work with his infrastructure and other connectivity resources that Joseph has at his residence?
- How do we ensure that IT issues don't interfere with the ability for the study staff and Joseph have continuity of care and a delightful experience?
- How do we validate the data we are receiving from the remote vitals monitor?
- How do we troubleshoot any access issues that the staff or Joseph may have?
- How do we integrate the streams of data to make it actionable for the trial staff and care team?
- How do we make Joseph's data available to Joseph and his clinical care team outside of the study?

Website Links

https://www.americantelemed.org/resource/why-telemedicine/

https://healthcare.mckinsey.com/virtual-health-a-look-at-the-next-frontier-of-care-delivery/

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https://datavant.com/2020/05/26/how-americas-health-data-infrastructure-is-being-used-to-fight-covid-19/

Questions and Answers

1. What is a Virtual Health Maturity Model?
   (a) A history Virtual Health over the last 10 years.
   (b) A concept that Virtual Health is made up of multiple capabilities creating specific values can be delivered over time.
   (c) The concern that older demographics react differently to the use of Virtual Health.

   ANSWER B: A concept that Virtual Health is made up of multiple capabilities creating specific values can be delivered over time.
2. True or False: When defining KPIs, high level descriptive goals are good enough.
   (a) True
   (b) False

   ANSWER

   False: Effective KPIs should be specific and measurable with a defined timeline.

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19 Digital Health Solutions Transforming Long-Term Care and Rehabilitation

Mohamed-Amine Choukou, XinXin (Katie) Zhu, Shwetambara Malwade, Eshita Dhar, and Shabbir Syed Abdul

Abstract

Emerging digital healthcare solutions (DHS) have opened wide range of opportunities for tele-monitoring and improvements in health behavior. These solutions not only help monitor health status, but also aid towards diagnosis, prevention and better management of health conditions. DHS have a broad scope in long-term care, disease management as well as addressing psychological and social needs of patients. In this chapter we discuss tele-monitoring solutions for long-term care and solutions for rehabilitation.

M.-A. Choukou
Department of Occupational Therapy, College of Rehabilitation Sciences, University of Manitoba, Winnipeg, MB, Canada
e-mail: amine.choukou@umanitoba.ca

X. (Katie) Zhu
Center for Biomedical Data Science, School of Medicine, Yale University, New Haven, CT, USA
e-mail: xinxin.zhu@yale.edu

S. Malwade
Taipei Medical University, ICHIT, Taipei, Taiwan
e-mail: sv14kekade@tmu.edu.tw

E. Dhar
Graduate Institute of Biomedical Informatics, Taipei Medical University, Taipei, Taiwan

S. S. Abdul (✉)
Artificial Intelligence and Digital Health, Taipei Medical University, Taipei, Taiwan
e-mail: drshabbir@tmu.edu.tw

Long-term care includes a wide range of care services for patients of varied age groups with chronic conditions or functional disabilities. Their requirements can vary from minimal help for conducting daily activities to complete care. Tele-monitoring assistance can aid self-monitoring for such patients while also being digitally connected with their health care providers. The scope of these solutions for long-term care includes addressing issues such as fatigue and anxiety, quality of life, nutrition, sleep, physical activity, etc.

The advancements in rehabilitation technologies are increasingly enhancing the role of rehabilitation in building and maintaining the self-dependence and quality of life of patients. The field of rehabilitation often requires complex technologies, such as virtual reality, robotics and haptic devices. The healthcare application of these technologies revolves around providing solutions for efficient home rehabilitation, multimodal approaches for recovery, to support activities of daily living and to enhance clinical assessment. Thus, the use of emerging technologies can aid family members of apparently healthy older adults and also detect mild symptoms while relying on a user-friendly solution.

Keywords

Tele-monitoring · Digital healthcare · Long-term care · Rehabilitation · Wearable devices · Quality of life · Self-management

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Learning Objectives
On completion of this chapters, the reader should be able to:

- Define and describe "Long Term Care" in terms of diversity re: patients, chronic disease and disability and opportunities for technology-based support
- List and describe tele-monitoring approaches to support home care for chronic conditions and opportunities and challenges in implementing them
- Describe the use of wearable devices and virtual reality in supporting recovery, chronic disease and geriatric cognitive and physical support

19.1 Emerging Digital Healthcare Solutions

Advances in digital technology and data analytics have created unprecedented possibilities for health behavior to be measured and monitored, thereby accelerating the ability of science to lead to better health management and health implications. Digital health is central to the use of digitalized tools to evaluate the health habits of individuals in everyday life and to have available digital therapy resources anytime and anywhere [1].

Digital Healthcare Solutions (DHS) are evidence-based clinical approaches powered by software applications of high quality to prevent, diagnose, control and assist in the treatment of health conditions [2].

DHS include a broad range of categories such as eHealth, mobile health (mHealth), internet of things in healthcare, telehealth, precision medicine, and more [3]. In addition, DHS such as telemedicine, can efficiently improve the management of hospitals, minimize wait times and reduce care cost [4]. The eHealth solutions developed for chronic diseases reflect a global trend towards self-management and health assessment [5].

Incorporating mHealth into the framework of oncology treatment can be a productive step in providing low-cost, real-time ways to promote preventive strategies or track and provide treatments for different behaviors, symptoms, and physiological markers of disease [6]. Clinical research has implied the advantages of these strategies for different populations either with or without disease, for instance cancer, as well as for various outcomes, such as physical activity, diet and fatigue [7]. Current approaches addressing the psycho-social needs of people (e.g., for elderly people or other illnesses) have been widely used to promote and improve assistance programs and supportive treatment in other contexts [8].

Thus, DHS have an extensive scope in long-term care, disease management as well as addressing psychological and social needs of patients. The following sections discuss the opportunities of DHS with a focus on long-term care during home stay and tele-monitoring solutions to reduce hospital readmissions and length of stay (Fig. 19.1). The current limitations and challenges have also been indicated.

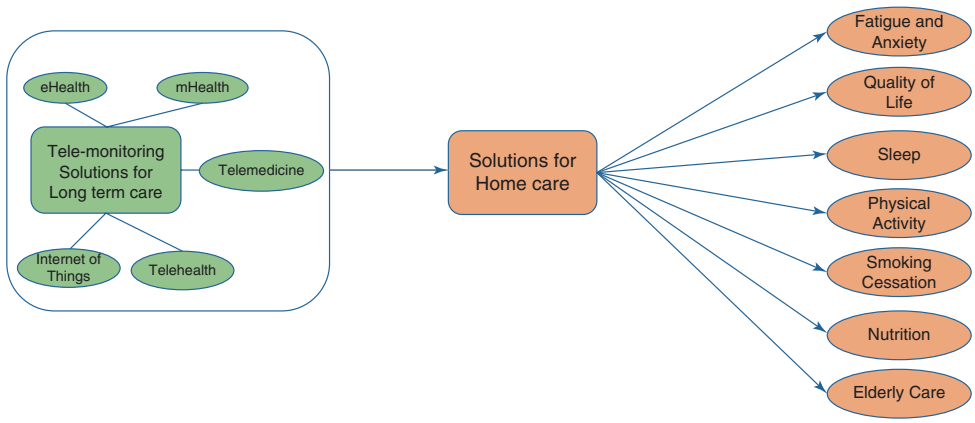

Fig. 19.1 Scope of tele-monitoring solutions for long-term care

19.2 Opportunities for Digital Solutions

19.2.1 Long-Term Care

Long-term care includes a wide array of care services to people of any age required by those with chronic conditions or functional disabilities [9]. Their requirements can vary from minimal personal aid for carrying out daily activities to complete care through virtual assistance. Patients who can be assisted virtually, can monitor their own conditions in a home setting accompanied by a digital link with their health care providers. As self-management grows more relevant, the e-health platform will also be approved by people with long-term illnesses to access healthcare services and fulfill supportive care needs [10].

19.2.1.1 Tele-Monitoring Solutions for Home Care

Fatigue and Anxiety

Fatigue and anxiety are conditions affecting most chronic conditions. Psychological symptoms, including depression, anxiety, alongside fatigue, are common subjective emotions observed in older population and are correlated with negative clinical endpoints [11].

Advancements in DHS are capable to comply with the unmet needs for supportive care for those requiring home care, including patients following treatment for chronic diseases and the elderly. There is an emerging evidence that mHealth interventions to support self-management can improve fatigue outcomes in cancer survivors, and some also hold promise for psychological distress [12]. Furthermore, patients with myeloproliferative neoplasm, experienced positive effects from using a meditation app "Calm" on their mental health, sleep, fatigue, and pain [13]. Text messages via mobile apps have also been able to control side effects for the patients undergoing chemotherapy [14]. They are also seen to be capable of promoting physical and mental health among cancer patients. A more promising approach could be by sending more individualized and tailored motivational messages to the patients, thus, encouraging patient engagement and patient empowerment. Despite the remote long-term care offered by the emerging DHS, tele-monitoring can enable the healthcare providers to keep track of patients' conditions, and provide suggestions for intervention modification, as required.

Quality of Life

Internet-based and mobile-based interventions are now used to promote the development of healthy behaviours. EHealth initiatives can be an efficient method to enhance physical activity and provide cancer patients with a better quality of life (QoL) [15]. For the elderly, particularly in cases of frailty, tailored motor and cognitive training programs are essential in maintaining a good quality of life. Wearable devices and m-health solutions in this regard have potentials to efficiently allow individuals, healthcare professionals, and long-term treatment centers to successfully integrate personalized therapy solutions by monitoring the stress level of every person amid an ongoing motor and cognitive training [16]. Early adoption and implementation of personalized palliative care have been recommended as a method for improving QoL in patients with lung cancer [17]. The "BENECA" mHealth app created by Lozano-Lozano and colleagues emphasized the value of using the mobile app to tackle the various problems of cancer survivors in order to inspire them to stick to healthy lifestyles. It enhanced QoL, moderate-to-vigorous daily physical activity, and decreased body weight [18]. A seven-module app called Pain Guard has successfully shown improvement in pain relief among cancer patients whilst at home. The technology managed to decrease adverse reactions, strengthened adherence to patient medications, and also enhanced patient's QoL [19].

A digital intervention tool, Happify, offered preliminary evidence in an observational study in the increase of subjective well-being among patients with chronic diseases. From the theoretical traditions of mindfulness, cognitive behavioral therapy, and positive thinking, users were introduced to well-being strategies [20]. Future studies could include Randomized Controlled Trials (RCTs) to investigate Happify's influence on other relevant results associated with chronic

disorders, such as symptoms of depression and anxiety, as well as physical and health-related measures [20].

Sleep

Sleep disorders are commonly seen in patients with chronic disorders such as cancer especially when undergoing chemotherapy, and are strongly associated with fatigue [21]. Patients with cardiac and kidney disorders also indicate their poor sleep quality [22]. In older adults, sleep disruptions arise from physical and comorbid medical conditions rather than those from sleep changes associated with age [23]. The society has also become increasingly interested in using apps to boost fitness and health, and as a result, the number of applications based on these issues has risen exponentially [24]. Tele-monitoring the rhythms of patients during their daily lives can establish measurable determinants of circadian and sleep disturbance. These findings support the patient-centered approach focused on e-Health tools and communication with patients [25]. Using smartphones, a recent study tested a mHealth software developed to teach oropharyngeal exercises to patients with severe obstructive sleep apnea-hypopnea syndrome (OSAHS). The severity of symptoms decreased and, after three months, the tone of the upper airway muscles showed improvements [26].

Digital cognitive behavioral therapy (CBT), a therapeutic pathway that addresses well-being, and quality of life has also demonstrated success in treating insomnia. The findings of a study by Espie et al. indicated that the therapy could improve both day and night aspects of insomnia, offering important support to insomnia treatment in clinical guideline recommendations of CBT [27]. A study that researched a tele-monitoring system for continuous positive airway pressure therapy showed a great deal of improvement in adherence and sleep quality among Asians suffering from moderate-to-severe obstructive sleep apnea [28].

The Breathe Easier app was designed as an in-person mindfulness-based intervention for early-stage lung cancer survivors and their family members in small groups. Post intervention, this pilot study found significant symptom reduction by both survivors and family members in sleep quality and fatigue [29]. Thus, for sleep disorders, an evolving field of healthcare innovation is remote patient monitoring based on internet-of-things devices [30]. A telehealth delivery system could offer unobtrusive monitoring and assist in self-management to improve sleep outcomes.

Physical Activity

Physical inactivity which is linked with raised morbidity, decline in health-related QoL and consequential health-care expenditure, is projected to be the fourth leading cause of death worldwide [31]. Physical activity is important in primary prevention among the general population, as well as secondary and tertiary care in patient populations. Approximately one-third of the global population fails to meet the minimum weekly requirement of physical activity by the World Health Organization, which is 150 min of moderate-intensity aerobic physical activity throughout the week, at least 75 min of vigorous-intensity aerobic physical activity throughout the week, or a comparable combination of moderate and vigorous-intensity activity [32]. Physical inactivity is also common among patients with chronic disorders such as renal diseases, cancer, and cardiac conditions, which can lead to reduced neuromuscular functioning, exercise tolerance and cardiorespiratory fitness [33]. Previous research has shown a substantial impact of physical activity on pain, functioning and quality of life [34]. DHS such as mobile apps, websites and wearable devices have shown capability in supporting physical activity engagement for these conditions [35, 36].

Observational studies have shown reasonable evidence that physical activity is a major contributor to healthy aging [37]. Mobile mental health apps and chatbots (conversational agents) can be an extension to medical treatment if they meet the application assessment process of the American Psychiatric Association, and are developed based on the context, threats, facts, accessibility and clinical functionality of the devices [38]. Several interventions are being developed and being studied for their efficacy in the improvement in

physical activity. Several pilot studies have demonstrated the effectiveness of a mobile web apps in encouraging physical activity among cancer survivors. Guidelines for behavior modification such as setting goals, self-monitoring, communication and social support were suggested as tools to strengthen usability of the physical activity app among cancer patients [39]. eHealth interventions can be delivered at relatively low rates and are more in line with the home-based physical activity program's choice for cancer survivors. Web-based self-management techniques may also be potential tools for increasing physical activity for younger cancer patients [40]. To study the importance of weight loss and physical activity for cancer survivorship treatment, Fitbit One, a commercially available fitness tracker based on accelerometry, was used to analyze physical activity patterns and the effectiveness of intervention in physical activity [41].

In addition, wearable actigraphy devices have shown the ability in the objective assessment of patients. A study showed that data from the actigraphy devices could be used to predict significant clinical outcomes due to their strong association with survival and quality of life scores [42]. Today, a plethora of physical activity monitors are available, showing the potential for clinical advancement in practice; however, more clinical evidence on a larger scale is needed to prove that physical activity is critical in both disease prevention and long-term care management.

Smoking Cessation

Within the framework of primary care, effective smoking cessation strategies have been a significant public health priority. Encouraging more smokers to make evidence-based quit attempts remains a major obstacle for clinicians within demanding patient care environments [43]. Fortunately, unique applications for smoking cessation have been created that can assure long-term abstinence. The advantage of these emerging innovations is their immediate accessibility and the low cost [44]. Acceptance and commitment therapy (ACT) is one model of smoking cessation therapy that has potential when delivered as a mobile application. Smartphone applications based in ACT theory such as Smart Quit, ACT-based cessation app, SmokeFree28, have proven effective in smoking cessation [45]. The currently available applications focus mainly on influencing the rate of success of a single effort to give up smoking. While some applications, such as SmokeFree28, do allow lapses to occur. More attention should be paid to them, considering the potential for such applications to help people use drugs more effectively, indicating the need for a randomized trial on a large basis [46]. Interventions such as behavioral and pharmacological strategies, when used in combination to stop smoking, could also significantly improve the quality of life, particularly in the case of a lung cancer study [47]. A mindfulness training via smartphone app (mobile mindfulness training with experience sampling) has also been found to increase awareness and decrease smoking and craving. In the longer term, this impact might be meaningful to encourage quitting [48].

"Be He@lthy, BE MOBILE" was a joint project by the World Health Organization (WHO) and international telecommunications union that enabled countries across low, medium and high-income nations to incorporate proof-based mHealth interventions within governance so as to monitor and manage non-communicable infections and their risk factors, particularly tobacco smoking and diabetes. They were successfully able to prevent diseases and manage information thus improving the health systems through telemonitoring [49]. Chatbots, regarded as conversational agents, are computer programs that have conversations with users through audio or written texts media. An experimental study showed that smokers assigned to receive the help of a supportive chatbot engaged more frequently with the app. Moreover, there is also an intervention with ongoing studies for mobile app based on personalized tailored health recommender system, aimed towards smoking abstinence for long-term [50].

Nutrition

Nutrition is considered highly significant for those requiring long-term care [51]. Malnutrition among elderly, may lead to a number of negative consequences on health: it can affect the prognosis of

various pathologies, reduce health-related QoL, and increase morbidity or mortality and hospital admission [52]. Self-learning systems have shown the ability to enhance an individual's health through diet management. Combining behavioral and physiological responses in the form of digital tools are seen to be useful to improve nutrition [53]. Following the growth of technology in health care, m-health interventions for nutritional support have flourished in the past decade.

Cancer patients are actively using mobile health apps for dietary consultation. The use of these apps with optimized nutritional data and individualized nutritional treatment is seen to boost the nutritional status especially in patients with cancer [54]. This research also demonstrated how nutritional objectives were met after the software was used. Nowadays, tailor-made guidance provided with the use of digital technology is gaining popularity to enhance diet and physical activity habits leading to weight loss [55]. Different approaches for efficacy and acceptance of digital healthcare solutions for nutrition are being demonstrated by a variety of studies.

Recently, in a study, researchers developed a novel web-based recommendation system (RS) called DIETOS (DIET Organizer System). This RS is applicable in both healthy users as well as those chronically ill, including Chronic Kidney Disease (CKD), diabetes and hypertension. DIETOS recommends individualized dietary choices, at the same time, prohibits the intake of foods that have adverse side effects on health [56]. In another RS study, researchers designed a snack recommendation system in Iran that was a knowledge-based smart phone application. This tool enabled diabetic patients to eat balanced diet, thus, contributing to a healthy lifestyle [57].

Tele-Monitoring Solutions for Active and Elderly Care

In regional care and services, telehealth systems may play a future role by encouraging more appropriate monitoring of older subjects, especially those suffering from chronic diseases. The biggest challenge today, however, is how to adapt technological frameworks to the needs and resources of patients with cognitive and physical disabilities and comorbidities, as well as how to make telecare facilities relevant and open to a wider community of aged persons [58]. Innovative e-health care programs are seen to be tackling these issues. In Italy, a family-centered facility kept track of critical parameters via telemonitoring and provided an effective psychological tele-counseling to their patients. Integrated into a local health care facility, the tele-health system dramatically changed the actions of elderly people and also reduced the workload of caregivers [58]. Even using wearable sensors, such as in the case of Parkinson's disease, can be useful in prevention of falls. A home-based observation study is a perfect illustration of such sensors being able to track falls in real life [59]. FitBit ® has also been used to replace supervised exercise therapy (SET) programs so as to assist walking especially among elderly. The use of a regulated step monitoring system such as the FitBit successfully led to significant increase in steps per day in the veteran population [60].

In the case of palliative care, telemedicine may be the future in terms of pandemic revival, facilitating safe and effective communication and high-quality treatment [61]. Tele-monitoring offers more comprehensive and far more consistent feedback to clinicians about symptoms and/or physiological assessments of patients, which can significantly promote overall care management, including more reliable and convenient drug usage [62].

19.2.2 Challenges in the Use of Digital Health Technologies

Telehealth offers a potential path to care for a population with chronic conditions, while strengthening the self-care capabilities of the patient. There have been certain shortcomings to the emerging e-Health technologies. For beginners, patient reported outcome (PROs) program enables patients to monitor their health status routinely and systematically, logging them into the system to manage their illness. The system would indeed be obsolete without these data

stream, further leading to ineffective assessment algorithms [63]. Such PRO programs have major obstacles to accessibility and universal acceptance [64], and self-reporting is a burden on patients, resulting in a reduction in the amount of data collected and hence a reduction in the efficacy of these solutions [65]. Moreover, not all digital health technologies have proved cost-effective [66], and that's a major obstacle to their adoption for the everyday practice of medical treatment. Therefore, innovative approaches to eliminate obstacles to e-health accessibility associated with collecting data from patients can help minimize the drastic psycho-social effects of cancer on their lives. Consequently, motivating patients would not be realistic unless the smoking cessation, nutritional and psychological needs of current comprehensive treatments models and support networks are adequately addressed. Thus, during the designing of DHS solutions, it is important to consider user preferences to increase the efficiency of the developed solutions.

19.2.3 Rehabilitation

Rehabilitation technologies are increasingly augmenting the role of rehabilitation in restoring and maintaining the independence and quality of life of patients. This role is increasingly supported by technology and is progressively being adopted by rehabilitation professionals globally. Smart technologies have been widely developed in the fitness market prior to being introduced to the narrower market of gerontology and rehabilitation. Several smart technologies have been developed to induce behaviour change among sedentary adults [67] and overweighed mid-aged and older adults [68]. The field of rehabilitation often requires more advanced and/or complex technologies, such as virtual reality, robotics and haptic devices. Virtual reality technologies provide complex environments enabling controlled multisensory stimulation that could hardly be achieved otherwise. In the real word, it is difficult for a therapist to ensure that the patient is sufficiently provided with multisensory input for a variety of reasons related to the distraction in the immediate environment and the degree of concentration on the activities that the patient may have. The key attribute of virtual reality technology is the ability to seamlessly provide visual and multi-sensory input and feedback. In fact, the latter is based on the visual representation of events involving selected 3D objects deployed in controlled spaces [69] proving a wide range of interaction, immersion and imagination [70].

Individuals with acquired neurological disorders, such as stroke, usually have proprioceptive impairments which hinder their usual feedback associated with a "typical" motor action [71]. In motor learning, feedback plays a determinant role in skill acquisition [72]. Feedback is important not only on the final outcome—'success or failure'—but also on movement execution, accuracy and the general performance [73]. This is made possible with the use of nowadays virtual reality technologies. Virtual reality-based interventions are becoming increasingly interesting therapeutic approaches. When used for health purposes, serious gaming and virtual and augmented reality are not only entertainment platforms for patients, but also have education, training and assessment purposes. These tools can be deployed through personal computers, smart devices, video game consoles, or specialized equipment dedicated to particular functions. Robotic technologies can support motor re-learning with the goal of restoring the function [74]. Robotic technology-based therapy offers many potential advantages over conventional therapies, most importantly the ability to offer high-volume and high intensity training and in some cases an immediate visual feedback to both the patient and therapist. Combining virtual reality and robotic technology is a particularly interesting approach, which can better stimulate neuroplasticity by activating most of the neural circuits involved in motor learning [75]. The following section addresses the range of approaches enabled by novel rehabilitation technology with a focus on telerehabilitation and home rehabilitation. Future and challenges of telerehabilitation and home rehabilitation technology are also discussed.

Table 19.1 Examples of technology-based multifaceted interventions targeting hand rehabilitation

Intervention					Example/description by the primary authors	
	Type					
Number of modalities of treatment	Robotics	Virtual/ augmented Reality	Gaming	Haptic feedback		Ref.
1	√				A robot-assisted therapy providing supplemental physical therapy	[89]
					A robotic training protocol that combines the ARMin III and HandSOME exoskeletons, allowing coordinated whole limb training in reach and grasp tasks	
		√			Virtual reality-based therapy used at home for assessing functional improvement and facilitating functional recovery	[90]
		√			Virtual reality training provided as an adjunct to standard rehabilitation	[91]
			√		An Android tablet-based game (FINDEX) with assessment and monitoring support that can be used to track a stroke patient's progress during rehabilitation. FINDEX is used to enhance the fine motor skills of stroke survivors	[92]
					A system that uses low-cost gaming technology to exercise the affected upper limb of people with stroke while their less-affected arm supports and assists the movements of the affected arm in a bilateral manner	[93]
2	√	√			A virtually simulated, robot-based intervention customized to match the goals and clinical presentation of a gentleman with upper extremity hemiparesis secondary to stroke	[94]
	√			√	A robotic therapy to treat the post-stroke arm in an inpatient stroke rehabilitation unit	[95]
					A haptic guidance method for functional driven rehabilitation after stroke called Time Independent Functional Training (TIFT) has been developed for the ARMin III robot. The mode helps retraining inter-joint coordination during functional movements, such as putting an object on a shelf, pouring from a pitcher, and sorting objects into bins	[90]
		√	√		Kinect-based virtual reality game training for upper extremity motor recovery in chronic stroke	[96]
					A simple augmented reality table-based system with a reaching task motivated by a computer game and a further development and user trial of a device to increase the exercise associated with the computer based reaching tasks	[97]
		√		√	Virtual reality technology to improve hand use and gait of individuals post-stroke	[98]
					A haptic-enhanced virtual reality system to simulate haptic pinch tasks to assist the recovery of fine motor function	[99]

Table 19.1 (continued)

Intervention					Example/description by the primary authors	
	Type					
Number of modalities of treatment	Robotics	Virtual/ augmented Reality	Gaming	Haptic feedback		Ref.
3	√	√	√		Chronic stroke survivors achieve comparable outcomes following virtual task specific repetitive training guided by a wearable robotic orthosis (UL-EXO7) and actual task specific repetitive training guided by a physical therapist	[100]
					Virtual reality-based treatment with an adaptive control method deployed in a robotic training device	[101]
	√	√		√	Virtual reality simulation to train finger motion for persons with hemiparesis. The system employs a simulated piano that presents visual, auditory and tactile feedback comparable to an actual piano. Arm tracking allows patients to train both the arm and hand as a coordinated unit, emphasizing the integration of both transport and manipulation phases	[102]
					Haptic Master: Using rich virtual environments, key features utilized in these simulations include, haptic effects, custom visual presentations, 3D scalable workspaces, direct motion analysis, and adaptive algorithms that modify task difficulty based on a user's success rate	[103]
	√		√	√	Robotic assistance for training finger movement Using a Hebbian model	[104]
4	√	√	√	√	Assessment and training in a 3-dimensional virtual environment with haptics in the so-called chronic phase after stroke	[105]

19.2.3.1 Telerehabilitation Solutions for Efficient Home Rehabilitation

Wearable Devices and Virtual Reality to Support Home Neurorehabilitation

Extensive research and development are produced focusing on telerehabilitation of patients post-stroke as it is the most significant cause of disability [76]. Stroke is a neurological condition that leaves patients with a range of health issues that require a lengthy recovery timeline including, but not limited to, poor balance, loss of coordination, partial paralysis, and memory loss. Considering the increasing need for home-based and self-administered rehabilitation, virtual reality-based telerehabilitation is a promising approach [77]. The role of virtual reality for telerehabilitation purposes has been widely discussed in the health community, often examining virtual reality as an assessment tool rather than a training equipment [77]. Portable and fancy virtual reality equipment are known as entertainment headsets and 3D screens, and as training equipment's in many fields, such as for pilots and drivers training. These equipment are not widely known as a (potential) therapeutic approach. However, there is growing interest in the use of virtual reality, augmented reality headsets and mixed reality systems involving holographic

objects, for healthcare applications. Such systems have become increasingly sophisticated, shifting from overlaying digital information to depth sensing and spatial tracking to give a more immersive and interactive experience. These systems are currently available as both tethered or standalone set-up.

The combination of sensing technologies and virtual reality has shown promising results in function recovery [78, 79]. Munroe et al. [80] designed and tested and augmented reality game to provide home-based neurorehabilitation consisting of electromyography electrodes and accelerometers in an armband to provide data and help children with cerebral palsy undergo physical rehabilitation by immersing themselves in slow and easy activities. Although virtual reality's contribution to increasing practice during a given therapy time is a well-perceived advantage, its benefit in terms of function and neuroplasticity is less known. For example, Clark et al. [81] reported that upper-limb virtual reality rehabilitation improves activities of daily living in patients with stroke but not upper-limb motor function, compared to conventional therapy. This suggests virtual reality as a complementary approach to conventional therapy to increase total therapy time and therefore treatment benefits [81]. Virtual reality has the potential to provide customized rehabilitation, monitor outcomes and provide instantaneous and documented feedback [82]. Technology has also the exclusive advantage of engaging the users outside of clinical sessions both inside and outside institution. Virtual reality constitutes a therapeutic tool for engaging stroke survivors in the rehabilitation tasks in the absence of a therapist which make it an adjunct approach to intensifying care and optimizing recovery and patient outcomes [83]. Indeed, it is established that virtual reality offers higher doses than conventional therapy can achieve [71]. Virtual reality also constitutes an interesting approach to quantifying the therapy progress and enabling therapists to interact and customize the therapy based on measured performance. Whether telerehabilitation is performed via teleconference with data transferred in real time or under a store-and-forward model, therapist still be able to monitor all the therapy steps and adjust intervention as needed to meet the patient needs in a timely manner.

Wearable Devices and Virtual Reality to Support Geriatric Rehabilitation

Geriatric rehabilitation aims to postpone the aging effects to maintain physical and mental capabilities as much as possible. Standard and adapted physical activity can help maintain basic elements of physical fitness and cognitive skills in older adults: cardiovascular efficiency, muscular strength as well as flexibility, balance and motor coordination. The recommendations of the American College of Sports Medicine and of the American Heart Association suggest that regular physical activity should include elements of weight and endurance training, stretching, and balance exercises [84]. Wearable devices and virtual reality platforms are playing an increasingly key role in geriatric rehabilitation. Both technologies offer comprehensive, playful and educational solutions to support training objective in a way that patients are immersed into meaningful tasks and motivating scenarios inspired from everyday functioning and activities. In fact, functional exercise programs are successful in reducing the risk of falls, improving the balance and muscle strength of the lower limbs, and the overall gait parameters [85, 86].

Telerehabilitation to Support Transition in Care

Successful transition in care is based on a thorough evaluation of patients as they switch from one healthcare environment to another. To overcome this complex challenge, transition in care increasingly require intersectoral collaboration between the medical team and telehealth vendor as well as the information technology, bioinformatics, and care management experts. In the case of patients discharged from hospital or rehabilitation centers to home, telerehabilitation addresses the triple aim objectives of "improving the experience of care, improving the health of populations, and reducing per capita costs of health care", while helping reduce avoidable readmissions and increasing patient self-

management [87, 88]. Telerehabilitation also helps patients in underserved populations, such as under-resourced countries or regions and people living in remote areas, access to care.

19.2.3.2 Multimodal Approaches to Rehabilitation and Home Rehabilitation

Virtual Reality, Robotics and Recovery Outcomes

Technology-based rehabilitation is multifaceted and increasingly based on multiple technologies targeting different sensory modalities and offering possibilities for more personalized rehabilitation and more amount and intensity of therapy delivered. Table 19.1 represents example of technology based multifaceted intervention targeting hand rehabilitation. These technologies corresponds to different therapeutic aims. While robotics and haptics focus on motor function by providing assistance while the patient is performing a task, virtual reality often focuses on performing a holistic activity of literally an activity of daily living. Clark et al. [81] have compared upper-limb virtual reality therapy to conventional treatment. They concluded that upper-limb virtual reality therapy compared to conventional treatment improves activities of daily living but not the motor function [81]. Similar role characterizes gaming applications that aim to offer a more playful therapy session. Clark et al. indicated that the combination of robotic and virtual reality technologies in a rehabilitation program is a successful way of improving rehabilitation outcomes [81]. Table 19.1 provides a non-exhaustive list of examples of complex technology-based interventions targeting hand rehabilitation.

Virtual and Augmented Reality to Support Activities of Daily Living

Virtual and augmented reality present huge opportunity for the evaluation and training of patients with dementia. Caring for people with dementia comes at a high expense, for example over $15 billion annually in Canada [106, 107]. García-Betances et al. have classified the domains of use of virtual reality for diagnostic and training purposes [108]. Virtual reality can be used to evaluate and train attention, executive functions, memory (i.e., short-term and working memory, allocentric and egocentric spatial memory, nonverbal episodic memory, prospective memory, temporal order memory, etc.), orientation (i.e., allothetic, visuospatial, spatial navigation, wayfinding, topographical disorientation, etc.) and executive functions and instrumented activities of daily living [108].

Virtual and Augmented Reality to Enhance Clinical Assessment

Dementia occurs on a continuum, starting with aging-related cognitive decline, transitioning to mild then moderate cognitive impairment and culminating with severe dementia. While there is a variety of screening tools available in healthcare settings [109] aging-related cognitive decline is not systematically screened in older populations yet [110, 111]. In fact, most cognitive declines are noticed and reported by family members [112]. While it must be taxing at many levels, reporting recognized mild symptoms to the patient's health provider is probably the best decision the family members should make [113, 114]. Thus, while family members often play a significant role in detecting mild cognitive impairment and even case finding, it has been documented that very little knowledge about the illness is available to family members [112, 115, 116]. Currently, unless one is a healthcare provider, available information about the illness is limited (e.g., Halbach et al. [117]). Therefore, it is essential to use emerging technologies to help the family members of apparently healthy older adults detect mild symptoms relying on a gamified and user-friendly solution, in total respect of dignity.

19.2.3.3 Rehabilitation and Telerehabilitation in the Post COVID-19 Era

Everyone has had to stop nonessential contact since COVID-19 hit and the lockdown stimulated the need for remote and online services, which continues to expand amid several stumbling blocks, such as legislations and service coverage,

to name a few. Inadvertently, the pandemic has resulted in disruptive growth in technology implementation, especially in geriatrics. The COVID-19 lessons are more likely to last post-pandemic. For example, wearable devices have reached an increased number of users among the general population and there has been a growing need to comprehend the inherent mechanisms of social, cultural, and business interactions between the networks of institutions, individuals and multiusers [118] in order to adapt the services closer to therapeutic applications. While the development of digital solutions reached an obvious maturity level with many devices widely commercialized and implemented, the needs of conceptualizing and evaluating the user experience seem to be the next priority. This section provides a collection of challenges and risks of digital solutions as premises for ideation.

Acceptance and Adherence

Prolonged usage of telerehabilitation services is determined first by acceptance of the solutions and secondly the adherence of the users to the treatments or protocols [119]. As an example, it is documented that users (neurological patients) are open towards assistive technologies to remain independent [120, 121] and have positive attitude towards virtual reality to support active aging thinking of this therapeutic approach as a useful and easy to use solution that offers an enjoyable experience [122].

Patient Engagement

Motivation and perseverance are keys in any treatment. Thanks to the digital interfaces used in telerehabilitation and home rehabilitation, patient may stay proactive, engaged and motivated with customized training sessions, digitally documented progress and online access to data. Based on patient baseline, treatment can be adapted, revised and updated in a versatile way throughout the progression of the therapy. Cost is often a concern and, in many cases, impedes access to care and perseverance in long-term treatment if the therapy is not covered by health insurances. The implementation of telerehabilitation platforms may be challenged by lack of computer literacy among patients and/or therapists, expensive equipment, inadequate telecommunication infrastructure and concerns about patient safety [70].

Online Shared Decision Making

Shared decision making is one way for patients to feel empowered and engaged in their journeys to treatment. Telerehabilitation can make it possible for patients to be involved in decision-making because it forces patients to be engaged in therapy. Active participation in care activates a variety of decision-making processes, such as gathering the appropriate information, testing some scenarios and assessing the 'return on investment'. By analogy, telerehabilitation drives the patient through certain knowledge and decision-making paths that are not common in conventional therapy. Although health literacy is needed to ensure the quality of shared decision-making [123], telerehabilitation still involves patients in many ways that have a positive impact on health outcomes.

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Learning Interprofessionally from a Real-Life Simulation in a Smart Home

20

Gabriela Mustata Wilson and Ruth E. Metzger

Abstract

This article introduces an innovative simulation that addresses the need for future health professionals to work as a team to identify and resolve barriers that people face in performing routine activities of daily living (ADLs) as they age in place in their own homes. The educational format was small team activities of daily living (ADL) assessments in a smart home incubation lab, followed by a structured debrief discussion. The format was chosen to enable students to collaborate interprofessionally with persons experiencing real-life disabilities as they performed ADLs in a home environment and explore together ways in which smart home technology might help them maintain an independent living.

The target audience included: (1) third-semester occupational therapy students; (2) resident physicians; (3) fifth-semester food and nutrition students: and (4) fifth-semester health informatics and information management students. Participating with the students were their course instructors, the simulation leaders, and three standardized patients (SPs): a 20-year-old blind woman, a retired man with Parkinson's disease and his wife, and a 27-year-old paralyzed woman who was dependent on a wheelchair.

Keywords

Simulation · Smart home technology
Interprofessional collaboration · Standardized patient · Aging in place · Independence
Activities of daily living (ADLs) · Minka

Learning Objectives

On completion of this chapters, the reader should be able to:

- Describe the use of standardized patients to help collaboration among multi-disciplinary students in discovering how smart home technology assists and impedes activities of daily living.

G. M. Wilson (✉)
Multi-Interprofessional Center for Health Informatics, The University of Texas at Arlington, Arlington, TX, USA
e-mail: Gabriela.wilson@uta.edu

R. E. Metzger
Indiana State Department of Health, Division of Long-Term Care, Evansville, IN, USA

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20.1 Objectives

Leadership from two different programs, the Geriatric Workforce Enhancement Program (GWEP) coordinator and the Chair of the Health Informatics and Information Management Program (HIIM), combined their intersecting goal to develop the simulation and the objectives.

The GWEP, a 5-year, grant-funded program directed towards improving health outcomes for older adults and developing a geriatric workforce, had as one of its primary objectives "the development of interprofessional simulations in its smart home technology incubation lab". To meet this objective, the simulation described herein focused on the application of emerging technologies to support aging in place. Specifically, the principal purpose was to observe and obtain feedback from SPs to explore ways technology might help overcome barriers to performing routine ADLs and enable them to continue to live independently longer.

The HIIM students were engaged in a Project Management course, with the learning objective of developing an entire Health Information Technology (HIT) project plan. For this simulation, the students' project plan focused on planning and implementing smart home technology to support aging in place. Specifically, the students' objectives were to:

(a) Describe the range and characteristics of Health Information Technology (Health IT) projects
(b) Describe the critical elements of project management
(c) Identify critical characteristics for project success and failure
(d) Identify the purpose and critical steps of effective planning
(e) Identify and describe each component of the project management plan to ensure efficient workflow and appropriate outcomes
(f) Define and prepare project planning documents
(g) Present best practices to support project time management, project cost, and procurement activities
(h) Identify the purpose and key steps for successfully planning an informatics project
(i) Develop the planning documents needed for the activities

The common objective for both programs was to increase interprofessional collaborative capability among the teams of students, faculty, and SPs. Outcomes were measured via quantitative feedback using the Interprofessional Collaborative Competency Attainment Scale (ICCAS), a validated 20-question survey for students to assess their competencies before and after a learning activity. In addition, students and SPs provided qualitative feedback based on observation and discussion of what they learned.

20.2 Activity Description

The basis for this activity was a small, accessible house that was built on a university campus to serve as a "smart home incubation lab." Its purpose was to provide a setting for students and faculty to explore how smart home technology might enable older people and persons with disabilities to live independently and age in place in their own homes. The house was based on the "Minka" design, a Japanese concept that means "house of the people". It was small (680 ft^2), compact, and energy-efficient with an open, modern interior, designed and built by an internationally-known geriatrician, Dr. Bill Thomas. The house was built with the necessary infrastructure to offer a blank slate for imagining possibilities, where faculty could develop hands-on interprofessional projects with each other for the students.

The simulation employed the model of immersion learning, a strategy that Zink et al. [1] described in the context of physician education. Health professions educators have applied the model to various disciplines and types of students, with the common denominator being an 'eye-opening' experience that increases their cultural sensitivity and competency, while also increasing their ability to be flexible and adapt to their circumstances" (Zink et al. p. 353). In addi-

tion, this particular approach helps develop the students' ability to be responsive to the clients' needs.

The simulation activity involved 16 students (i.e., one (1) medical student, five (5) Occupational Therapy (OT) students; two (2) Food and Nutrition students; eight (8) Health Informatics and Information Management (HIIM) students), and it occurred in several steps:

- ***STEP 1***: The simulation leaders, SPs, students, and faculty convened in a classroom for a 20-minute orientation. During the orientation, the leaders introduced the SPs to the rest of the group and provided instructions for how the activity would proceed. The leaders assigned six teams, each team consisting of four students, one from each discipline, and one SP. Food & Nutrition and OT students participated in more than one group but with a different SP. Each SP was assigned to two teams.
- ***STEP 2***: Following the orientation, all the teams and faculty proceeded to the house, where the teams were divided into two groups of three teams each. The first group of three teams entered the house, while the second group of three teams proceeded to a classroom to participate in a project management discussion.
- ***STEP 3***: Each of the three teams in the house went to a different station to begin the simulation. At each station, the SP had a list of routine activities of daily living (ADLs) to perform, such as putting away groceries, making the bed, etc. The students accompanied the SP through the stations, observed any difficulties they had, and listened to feedback on how the ADLs could become more comfortable via assistive technology. A timer was set to allow a specific amount of time at each station. At the end of the allotted time, the teams proceeded to the next station, and the SP performed the ADLs for that station. The faculty and the GWEP project coordinator supervised the activity.
- ***STEP 4***: After the teams at the house had completed all four stations, they and the students from the classroom discussion switched places, and the activity was repeated. The SPs remained at the house and went through the stations with the second group of teams.
- ***STEP 5***: After both sets of teams completed the simulation, the entire group reconvened in a classroom to debrief. Leaders asked the students and SPs for their biggest "take-aways" from the experience. The students were then challenged to think about their teamwork skills using a "thumball", a fun learning tool that students toss to each other in class. The student who catches the ball must answer the teamwork question that lands under his/her thumb (available from several online sellers).
- ***STEP 6***: At the end of the discussion, the students completed the Interprofessional Collaborative Competency Attainment Scale (ICCAS), a validated 20-question survey for students to assess their competencies before and after a learning activity [2, 3]. In addition, students provided qualitative feedback to the leaders on how to improve the experience in the future.

The project was reviewed and determined to qualify as a quality improvement by the University of Southern Indiana's Institutional Review Board and was not reviewed as human subject research.

20.3 Required Materials

20.3.1 Setting

The Minka house had one bedroom, bath, kitchen, and living/dining area, with basic furniture and appliances (see Fig. 20.1). For the simulation, four areas in the house where people perform normal ADLs were set up with items usually used in that area:

1. Kitchen – groceries, coffee pot, trash can with trash, voice-controlled intelligent personal assistant service Alexa, which responds to commands when you say "Alexa"
2. Bathroom – shower, toilet, sink, soap, towels, toothbrush and toothbrush

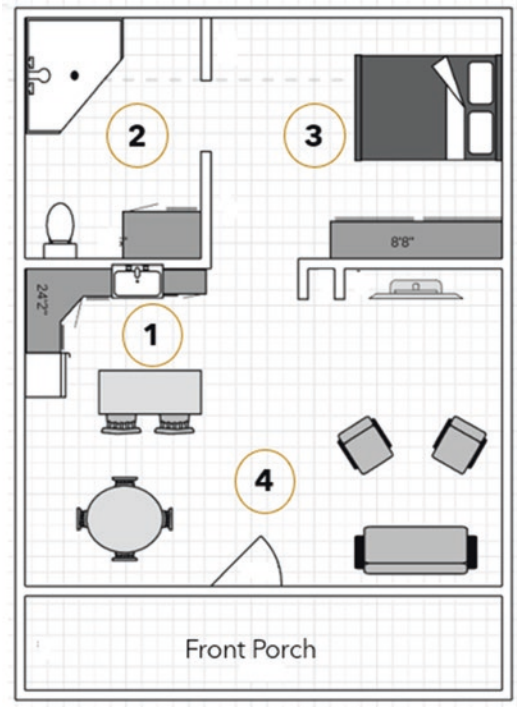

Fig. 20.1 Floor Plan of Simulation Setting. (*1*) Kitchen. (*2*) Bathroom. (*3*) Bedroom. (*4*) Living/Dining area

3. Bedroom – bed with sheets and bedspread
4. Living/dining area – furniture, smart tv, plants

The setting could be reproduced in a simulation lab, an apartment, or a house.

20.4 Assessment

To assess changes in students' interprofessional collaborative competencies, the students were asked to complete the ICCAS. Possible responses were on a scale of 1 to 7, with 1 indicating the lowest level of interprofessional skill and 7 indicating the highest skill level. Differences between pre- and post-activity were analyzed by Student's t-test, assuming unequal variances. All data were analyzed using the statistic functions in Excel-XLStat, with probability values set at 0.05. Qualitative feedback was obtained as part of the survey and provided to the HIIM students to be analyzed as part of their final MINKA House Project Management (PM) project. Each HIIM project focused on the assigned SP and the different technologies and areas of improvement for their daily living.

Ten of the sixteen students completed the ICCAS (i.e., one (1) medical student, two (2) OT students, two (2) Food and Nutrition students, and five (5) HIIM) students). Responses to 17 of the 20 questions indicated a statistically significant increase in students' perceptions of their own interprofessional collaborative competency attainment at the $P < 0.05$ level. Responses to two questions indicated no change, and one question indicated a decrease in skills. Overall, 90% of responses indicated an increase in interprofessional skill after the learning activity – 60% indicated "much better now," and 30% indicated "somewhat better now". 10% indicated their skills were "about the same". As indicated in Table 20.1 The students' mean perception of their interprofessional skills increased from 3.447 before the activity to 3.814 post-activity, with the variance decreasing from 0.08 before the activity to 0.01 post-activity.

Students were also asked to evaluate their overall perception of the learning activity. On a scale of 0–5, with 0 being the worst and 5 being the best, the mean score was 3.8. The most important change in the students' IPE perception was related to using an IP team approach with the patient to address the health situation and provide whole-person care (see Table 20.1 – items 12 and 13).

Qualitative feedback was obtained as part of the survey and provided to the HIIM students to be analyzed as part of their final MINKA House Project Management project. The objective was to enable the assigned SP to live independently and complete daily living activities by describing the following: (1) Statement of the Problem; (2) Objectives; (3) Method or Activities; (4) Resources; (5) Schedule and Milestones; (6) Budget; (7)Evaluation/Assessment. The senior-level HIIM students were well prepared to complete this project through rigorous training and curriculum that provides the knowledge needed to be a valuable designer, implementer, and manager of health information technology and information systems.

Table 20.1 Students' perception of their Interprofessional Education (IPE) skills before and after the simulation

	USI interprofessional simulation at the Minka house on USI campus Student responses to ICCAS	Pre-activity	Std deviation	Post-activity	Std deviation	Difference
1	Promote effective communication among members of an IP team	3.20	1.08	3.80	0.75	0.60
2	Actively listen to IP team members' ideas and concerns	4.20	1.54	3.80	0.87	−0.40
3	Express my ideas and concerns without being judgmental	3.50	1.36	3.80	0.75	0.30
4	Provide constructive feedback to IP team members	3.30	1.10	3.70	0.78	0.40
5	Express my ideas and concerns in a clear, concise manner	3.30	1.42	3.80	0.87	0.50
6	Seek out IP team members to address issues	3.50	1.43	3.80	0.87	0.30
7	Work effectively with IP tea members to enhance care	3.40	1.11	3.60	0.80	0.20
8	Learn with, from, and about IP team members to enhance care	3.40	1.02	3.70	0.78	0.30
9	Identify and describe my abilities and contributions to the IP team	3.40	1.11	3.70	0.78	0.30
10	Be accountable for my contributions to the IP team	3.60	1.02	3.80	0.87	0.20
11	Understand the abilities and contributions of IP team members	3.60	1.28	3.90	0.70	0.30
12	Recognize how others' skills and knowledge complement and overlap with my own	3.50	1.36	3.89	0.74	0.39
13	Use an IP team approach with the patient to address the health situation	3.10	1.30	3.90	0.70	0.80
14	Use an IP team approach with the patient to provide whole-person care	3.00	1.18	4.00	0.77	1.00
15	Include the patient/family in decision making	3.30	1.27	3.89	0.87	0.59
16	Actively listen to the perspectives of IP team members	3.60	0.92	3.90	0.70	0.30
17	Take into account the ideas of the IP team members	3.44	1.07	3.90	0.83	0.46
18	Address team conflict in a respectful manner	3.80	1.25	3.80	0.87	0.00
19	Develop an effective care plan with IP team members	3.80	1.54	3.80	0.60	0.00
20	Negotiate responsibilities within overlapping scopes of practice	3.00	1.10	3.80	0.60	0.80
	Mean	3.447		3.814		
	Variance	0.08		0.01		

Qualitative feedback included:

- People from different professions could ask the same question but have entirely different ideas/viewpoints
- Having real patients is valuable
- Our senses impact our ability to interact with our surroundings, and we must adapt the environment to meet the changing needs
- We all came up with ideas to help each other

The HIIM project management students' attainment of their objectives was assessed by the HIIM faculty according to the written project plans they submitted for class.

20.5 Evaluation

The completion of the simulation met the GWEP objective of developing and implementing the first of five planned interprofessional smart home simulations and provided the HIIM students with the basis for their HIT project plans. The HIIM students' project plans contained the required project management steps followed in any Health IT-related project. Students were charged with developing budget-conscious ideas for user-friendly assistive technologies that promoted a high quality of life for older adults. They also had to find innovative ways to evaluate the various changes to the Minka house, such as measuring how the technology proposed would impact the resident's quality of life and the effect of the structural changes made to the house on the resident's independence.

20.6 Impact

In addition to the increase in interprofessional capabilities, the most important aspect of a simulation like this is what students truly take away from it that becomes part of their knowledge base. Here are some of those reflections:

- *I did have a few AHA moments…I never thought how a Minka house would make me see reality with different eyes*
- *This course taught me how to work as a team during a project. I would like to get certified in project management later in my career*
- *One aspect of the course that I found highly valuable is that most of the class was one massive project. Getting hands-on experience with how we could help certain populations was a great motivator*
- *The team project helped me learn as a team and communicate with members with different personalities*
- *This class challenged me to think outside of the box. I worked with various group members both in my class and from different departments, and I learned a great deal about project management*

Sometimes the impact of an activity extends beyond what was planned. Developing a successful learning activity is part of 'good planning,' and sometimes it is part of 'serendipity' because unexpected occurrences happen in the most delightful and valuable ways. This underscores the importance of keeping an open mind and remembering that faculty, too, continue learning alongside their students.

- The first occurrence happened because there were no trained standardized patients. Though one of the goals of the grant was to hire and train a group of SPs, this simulation occurred early in the grant before that goal was accomplished. The result was that we recruited persons with real disabilities from the community to participate on the teams. This made the SPs' circumstances very real to the students. They were not pretending but listening to real people with real conditions. Feedback from the students indicated this was most valuable.
- The gentleman with Parkinson's Disease brought his wife with him. While he was participating on the teams with the students, she spoke with the simulation leaders and provided a wealth of in-depth information about how the disease affects his whole body, not just his movements, and connected us with the Parkinson's Disease support group for future participation.

- The blind woman always had her service dog with her and brought the dog to the simulation. A totally unexpected occurrence was that the dog's name was Alexa. Because of this, we had to change the name of the voice-activated Alexa computer in order not to confuse the dog. If we were to give the computer Alexa a command, the dog Alexa would think we were giving the command to her.
- The woman in the wheelchair failed to show up and was unable to call beforehand to let us know. Because of this, the OTA faculty quickly recruited her administrative assistant and grabbed a wheelchair from the OTA lab to take her place. The assistant was delighted to be part of the simulation and added an element of fun.
- The activity resulted in some spur-of-the-moment faculty team-building as we all worked with each other to pinch-hit and quickly resolve unexpected problems.

One of the most creative challenges the simulation posed to the students was to envision technology that would focus on the need and what the SP would need to overcome it, even if the technology did not exist yet. They were challenged to let their thoughts venture into the unknown, looking for answers and creating solutions where they found none. This type of abstract thinking [4, 5] is essential for health care professionals that must grasp many different concepts related to solving numerous problems and helping patients achieve their goals. All the data ever collected serves no useful purpose unless people can "look at the numbers, detect patterns, analyze what those patterns mean, and develop narratives to explain them to everybody else" [5]. Good abstract thinkers can observe something, then imagine concepts far beyond what they see. This IPE activity contributed to helping students develop that skill with empathy and professionalism while applying concepts in healthcare, information technology, and project management, an invaluable learning experience for their future careers.

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Predicting Preventive Care Service Usage in a Direct Primary Care Setting Using Machine Learning

21

Sugato Bagchi, Ching-Hua Chen, George R. Kim, Judy George, Thomas A. Gagliardi, Marion J. Ball, Sasha E. Ballen, and Jane L. Snowdon

Abstract

The growing availability of data from electronic health records (EHRs), digitized claims, and patient-provider communications is providing opportunities to understand and improve primary care and patient engagement. Computational tools such as artificial intelligence (AI), machine learning (ML), analytics, and visualization are providing novel, data-grounded insights into individual and population health behaviors and healthcare quality. The application of ML to electronic patient data (EHRs, claims, patient-provider communications metadata) from a Direct Primary Care (DPC) practice is explored. DPC, a low-to-no (additional) cost, retainer-based ambulatory practice model emphasizes patient access to providers and low administrative overhead expenses. Six ML models are described and applied, first, to a training set of DPC data, and then to a 3-year test set for established practice patients. Prediction rates of the six models are compared, followed by a discussion of the possibilities of applying ML techniques to DPC and other ambulatory practice models to understand factors associated with both preventive care service and preventive screening test usage.

Keywords

Health services research · Patient engagement
Machine learning · Communication
Primary health care · Preventive medicine

S. Bagchi · C.-H. Chen
IBM T. J. Watson Research Center,
Yorktown Heights, NY, USA

G. R. Kim
Johns Hopkins School of Medicine,
Baltimore, MD, USA

J. George · T. A. Gagliardi · J. L. Snowdon (✉)
IBM Watson Health, Cambridge, MA, USA
e-mail: snowdonj@us.ibm.com

M. J. Ball
IBM T. J. Watson Research Center,
Yorktown Heights, NY, USA

Johns Hopkins School of Medicine,
Baltimore, MD, USA

University of Texas, Arlington, TX, USA

S. E. Ballen
R-Health Inc, Elkins Park, PA, USA

Learning Objectives

After reading this chapter, the reader should be able to:

- List three distinctive characteristics of a Direct Primary Care healthcare practice.
- List and describe three different supervised machine learning (ML) methods that can be used for classification.

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- Explain the differences between "accuracy" and "F1-score" as measures of ML performance and explain why "baseline majority" is used as a benchmark for gauging such model performance.
- Provide examples of features from electronic patient data that may be helpful in predicting preventive care visits and preventive screening test utilization.

21.1 Introduction

Information technology (IT) is creating fundamental changes in United States (US) healthcare. First, increasing availability of networked digitized health data via electronic health records (EHRs) and wireless/cloud technologies are transforming patient care from isolated encounters to longitudinal and meaningful therapeutic relationships with providers. Second, data tools such as analytics, artificial intelligence (AI), machine learning (ML), and visualization are bringing timely insights to providers and patients that can inform and optimize care. Third, the increasing digital infrastructure is permitting organizational awareness of individual and population health to optimize utilization, decrease costs/waste, and improve resiliency. As US healthcare IT continues its forty-year growth, it now embraces newer technologies, including telehealth, big data, cognitive computing, and streaming analytics.

Parallel to the growing ubiquity of health IT has been the evolution of healthcare practice, delivery, and payment to leverage its power to the benefit of patients and providers. This trend is of high interest in primary care, which focuses on front-line patient engagement and disease prevention. In this chapter, we describe the application of machine learning to electronic patient data (EHRs, claims, and patient-provider communications) from a Direct Primary Care (DPC) practice to explore patient/practice characteristics associated with the use of preventive care services (PCS) and screening tests.

21.2 What Is Direct Primary Care?

Direct Primary Care (DPC) is an attractive ambulatory practice and payment model for providing timely and personalized first-line and preventive healthcare for a fixed periodic cost (monthly, quarterly, or annual fee) per patient (or as a no-additional-cost primary care option to "wrap-around" main coverage in employer-based health insurance programs) [1–3]. DPC is removed from standard managed care payment programs (e.g., Health Maintenance Organization (HMO), Patient-Centered Medical Home (PCMH), Medicare/Medicaid). DPC aims to improve the quality of primary care for patients and providers (better population health, better patient/provider experience of care, lower per capita costs) by (a) encouraging patient engagement through direct patient-provider communication, (b) removing barriers to early access and evidence-based prevention practices, and (c) lowering administrative and billing overheads. Of business and research interest is the sustainability and effectiveness of DPC in different patient populations, community settings and practice configurations, with respect to features that predict and influence better health via prevention, as measured by completion rates of specific preventive care services in the context of barriers (e.g., enrollment costs, co-pays, communication, distance).

Evidence-based preventive care services [4–10] such as health maintenance visits, immunizations and screening tests are recommended according to patient features: age, sex, and presence of chronic disease and co-morbidities. Examples include colorectal cancer (CRC) screening for adults [9], nutritional recommendations in children [11], and behavioral and mental health screening for youth [12]. Current population prevalences of breast, colorectal and cervical cancers (among other conditions) indicate that PCS/screening rates can be improved [13]. The study of DPC practice model features can provide insights into how to improve these rates via outreach [14].

There is a dearth of literature on tracking preventive care use in DPC settings [15, 16]. A retro-

spective cohort study of Medicare Advantage patients showed that a "high-touch" primary care model is associated with higher rates of preventive care visits and medication adherence and lower hospital admissions and total monthly healthcare costs when compared to a similar cohort in a "standard" primary care model [17]. Thus, a research study question that arises is: What characteristics of DPC are linked to higher rates of PCS completion and how can these characteristics be discovered from existing electronic practice data?

21.3 Machine Learning

ML is an implementation of artificial intelligence that enables computational methods/algorithms to automatically learn patterns over time by exposure to new data. ML methods fall into three major categories: supervised, unsupervised, and reinforcement learning, each dependent upon the type of "response" (output) associated with the input data [18].

- In *Supervised Learning*, models/algorithms are trained with a training data set comprised of input data and correct (labeled) output (the response). When trained, models/algorithms are then evaluated on their performance in assigning labels to new (test) data. Supervised learning is used in classification or regression.
- In *Unsupervised Learning,* models/algorithms are provided very large amounts of unlabeled data and find patterns to help solve clustering with similar features. This approach can be faster and can provide insights to understand data and to guide the design of supervised learning.
- In *Reinforcement Learning*, models/algorithms receive continuous data (there is no sample or training set) and learn through trial and error to solve a given problem. Reinforcement Learning can be used for robotic tasks.

This chapter focuses on the use of supervised learning, in which training data is obtained from EHR, claims and patient-provider communications and labeled responses are specific patient record items, for example the completion of a specific PCS such as immunization. Once trained, the algorithm is applied to unlabeled (test) patient data to make predictions about, for example, which patients will complete a PCS such as immunization.

21.3.1 Classification Using Supervised Learning

Supervised learning herein is applied to classifying or predicting a class to which a data instance (a patient record) belongs (for example, completion of a specific PCS such as immunization) according to its input data (EHR, claims, communication). For DPC data, to predict if a patient will be likely to obtain a specific immunization or test, based on other characteristics, we look for algorithms that predict this well, but that may also explain factors that contribute to the classification. Specific algorithms include:

- ***Logistic Regression (LR)*** is a statistical model that predicts the probability of a certain event or class [19]. It uses a logistic function to map a linear combination of input features (from EHR, claims, communications data) to the probability of the event or classification according to a threshold on that probability.
- ***Support Vector Machines (SVM)*** create a geometric model of training data to find the "widest boundary" between positive and negative cases. This type of algorithm is potentially more robust than LR in predicting "outliers". This algorithm was developed by Vapnik [20]. *Linear Support Vector Classification* is a version of SVM where the separation boundary is assumed to be linear.
- ***Neural Networks (NN)*** mimic the operation of interconnected neurons in the human brain [19]. NNs use three or more layers of nodes (algorithms)**:** an input layer, one or more hidden layers, and an output layer. Raw data is ingested by the input layer, from

which it is forwarded to and modified in hidden layer(s), then it is sent to the output layer for further processing. A NN may contain thousands of connected "nodes" within many hidden layers. *"**Deep Learning**"* uses multiple hidden layers in an iterative manner to learn patterns from data, in which case the NN is termed a *Multiple Layer Perceptron (MLP)*. Such an approach is used in image recognition.

- ***Decision/Regression Trees*** use input features and split data recursively to predict a class, but are susceptible to "overfitting" (placing too much weight on random noise in training data), "bias" (over-restricting training results) and "variance" (large changes in results due to small changes in data), which can decrease performance on test data. Methods to overcome these problems include:
  - ***Random Forest (RF)***: in which **decision trees** using multiple input data sets ("forest of trees") [21] are used to create a **collective**, more accurate and stabler **prediction.** The training process takes longer and is more **complex** to interpret than for a single decision tree. RF is used to reduce overfitting.
  - ***Boosting***: in which a set (ensemble) of weak classifiers (trees/algorithms that are poor predictors) are used to build a strong classifier (algorithm that is a good predictor) in a different (serial) fashion than used in RF. This can result in better performance than RF and can reduce bias and variance but is susceptible to overfitting. Two versions of boosting are used in this study:

    AdaBoost (Adaptive Boosting), developed by Schapire and Freund [19], uses statistical methods to weight and combine weak classifiers in training the algorithm. This method is useful in binary (yes/no) classification problems.

    Gradient Boosting, developed by Friedman, is a more sophisticated ML boosting method for optimizing algorithm training. This method is useful in a wider range of classification problems (multi-class, regression) than AdaBoost.

    An efficient and scalable implementation by Chen and Guestrin, ***eXtreme Gradient Boosting (xgboost)*** is useful for classification, regression, and ranking [22–24].

21.3.2 Evaluating Classifier Model Performance

Accuracy and **F1 score** are two measures for evaluating MLM performance [19]. **Accuracy** is defined as (the number of correct predictions) ÷ (the total number of predictions) made by the model/algorithm on a test set of data. For a binary (positive or negative) classification:

$$\text{Accuracy} = (\text{TP} + \text{TN}) \div (\text{TP} + \text{TN} + \text{FP} + \text{FN}) \text{ where}$$

TP = True Positives (the model/algorithm correctly identifies a positive classification)
TN = True Negatives (the model/algorithm correctly identifies a negative classification)
FP = False Positives (the model/algorithm misidentifies a positive classification)
FN = False Negatives (the model/algorithm misidentifies a negative classification).

	Model/Algorithm identifies item as positive	Model/Algorithm identifies item as negative
Test set item is positive	True positive (TP)	False negative (FN)
Test set item is negative	False positive (FP)	True negative (TN)

Accuracy ranges from 0 (a very poor model/algorithm) to 1 (a perfect model/algorithm) but may

not be sufficient when FP and FN are of importance but rare ("imbalanced classification"). Therefore, two additional measures of importance are **Precision** and **Recall** where:

$$\text{Precision}\left(\text{Positive Predictive Values}\left(\text{PPV}\right)\right) = \text{TP} \div \left(\text{TP} + \text{FP}\right)$$

$$\text{Recall}\left(\text{True Positive Rate or Sensitivity}\right) = \text{TP} \div \left(\text{TP} + \text{FN}\right)$$

The **F1 score** for a model/algorithm with respect to a test data set is the harmonic mean of precision and recall, where:

$$\text{F1 score} = 2 \times \left(\left(\text{Precision} \times \text{Recall}\right) \div \left(\text{Precision} + \text{Recall}\right)\right)$$

F1 also ranges from 0 to 1 and takes FP and FN into account.

Thus, **accuracy** is a measure of how well a model/algorithm performs on a test set but the **F1 score** provides a balanced insight on model/algorithm performance with respect to precision and recall (i.e. when FP and FN are important). In most real-life classification problems, the F1 score is the most useful for assessing model/algorithm performance.

21.4 Case Study: Predicting Preventive Care Service Usage in a Direct Primary Care Setting Using Machine Learning

We describe the development and evaluation of machine learning models (MLMs) using the six classification algorithms described to identify patient and practice features (input data) associated with the use of preventive care services and screening tests in a DPC practice. MLMs are applied to discover features that predict the likelihood of a patient receiving a PCS, based on EHR, claims and patient-provider communications data. There have been reports of non-ML prediction of primary care use in various contexts [25–27]. A scoping review by Kueper et al. [28] notes recent interest and application of ML in primary care research, advocating the use of interpretable machine learning techniques. A tutorial on applying ML methods to healthcare outcomes research by Doupe et al. [29] is available.

21.4.1 Data Source and Cohort Definition

Deidentified EHR, claims and communications data were obtained (via a trusted broker) from R-Health, a healthcare organization that offers preferred provider organization (PPO) plan subscribers an option to subscribe to R-Health DPC. Specific DPC data sources (linked but deidentified) included: (a) EHR encounters, laboratory and test orders/results, (b) external claims (for all non-DPC encounters, services, billing) and (c) patient-provider communications metadata (time-stamps, but *no* messaging content) from secure messaging, telephone and voicemail apps provided by the practice. Retrospective data from 7040 DPC patients (enrolled for at least 1 year from Oct 2016 to Nov 2019) was used. Data from minors included preventive visits but excluded screening tests. Patients were neither incentivized nor penalized for receiving preventive care. A patient was defined as "engaged" if his/her EHR recorded at least one preventive care visit during the cohort period (excluding hospice care).

Collected data included performance of specific screening tests for: (1) breast cancer (women aged 52–74 who had not undergone bilateral or two unilateral mastectomies), (2) cervical cancer (Pap only; women aged 24–64 excluding those with previous hysterectomy and no cervix), (3) colorectal cancer (men and women aged 51–75 excluding those who have had colorectal cancer or a total colectomy), and (4) hemoglobin A1c (HbA1c) for men and women aged 18–75 diagnosed with, or being screened for Diabetes Mellitus, Type 1 or Type 2 (excluding gestational or steroid-induced diabetes).

Data on screening tests performed by R-Health were extracted from EHRs while those performed elsewhere were extracted from claims data. Relevant screening data that occurred prior to the time window, such as for CRC, were manually entered into the EHR. CPT, ICD and LOINC codes and descriptors for diagnoses and tests were used to extract the data. Specific disease and procedure codes were determined by proprietary IBM Watson Health algorithms under license from the National Committee for Quality Assurance (NCQA) which maintains the Healthcare Effectiveness Data and Information Set (HEDIS®) measures of clinical care [30].

21.4.2 Model Descriptions and Scope

Two types of predictive ML models were built. First, a single preventive care model was developed to determine influential features that predict if a patient will engage in preventive care from R-Health (DPC) providers. Second, a set of predictive "screening test" models was developed to determine if eligible patients in a cohort of patients receiving preventive care at R-Health (DPC) will undergo a preventive "screening test". These models were then used to identify R-Health patients most likely NOT to complete recommended preventive visits and screening tests and to identify the features linked to these actions.

21.4.3 Predictive Preventive Care Model

The first MLM generated a binary classification (if a patient will or will not engage in preventive care) using patient and provider data as input features (a) to evaluate the accuracy of predicting patients who WILL engage in preventive care, and (b) to infer which input features are associated with the patient decisions. Classifiers were built using six ML approaches (Linear Support Vector Classification, Logistic Regression, Neural Network, Random Forest, AdaBoost, and the Extreme Gradient Boosting algorithm [23, 24]) and their performance was compared to determine which approach was best and to identify important input features [31].

Input features and their categorizations with respect to the predictive preventive care model are shown in the first five rows of Table 21.1. These features may be non-linearly related with the classification or may interact with other features in the model. Once important features are identified, further analysis may be required to understand how they influence the decision to obtain preventive care.

When developing the predictive model, it was important to ensure that input features were based on data that was neither influenced by preventive care encounters, nor by data collected after these encounters. For example, patient allergies are captured during preventive care visits, but if a patient has never had a visit, it will be blank, therefore, patient allergies cannot be considered an input feature. Also, patients and providers may engage in higher than usual electronic communications after a preventive care visit, therefore, care must be taken to include only electronic communications that are noted prior to a patient's first visit.

21.4.4 Set of Predictive Preventive Screening Test Models

Predictive classifiers for (a) identifying patients who are likely NOT to complete recommended

Table 21.1 Input Features for the Predictive Preventive Care Model and Predictive Preventive Screening Test Model

	Category	Input features
Predictive preventive care model	Member/patient demographics	• Age • Gender • Number of household patients • Distance to R-health provider
	R-Health enrollment information	• Relation to primary insured (employee, spouse, other) • Primary care provider and organization
	Communication (before first visit)	• Time window of first communication after enrollment (30, 60, and 90 days) • Days and weeks of communications with patient participation (normalized over number of days/weeks) • Frequency of communication by modality (smartphone app, email, SMS, phone) • Word counts for text-based communication modalities
	Chronic conditions (from R-Health and claims records)	• Obesity • Diabetes • Hypertension • Hypercholesteremia • Anxiety • Depression • Charlson comorbidity index (CCI) [32, 33] • Number of conditions considered chronic by the U.S. Centers for Medicare and Medicaid Services (CMS) [34]
	External (non-R-Health) utilization (from claims):	• Preventive care prior to enrollment • Specialist visits • Hospital visits (ER, in-patient, out-patient) • Payments from insurance • Months of claims
Predictive preventive "screening test" model	Labs[a] and vitals	• Frequency of body mass index (BMI) • Blood pressure (BP) measurements • Lipid panel • Comprehensive metabolic panel (CMP) • Complete blood count (CBC) with differential test • Urinalysis
	Smoking status	• Never smoker • Current smoker • Smoking status unknown
	Visits	• Frequency of visits • Virtual visits
	Allergies	• Number of allergies
	Immunizations	• Number of immunizations

SMS short messaging service, *ER* emergency room
[a]Lab values were excluded as features for the HbA1c test prediction because they were associated with (but not the cause for) getting the HbA1c test

screening tests and for (b) discovering the features linked to those actions were built with the Extreme Gradient Boosting (xgboost) algorithm. Input features for this approach are a combination of all ten categories described in Table 21.1. As the cohort for "Screening Tests" (rows 6–10) only considers patients who are engaged in preventive care at R-Health, these additional features may be influenced by Preventive Care encounters (rows 1–5).

21.4.4.1 Model Performance Testing

The supply of data for training and testing a predictive model is often limited. Cross-validation is a vital step in evaluating a model. Cross-validation maximizes the amount of data that is used to train

a model and makes use of all data to assess a model's performance [19]. For the case of K-fold cross-validation, the training data is partitioned into K equally sized subsamples. For each fold, the other K-1 subsamples are used as training data while the last subsample is used as validation.

The accuracy and F1 score were assessed for each machine learning technique using 5-fold cross-validation, with the assumption that the folds (random sampling) would approximately preserve the 0.69 ratio of class labels [19].

21.5 Results

The total population of R-Health DPC patients, including minors, in the study was 7040 (4341 (62%) female and 88% adults ≥18 years old). Enrollment length ranged from 12 to 36 months, with a mean of 12 months (median 12.16 months). Patients meeting the criteria for preventive care analysis (DPC enrollment for at least 1 year) was 3707 (53%), of which 2548 (69%) received preventive care from R-Health, while 1159 (31%) did not. Some patients who did not engage in preventive care at R-Health received it elsewhere (Fig. 21.1). This cohort of 3707 patients ranged in age from 1 to 79 years old with a median of 42 years (interquartile range [IQR], 27–54) and 2337 (63%) were female.

The proportions of eligible patients engaged in preventive care from R-Health providers for one year or more had preventive "screening test" rates for breast cancer (88%), colorectal cancer (52%), cervical cancer (Pap only) (60%), and HbA1c (83%) are depicted in Fig. 21.2. Evidence

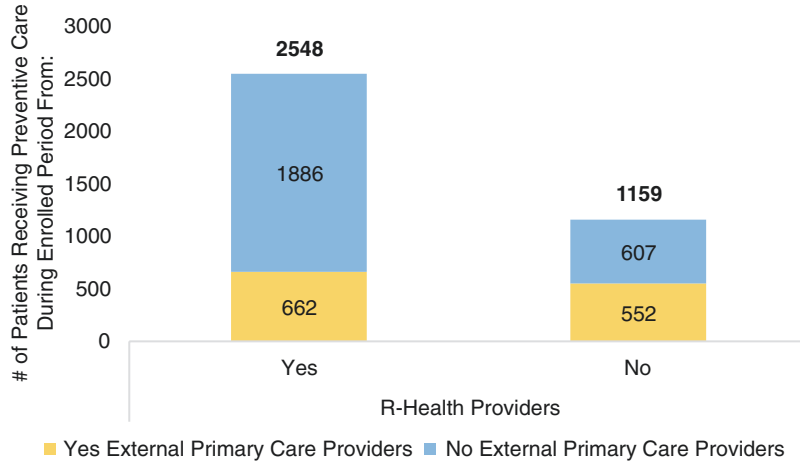

Fig. 21.1 Patients Engaged in Preventive Care from R-Health or External Primary Care Providers

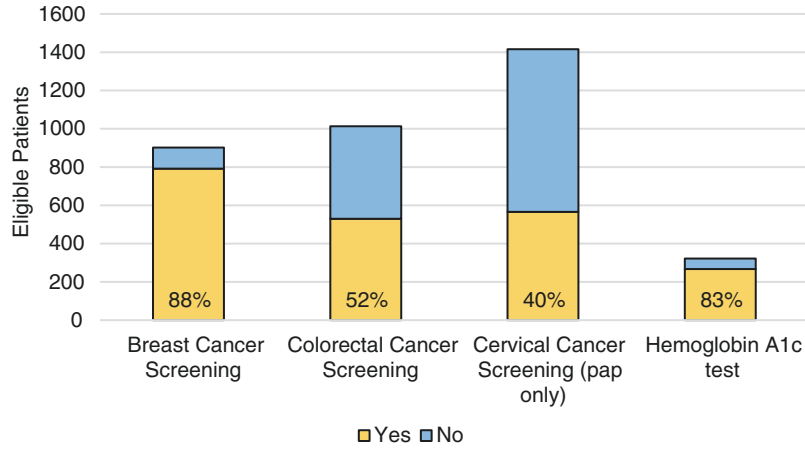

Fig. 21.2 Preventive "Screening Test" Rates for Eligible Patients Engaged in Preventive Care for 1+ Years at R-Health

for "screening tests" was based on CPT codes/and examination descriptions for breast, colorectal and cervical cancer tests and on LOINC codes in recorded lab results for HbA1C.

Six ML approaches were applied to test data sets to predict which patients would engage in R-Health preventive care based on patient/provider data as input features. Data generated as a result of preventive care visits were withheld in the training data set to prevent introduction of bias. Five-fold cross-validation of accuracy and F1-measures was used to evaluate the predictive modeling performance for each ML technique as shown in Table 21.2. The Extreme Gradient Boost (xgboost) method [22] performed best in predicting ambulatory preventive care visits with an accuracy of 0.86 and F1 score of 0.89.

The most important features of the predictive preventive care model were identified using the SHAP (SHapley Additive exPlanations) value applied to gradient boosted trees [35] as shown in Fig. 21.3. The top three features associated with preventive care (i.e. with the highest SHAP values) are related to the timing, duration, and frequency of patient-provider communications.

Figure 21.4 visualizes positive and negative associations of patient/provider features relative to predicting R-Health preventive care with respect to five major categories (Member/Patient Demographics, R-Health Enrollment Information, Communication (before first visit), Chronic Conditions, and External (non-R-Health) Utilization). The most positively associated feature for predicting preventive care was patient communication within 90 days of enrollment, with other positive associations related to the volume of patient communications prior to the first visit (the number of days of electronic communication with the patient and the frequency of

Table 21.2 Predictive Modeling Performance for Preventive Care Visits

Method	Accuracy	F1
Majority baseline	0.69	0.81
Linear support vector classification	0.78 (+/− 0.02)	0.84 (+/− 0.02)
Logistic regression	0.78 (+/− 0.03)	0.84 (+/− 0.02)
Neural network (MLP)	0.78 (+/− 0.03)	0.84 (+/− 0.02)
Random Forest	0.83 (+/− 0.03)	0.87 (+/− 0.01)
Adaboost	0.84 (+/− 0.03)	0.88 (+/− 0.02)
Extreme gradient boost	**0.86 (+/− 0.04)**	**0.89 (+/− 0.03)**

MLP multi layer perceptron

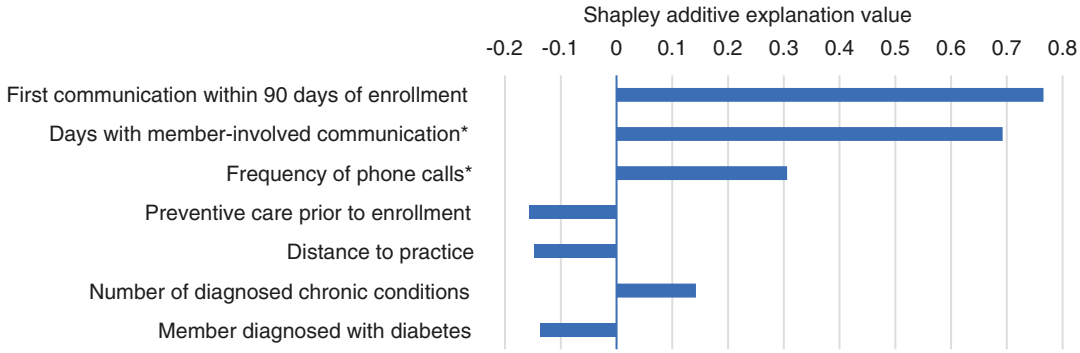

Fig. 21.3 Feature Importance (Gain) for Engagement in Preventive Care. *Each feature's magnitude of importance is shown with bars indicating whether the feature is positively or negatively associated with engagement in preventive care. Features with * relate to the time period after enrollment and prior to first visit to exclude temporal effects following the visit from prediction. A feature that has either a positive or a negative association with patient engagement in PCS are predictors*

Fig. 21.4 Positive (Purple Outline) and Negative (Turquoise Outline) Features Associated with Preventive Care Utilization

phone calls). Another feature that predicted preventive care engagement was the patient's burden of chronic conditions (number of conditions such as diabetes, obesity, depression, and anxiety). Features negatively associated with engagement in preventive care included diabetes diagnosis, increasing distance to the provider's office and receiving preventive care prior to R-Health enrollment (i.e. having a primary care provider outside of R-Health).

Table 21.3 shows the 5-fold cross-validation accuracy of the predictive preventive "screening test" models, trained using Extreme Gradient Boost (xgboost). Compared to the baselines of always predicting the Majority Class in Fig. 21.2, accuracies for xgboost for predicting preventive "screening tests" were significantly superior (95% CI) for predicting screening for breast cancer (from 0.88 to 0.92), colorectal cancer (0.52 to 0.70) and cervical cancer (0.60 to 0.66), but not for HbA1c screening (0.83, no change). HbA1c screening was excluded from further analysis.

Table 21.3 Predictive Modeling Performance for Preventive Screening Tests (5-fold Cross-Validation Using Extreme Gradient Boost (xgboost))

Preventive screening test	Majority baseline	Predictive accuracy
Breast cancer screening	0.88	0.92 (+/− 0.02)
Colorectal cancer screening	0.52	0.70 (+/− 0.03)
Cervical cancer screening (Pap)	0.60	0.66 (+/− 0.01)
Hemoglobin A1c (HbA1c) testing (diabetes)	0.83	0.83 (+/− 0.02)

Table 21.4 shows key features identified for predicting preventive "screening tests", their relative importance and whether a feature was positively or negatively associated with the type of screening. Demographically, increasing DPC patient age was associated with a lower likelihood of undergoing preventive screening. For DPC patients who sought specialist or hospital

care outside of R-Health, lower patient age and the cumulative amount of insurance payments were the most important predictors for undergoing breast cancer screenings. Lower patient age and a higher number of (non-screening) surgeries were the most important predictors for undergoing colorectal cancer screenings. Finally, higher months of claims and higher number of specialist visits were the best predictors for cervical cancer screenings (albeit comparatively poor). Patient-provider communication is no longer a discriminating feature for preventive "screening tests" because the cohort for this analysis was already defined as being engaged in preventive care at R-Health (for which communication is a key explanatory feature (see Fig. 21.3)).

Table 21.4 Key Features, Their Importance, and Positive or Negative Association with Preventive Screenings

Feature	Breast cancer screening	Colorectal cancer screening	Cervical cancer screening
Patient age	1.21 (−)	0.56 (−)	0.21 (−)
Cumulative insurance payments	0.30 (+)	0.41 (+)	0.08 (+)
Number of specialist visits	0.28 (+)	0.10 (+)	0.22 (+)
Months of claims	0.21 (+)	0.28 (+)	0.32 (+)
Number of surgeries (non-screening)	–	0.49 (+)	–

Figure 21.5 summarizes the two categories of features which predict preventive "screening test" use. Age, a patient/member demographic feature, was negatively associated with preventive "screening test" use, i.e. as patient age increases, preventive "screening test" use decreases. Features related to external (non-R-Health) utilization (external specialist visits, hospital visits, payments from insurance, months of claims) were positively associated with preven-

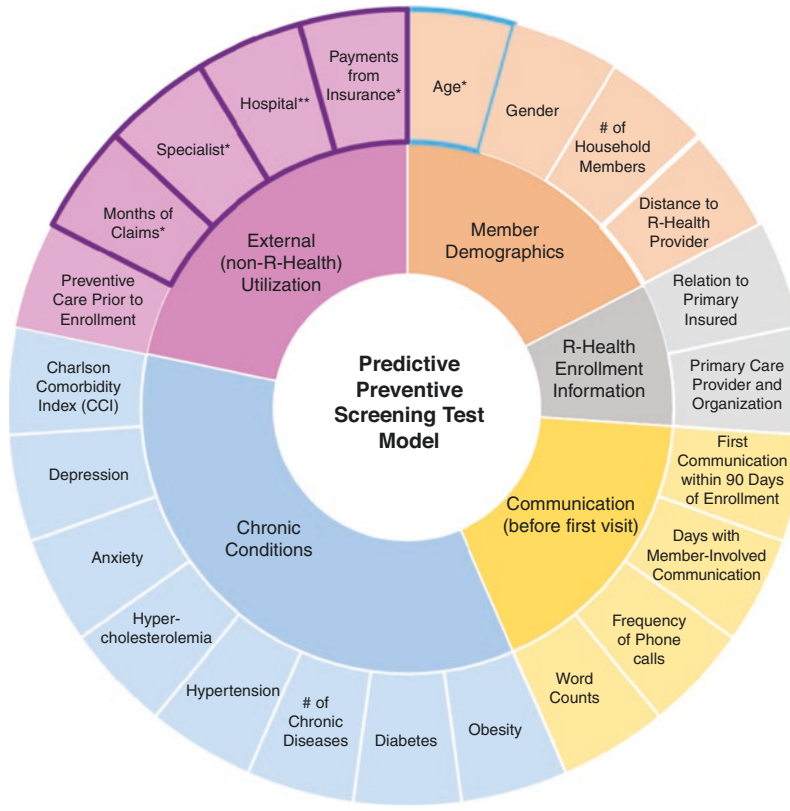

Fig. 21.5 Positive (Purple Outline) and Negative (Turquoise Outline) Features Associated with Preventive Screening Test Utilization. *Features with * relate to breast, colorectal and cervical cancer screenings and with ** relate to colorectal cancer screenings only*

tive "screening test" use, i.e. patients who see specialists, visit the hospital, have more months of claims, or undergo more preventive "screening tests".

21.5.1 Discussion

The application of ML models to multi-dimensional patient data from EHRs, claims and patient-provider communications can help predict patterns in healthcare behaviors (such as preventive care utilization) and identify features associated with behaviors in different practice settings (such as DPC). In this example of ambulatory care, ML provided data-grounded insights about patient engagement in primary care and prevention and about the importance of patient-provider communications in predicting patient engagement as indicated by active use of preventive care services.

Of the six different ML models/algorithms applied to patient data, the implementation of Extreme Gradient Boost (xgboost) associated primary care engagement (represented by higher PCS utilization) with early and frequent patient-provider communications. In addition, prediction of preventive "screening test" utilization was associated with extensive use of external (non-DPC) specialist and hospital services. This work suggests directions to help identify patients who are not engaged in preventive care and who may benefit from practice outreach.

The top three patient/practice features associated with PCS utilization were linked to patient-provider communications, their frequency, duration, and timing. This result may provide insights regarding low-cost, targeted interventions to improve PCS utilization/patient engagement: (1) early proactive outreach to patients (before their first visit) with multiple chronic conditions who are not otherwise engaged in preventive care, (2) study and tailoring of patient-provider communications and other workflows that improve patient PCS use, and (3) discovery and understanding of other barriers to PCS use.

21.6 Conclusions/Future Directions

This exploration of the application of ML to electronic DPC practice and transactional data provides the groundwork for further work.

Recent exploration has examined the impact of COVID-19 on DPC practice and vice versa. During 2020, face-to-face visits and services dropped dramatically, while the adoption and mainstream acceptance of telehealth telecommunication tools and virtual visits rose. Ongoing capture of patient care transactions for DPC allowed (and continues to allow) ML-driven efforts to discern changes in practice and patient behaviors throughout the course of COVID-19.

Further work in the development of MLMs, in conjunction with initiatives in the development of common data models (such as the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) [36]), will promote study and comparisons of DPC and other healthcare practice models to find common themes, associations and methods to improve healthcare quality processes and outcomes.

Questions and Responses

1. What are three distinctive characteristics of Direct Primary Care (DPC) practice?
   (a) *to encourage patient engagement and direct patient-provider communication.*
   (b) *remove barriers to early access and proactive evidence-based prevention to reduce per capita costs.*
   (c) *lower the administrative, cognitive and billing overhead of care delivery.*
   (d) *low to no cost primary care for subscribers.*
   (e) *reduced panel sizes and more time for clinicians to spend with patients.*
   (f) *no participation in commercial insurance, requires (usually) wraparound insurance for other care.*
2. What are three different supervised machine learning methods that can be used for classification and how do they differ?

(a) *Logistic Regression (LR) is an interpretable method that uses a logistic function to map a linear combination of input features onto the probability that a data point belongs to a particular class. By selecting a threshold on the probability, the regression result can be used to classify a data point into a particular class.*
(b) *Support Vector Machines (SVM) learn the widest possible separation boundary between positive and negative examples of a class making it potentially more robust to unseen data than logistic regression.*
(c) *Neural Networks (NN) use a process that mimics the operation of interconnected neurons in the human brain where connections between nodes have real-valued weights representing excitatory or inhibitory connections and an activation function that determines the output of a node.*
(d) *Decision trees are an interpretable way to learn non-linear combinations of input features that may help to predict a class.*

3. What are examples of the types of features that can be generated from electronic health records, administrative data, and patient-provider communication metadata for predicting use of preventive care services and preventive screening tests?
   (a) *See* Table 21.1. *Input Features for the Predictive Preventive Care Model and Predictive Preventive Screening Test Model*
4. For the analysis presented in this chapter, which features were found to be more strongly associated with use of preventive care services and preventive screening tests?
   (a) *The strongest features associated with use of preventive care services were whether the provider and patient have communicated within the first 90 days after enrollment, the volume of electronic communications in the time period prior to the first visit, and frequency of phone calls. See* Fig. 21.3*: Feature Importance (Gain) for Engagement in Preventive Care.*
   (b) *The strongest features associated with use of preventive screening tests were patient age, cumulative insurance payments, number of specialist visits, months of claims, and number of surgeries. See* Table 21.4*: Key Features, Their Importance, and Positive or Negative Association with Preventive Screenings.*

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Part III

Horizons

The preceding chapters have examined changes in US healthcare that have resulted from the incorporation of information technology to extend the measurement and improvement of healthcare processes and the health of individuals and populations. This section concludes the book (but not the dialogue) on where these and other developments have led, and of new and persistent questions that must drive the evolution of technology and US healthcare in the quest for better health.

Chapters in this section include considerations of:

- Healthcare Delivery in the Digital Age by M. Chris Gibbons and colleagues
- Workforce informatics competencies and skills by William R. Hersh from Oregon Health & Sciences University
- An emerging need for a new vision of multi-interprofessional training by Gabriela Mustata Wilson and colleagues
- Healthcare disparities and data bias, their implications for health systems, health equity, and artificial intelligence applications by Eileen Koski and colleagues from IBM
- A future healthcare analytic system by Stephen Bandeian and colleagues
- Health information technology and ethics by David Meyers
- Nurse informaticists and the coming transformation of the US healthcare system by Mark Hagland of Healthcare Innovation
- The future of health systems and "health intelligence" by John Silva and colleagues
- And we end with a look at some questions of the future of HIT that go beyond just the technology by Stephanie Reel and Steven Mandell from Johns Hopkins

Healthcare Delivery in the Digital Age

22

M. Chris Gibbons, Yahya Shaihk, and Frances Ayalasomayajula

Abstract

Emerging technologies are having a disruptive effect on healthcare delivery as systems evolve to meet changing healthcare needs of individuals and populations. Eight realities/trends are briefly examined, and a vision of a transformed healthcare system is presented.

Keywords

Emerging technologies · Healthcare delivery
Home-based care · Hospital-at-home
Retail-based clinics · Employment-based care
Community-based healthcare · Health apps
Mobile health · Consumer health · Patient engagement · Patient empowerment

M. C. Gibbons (✉)
The Johns Hopkins School of Medicine, Baltimore, MD, USA

The Greystone Group, Inc., Greenbelt, MD, USA

Reach Thought Leadership, San Diego, CA, USA
e-mail: mcg@greystonehit.com

Y. Shaihk
The MITRE Corporation, McLean, VA, USA

F. Ayalasomayajula
Reach Thought Leadership, San Diego, CA, USA

HP Inc., San Diego, CA, USA

Learning Objectives

- Cite current technology-based realities/trends that are driving change in current healthcare delivery and examples
- Describe projected changes in healthcare delivery due to these realities/trends in terms of where, how and by whom healthcare will be delivered
- Describe barriers that need to be overcome to realize the change

22.1 Introduction

Much has been written about the impact of emerging technologies on healthcare. Many entrepreneurs and investors are developing innovations to improve clinical workflows, to enable predictive analytics, and to deploy wide scale interoperability. Many of these innovations are disruptive to *current* healthcare delivery, but over time, *together and synergistically,* they will form the basis of sustainable transformations that have not before been possible, but that will have far reaching impacts on future healthcare delivery. We consider eight realities/trends that are already impacting and transforming healthcare.

1. *Reductions in Hospital-Based Care*

   For many reasons: economic, policy and regulation, disease epidemiology, and prac-

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tice changes, hospitalization/inpatient length-of-stay (LOS) has dropped significantly [1, 2]. Two major types of technical/workflow innovations that are making this overall reduction possible are:

(a) Innovations in clinical care technology, in medical devices that are miniaturized, handheld, ingestible, wearable, mobile, and operable and connected by broadband connection [3–8], have helped reduce LOS in intensive care and inpatient facilities by allowing patients to receive the same level of care and quality in home and community settings [5].

(b) Innovations in care coordination, which extend clinical supply chain and services beyond the hospital. "Hospital at Home" is a care model that organizes and leverages medical goods and services: pharmaceuticals, laboratory, imaging, 24-hour physician and nursing coverage and other bedside support [9], uses business, logistics, and engineering to deliver "High-Tech Home Care". Services, including intravenous infusion therapy, total parenteral nutrition, chemotherapy, analgesia/pain management, respiratory support (ventilators, oxygen), and telemedicine, reduce costs and safety risks of hospitalization. "Hospital at Home" has been shown to deliver as good or better outcomes in patient mortality, health, functional ability, quality of life, disease-specific outcomes, and overall satisfaction, in comparison to inpatient care. And despite a heavy reliance on technology, care has been shown to be less costly than traditional hospitalization [10].

2. *The Rise of Retail Healthcare*

Retail Healthcare is still in its infancy, with compelling evidence of emerging innovative models, of which we examine three exemplars – Community-Based Retail Clinics, Community-Based Telehealth and Employment-Based Care.

(a) Retail Clinics: MinuteClinic®

Prior to 2001, most healthcare encounters occurred in hospitals/emergency departments, clinics, or offices. In 2001, MinuteClinic® of Minnesota piloted retail clinics to provide acute care in community-based stores. In 2005, MinuteClinic® was acquired by CVS Health. As of 2021, CVS Health's MinuteClinic® currently leads the industry with more than 1100 locations in the US, with plans to increase its healthcare offerings by creating an additional 1500 "HealthHUBs" to focus on chronic disease management. Other chain stores have created similar products (Other examples are Walgreens HealthCare Clinics® and Kroger Little Clinics®).

In 2017, over 2200 retail clinics in the US reported revenues of $1.4 B in 2016, with a 20% increase for each of the previous six years. In 2021, nearly 9000 retail and free-standing urgent care centers in the US are spurred by strong patient and consumer demand and high satisfaction with short wait times, walk-in options, extended hours, convenient locations and transparent pricing [11–13].

Retail clinics leverage health technology to deliver care: electronic medical records, rapid diagnostic testing, electronic prescribing and telehealth. Initial clinician concern about lack of continuity and the quality of care by non-physicians have been offset by the accessibility and acceptability of retail clinics, comparable to emergency departments or physicians' offices [14–16]. **A**mong consumers/patients, **r**etail clinics have rapidly become popular, with evidence of higher patient satisfaction, shorter waiting times, lower costs, and care quality on par or better than traditional healthcare settings. There is also evidence that retail clinics may provide healthcare access to medically underserved populations.

(b) Community-Based Telehealth: VA-Walmart Partnership

In December 2018, the Department of Veteran Affairs (VA) and Walmart announced a collaboration to enable Veterans to access VA-led telehealth services in Walmart stores "to serve Veterans

through technology…providing Americans with more affordable health care," and to provide "integrated, seamless access to healthcare no matter where a Veteran resides…from anywhere to anywhere."[1]

This model is a departure from traditional VA-led healthcare offerings as the first formal collaboration between the US federal government and a private retail conglomerate, designed to enable healthcare anywhere, to increase convenience and to lower costs for patients and consumers, thereby improving the population health of Veterans.

(c) Employment-Based Care: AmazonCare®

In September 2019, the Amazon Corporation launched Amazon Care®, a service to provide its employees immediate access to high-quality care via chat or video conference (typically in less than 60 seconds). Amazon Care® has two components: 1) virtual care, which connects patients via smartphone app messaging/video (Android and iOS) to confidential live chat with a nurse or doctor, and 2) in-person care, which dispatches medical services to a patient's location, ranging from prescription delivery and routine blood draws to listening to a patient's lungs.

Until March 2021, Amazon Care® was available only to employees in Washington state, when Amazon announced plans to make its virtual care component available to companies and to Amazon employees in all 50 states by Summer 2021. There are plans to expand its in-person care component to Washington, DC, Baltimore, and other cities in coming months.[2] It remains to be seen if this form of retail healthcare will ultimately succeed.

(d) Retail Pharmacy: Amazon Pharmacy®

In November 2020, Amazon announced two new pharmacy offerings. Amazon Pharmacy, a new store on Amazon, allows customers to complete an entire pharmacy transaction on their desktop or mobile device through the Amazon App. Using a secure pharmacy profile, customers can add their insurance information, manage prescriptions, and choose payment options before checking out. Prime members receive unlimited, free two-day delivery on orders from Amazon Pharmacy included with their membership. Also Prime members can access savings on medications at Amazon Pharmacy when paying without insurance, as well as at over 50,000 other participating pharmacies nationwide. The Amazon Prime prescription savings benefit saves members up to 80% off generic and 40% off brand name medications when paying without insurance. Through this program some medications will be available for as little as $1 per month. Customers also have online self-service help options combined with phone access to customer care at any time 24/7 to answer questions about medications.[3]

Insights gleaned from the Amazon Care® and Amazon Pharmacy® experience include:

- There is compelling evidence of the acceptance of the Amazon Care® model from its national expansion, after an 18-month local pilot.
- Amazon Care® is largely outside of traditional healthcare insurance (and regulation), representing potential dis-

[1] https://www.managedhealthcareconnect.com/content/walmart-va-collaborate-new-partnership-offer-telehealth-services

[2] Amazon Care to launch across U.S. this summer, offering millions of individuals and families immediate access to high-quality medical care and advice—24 hours a day, 365 days a year, March17,2021 https://www.aboutamazon.com/news/workplace/amazon-care-to-launch-across-u-s-this-summer-offering-millions-of-individuals-and-families-immediate-access-to-high-quality-medical-care-and-advice-24-hours-a-day-365-days-a-year

[3] Introducing Amazon Pharmacy: Prescription Medications Delivered. BusinessWire, Nov 17, 2020. URL: https://www.businesswire.com/news/home/20201117005429/en/ [last accessed 27 October 2021].

ruption to traditional healthcare insurance/business models.

- Amazon Care®, unlike traditional healthcare, appears to occur without the need for (or for less) inpatient care, representing potential but significant disruption to traditional hospital finances.
- The Amazon Care® paradigm could represent a new patient experience of healthcare, driven by a) the speed of access to a medical provider (nurse or doctor) within 60 seconds of a patient request and b) unparalleled convenience, empowered by the two-way Web-enabled interaction, regardless of time or patient location. These enhancements may be powerful enough to outweigh potential hesitancies they have with the service.
- Amazon Pharmacy® is a hybrid service integrating some traditional pharmacy services with medication and customer service benefits not previously seen in healthcare. This service is offered to employers but is also offered directly to all consumers. The costs, benefits and convenience of the service may be hard to replicate in traditional pharmacy systems.

3. *Shifts in Population Demographics*

America is graying. In 2016 in the US, there were 49 million people 65 years or older. By 2030, all US "boomers" will be over 65 with one in five being an "older adult". By 2060, 95 million will be over age 65, representing growth in this population (from 15% to 25%) and in the "over 85" population (doubling to 11.8 million by 2035, and tripling to 19 million by 2060). Beyond 2030, older adults are projected to outnumber children for the first time in US history (2034). The total US population is expected to grow by 79 million people by 2060, crossing the 400-million threshold in 2058 [17].

The aging population is also becoming increasingly diverse, racially, and ethnically. In 1900, one in eight people in the US were "non-white". Starting to rise in 1970, one in five were a race other than white by 1990, growing to one in four over the next decade. By 2060, this proportion of "non-white" is projected to be one in three, or 32 percent of the US population. The non-Hispanic white population is projected to shrink from 199 to 179 to 199 million due to falling birth rates and rising number of deaths.

From a different perspective, millennials, who currently represent 30 percent of the population, are diverse, with 44 percent represented by ethnic and racial minorities, compared to 25 percent of baby boomers [18]. Millennials report not having a personal healthcare provider, and not wanting one, satisfied to obtain their healthcare through digital means or from retail healthcare outlets.

These changes in patient demographics will affect population health needs, thereby shaping healthcare services:

(a) More senior patients with more and progressively complex chronic diseases of varying severity will require comprehensive ambulatory services.
(b) Increases in patient diversity will require care and support services to be culturally appropriate to promote patient engagement and empowerment.

To meet these needs, traditional healthcare delivery service structures and processes will need to change, to evolve, especially in their increasing dependence on digital health solutions and technologies for outreach to patients, when and where they need it.

4. *The Rise of Consumer Health Technologies*

Consumer digital health technologies assist patients and their families in managing health and chronic disease. The prevalence of digital tool ownership is high, with 96% of Americans owning cellphones, 81% owning smartphones, 75% owning a laptop/desktop and 50% owning a tablet/e-reader. Reliance on smartphones for online access is especially common among younger adults, non-whites

and lower-income Americans.[4] Use of smart TVS, wearables and speech-enabled tools is growing, with 46% using digital speech assistants.

Smartphone platforms provide consumer-accessible mobile app programs that are transforming users' engagement with people, products and services:

(a) Apple and Google Play stores have approximately five million apps/programs available that are actively used by smartphone users at least 11 times per day [19]. There are now over 318,000 health apps available in app stores worldwide, with over 200 health apps added each day. Collectively, health apps have been downloaded almost three and a half billion (3.35 billion) times.

(b) "Health & Fitness" apps [20] can be categorized as:
- *General Health & Wellness Apps* that track nutrition and calories, sleep patterns, and help manage stress
- *Telemedicine Apps* that provide virtual patient care by licensed doctors
- *Health Management Apps* that
  - support self-care and monitoring of specific health conditions (heart disease, diabetes, pregnancy, mental health etc.)
  - allow patients and providers to share personal health data, remotely
  - assist patients and their caregivers to track and manage medications

Consumer health apps can work in concert with other medical technologies. For example, the PatientKeeper® app (from Epic Systems) enables providers to access patient clinical/EHR data via mobile devices, laptops, tablets and other devices, allowing access to data and information anywhere and anytime patients need or want to access them. It has been estimated that if health apps were used across all diseases, a potential savings of as much as *$46 billion* a year could be realized.

The evolution in personal digital and health technology is changing consumer expectations in healthcare as it is in all sectors of the service economy. New value propositions: more and faster healthcare delivery options, increased convenience and lower costs, are going beyond the Institute of Healthcare Improvement's Triple or Quadruple Aims [21]. New variables of importance are being included in healthcare value propositions as provider systems seek competitive advantage in attracting and retaining patients.

5. *The Availability of Broadband Internet/5G*

Increasingly, Broadband Internet connectivity is required to assure interoperability and security of medical devices and the availability and reliability of data flow for effective and secure healthcare. Broadband Internet can be delivered via fixed (fiber optic, cable, DSL) or Mobile (cellular or wireless) connections to the network. The current network architecture, 5G (the fifth generation) will enable higher data transmission speeds than previously, with much lower latency and a higher network density (allowing more devices to connect). This is the critical infrastructure for enabling the Internet of Things (IoT, the network of computing devices embedded in everyday objects) to become a practical reality and to develop robust digital health ecosystems that can deliver "on demand" "anytime/anywhere" care services to patients [22].

6. *The Use of Artificial Intelligence*

Artificial Intelligence (AI), the simulation of human intelligence or behavior for learning, reasoning, and problem solving, is not a single technology, but a range of processes and behaviors generated by computational models and algorithms. Progress in handling massive and "big" data has accelerated advancements of AI, Machine Learning (ML) and Natural Language Processing (NLP). New powerful solutions have been developed to solve complex real-world problems in image and speech recognition, "big data" analytics, with applications in healthcare.

[4]Mobile Fact sheet, Mobile phone ownership over time, Aptil 2021, https://www.pewresearch.org/internet/fact-sheet/mobile/

(a) Machine Learning, (ML) the current dominant approach in AI, uses model ("training") data to identify patterns, then uses the model to make predictions from new ("test") data. ML algorithms can thus learn and improve from experience over time without explicit programming. ML is widely used in other types of AI technologies, such as NLP, voice and vision technology, and robotics.

(b) Natural Language Processing (NLP) uses computational methods to automatically analyze and represent human language. NLP can be used to extract critical information about patients from data, to improve diagnostic and therapeutic recommendations [23].

AI and ML have many applications across healthcare, from wellness, screening and diagnostics, predictive modeling and analytics to interventional and treatment support, including robotics and other forms of assistive devices, virtual care, remote patient monitoring, drug development, testing and prescribing just to name a few. These innovations are generating insights that are instantly available to medical providers at the point of care [24, 25].

Many practitioners (83%) experience a steep learning curve in using AI based digital health technologies in care, with most (84%) remaining receptive to its use in clinical practice (84%). At the same time, half of physicians (51%) worry about the longer-term impacts, including job loss, in using these technologies for patient care. Other concerns include: inherent racial and gender bias in AI-based technologies, including clinical decision support [26] that may be "… related to missing data and patients not identified by algorithms, [and by] misclassification, observational error, and misapplication…". Diligent attention must be taken to ensure AI systems are developed and utilized in an equitable manner that does not exacerbate existing healthcare disparities and inequalities.

7. *The Use of Robotics*

"Robotics" represent different kinds of tools that support healthcare delivery:

(a) *Surgical Robots*: Three types of systems are currently in use.
- *Active Systems* that work without human involvement and complete pre-programmed tasks.
- *Semi-Active Systems* that allow both pre-programmed and direct human control
- *Master-Slave Systems* that are controlled entirely by human activity (ie. a surgeon's hand movements transmitted to and reproduced by a robot) [27].

(b) *Socially Assistive Robots (SARs)*: These aid patients through social interaction. SARs can enhance the quality of life for the elderly, for individuals with physical impairments and for rehabilitation therapy for cognitive, developmental and social challenges and to support therapists. SARs:
- Provide education and feedback, coaching patients through tasks, assisting with treatment compliance, and monitoring treatment progress.
- Interact physically (not socially) by moving a user's body through motions [28–32].

(c) *Software Robots ("Bots")*: These are software programs that automate tasks. Conversational agents are frequently implemented[5]
- *Chatbots* can simulate conversations via text, image, or voice. Simple Chatbots are rule based and limited in their range, dependent on predetermined keywords and commands programmed by the developer.
- *Voice Assistants* can interpret speech, respond verbally and take actions (Examples include: Siri, Alexa, Cortana).
- *Simple agents* are increasingly used to execute tasks such as booking appointments, medication reminders, appoint-

[5] What are software Robots, Think Automation, https://www.thinkautomation.com/bots-and-ai/what-are-software-bots/

ment reminders and sharing other health information without human involvement.

- *Smart agents* are enabled by AI/ML and NLP/Natural Language Understanding (NLU) and have the potential to undertake more complex tasks that involve greater interaction, reasoning, prediction, and accuracy including triaging patients, conducting follow up patient evaluations and even sophisticated patient health education [33–35].

In summary, Robots are actively being used in healthcare: to aid surgeons in performing procedures remotely [36–38], to engage patients in health education and to assist them in accomplishing complex tasks, and to automate clerical tasks such as scheduling appointments, reminding patients about appointments and assisting in other patient care tasks.

8. *Evolution of the Internet of Things (IoT)*

The Internet of Things (IoT) is the collection of physical objects, digital tools, devices, platforms and systems, connected by wireless or wired broadband Internet networks to allow bidirectional transfer of data and instructions between components in an active data ecosystem [39], to provide access to data and functionality for coordinated actions at the point of need. The transformative power of the IoT lies not only in the intrinsic capabilities of its components, but also in the integration and coordination of automated activities across a network anytime and anywhere it is needed. Examples include:

(a) Retail pharmacy chains such as Wal-Mart use IoT to monitor and maintain food temperature in refrigeration units and to optimize energy consumption for environmental heating and cooling control during shopping and non-shopping hours
(b) Smart Homes and Smart Communities will use IoT to help improve wellness and optimize human performance in every aspect of life [40]. Smart products like scales, blood pressure cuffs, fitness and sleep monitoring devices in the home will actively integrate to form a "health-aware" ecosystem [41], that will be transparent and "always on" to detect, understand and respond to individual health problems as they happen anywhere the patient is located within the community [42].

22.2 Implications of Digital Transformation in Healthcare

The realities/trends described are already occurring in medical practice, healthcare delivery and in daily life. First, digital health tools are already supporting personalized direct healthcare of individuals with new levels of access to real-time data for ongoing diagnosis and therapy. Second, the organization and delivery of healthcare is changing, out of necessity, bringing it out of the office and hospital to wherever the patient is, whenever the patient needs and wants care.

This new reality raises two questions:

- With better (lower risk and lower cost) care options available to patients, is there any compelling reason for maintaining traditional (high risk and high cost) forms of care and care delivery (ie. Will there be ongoing need for hospitals and inpatient facilities)? The compelling answer is no.
- If there is no reason for maintaining traditional forms of high-cost care (ie. hospitals, as we know them), what WILL healthcare systems of the future look like?

Predicting the future is fraught with challenges, but it is increasingly clear that those hospital systems that will survive will be those that proactively embrace these realities/trends and the opportunities and challenges they present, and that can innovate to provide quality and value of care to patients.

22.3 A Possible Vision of the Future

Possible scenarios for the future organization and delivery of US healthcare have been described [43–47], without a comprehensive vision or consensus that accounts for realities we have described and for the national trends that are shaping healthcare today. These trends include:

- an increasingly aged and diverse national demographic,
- significant and growing shortages maldistribution in healthcare providers,
- a focus on both social and medical/genetic determinants of health,
- the rising costs of care, and
- the possibilities and roles of technology.

We briefly assess future healthcare delivery toward a more comprehensive vision. We do not believe this, nor any other model is perfect, yet it provides a valuable basis for continuing discussion.

22.4 Components and Distribution of a Future Healthcare Delivery System

Figure 22.1 summarizes the major components of this vision. In brief, there will be a continuing contraction in inpatient (hospital) services. This contraction will likely be fatal to many current institutions, resulting in a major restructuring of inpatient care.

1. *(Inpatient Care) Critical Care Remaining in Hospitals: 10–15%*

   Surviving institutions will focus on high acuity, critically ill and medically complex patients who will require procedures and therapies that cannot be provided in a less structured settings, and after all other alternatives have been exhausted. Many conditions that could only be treated in intensive care units previously, are progressively being managed with clinical technology support in ambulatory and home settings. Thus, even hospital-based critical care will decline in demand. Likely, care in remaining facilities will be carried out by physician providers and teams. Unlike today, though, this type of care will likely represent the smallest proportion of care volume nationally, eventually only 10% to 15% of all care.
2. *(Hospital at Home) Inpatient Services at Home 15–25%*

   Due to advances in patient care technologies, more patients will receive care that had traditionally been performed in inpatient settings, in community, ambulatory or home settings (ie. NOT non-inpatient). Advances in broadband enabled health technologies will further contribute to the value and cost effectiveness of this and ambulatory models of care. This trend is already increasing with the advantages and progression of the "Hospital at Home" care model [48–53]. The share of total volume for the Hospital at Home care model may comprise as much as 15% to 25% of the total of all care.
3. *(Smart Care Communities) Geographic Ecosystems of Care 30%*

   Healthcare and technology partnerships, with stakeholders from IBM, Microsoft, Google, Apple, and Amazon, as well as from the automotive [54] and residential [40, 55] industries are exploring opportunities in the health sector. In near future, patient care encounters, delivery and transactions will take place "anytime/anywhere" within Accountable Care Organizations (ACOs), in which virtual healthcare systems/teams (all participants) will be responsible for the care of people living within a geographic region. Such Geographic Ecosystems, as part of Smart Cities and Smart Communities could be optimized for post-acute care and chronic disease self-management at both individual and population levels. Management teams, including patient navigators, community health workers ("promatores") would be overseen by physicians, nurse practitioners and nurses [56–60]. In the more distant future, this regional model of healthcare delivery may account for as much as 30% of total.

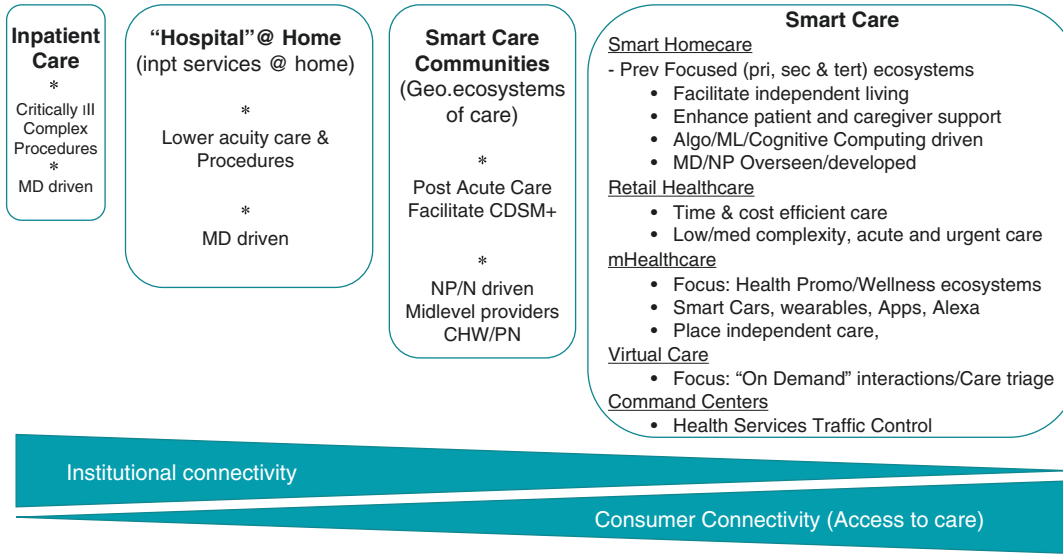

Fig. 22.1 The Future Organization of Healthcare Delivery

4. *Smart Care 40–50%*

   Digital health and consumer health informatics may well become the largest component of such a care delivery model, accounting for 40% to 50% of total care volume. The term "Smart Care" highlights the fact that more sophisticated broadband-connected consumer devices, will autonomously detect, decide, and react to patient needs based on predetermined algorithms. Many solutions will be built into the environment as part of a health-centric IoT, interacting with patients continually and ubiquitously. Smart Care tools and environments have the potential power of passive intervention, with impacts similar to that of water fluoridation, iodination of salt, and airbags. Likewise, Smart Homes and Automobiles could be integral components of a broader consumer health ecosystem that is "always on", following people wherever they are, to help individuals live independently, safely, to focus on wellness and prevention.

   As this model of care delivery grows, there will be need for health technology "air traffic controllers" and "control centers" with key responsibilities for optimizing data and information flows and use of community resources. Some health systems are already thinking about these possibilities and preparing to act. For instance, Mercy Hospital system in Missouri has developed the first operational "Hospital Without Beds" – focusing on optimizing care via technology, at a distance to patients within its network [61].

5. *Broadband: Making it all work together*

   Full-scale broadband connectivity – both institutionally and in the home – is central to this vision of health care delivery. As the two arrows at the bottom of the Fig. 22.1 illustrate, if we focus on only on institutional connectivity, some consumers may have little or no access to services. If, instead, we also prioritize consumer access to Broadband Connectivity, all consumers will have access to at least some forms of effective health care goods and services.

22.5 Two Examples of Ecosystems of Care

We present two hypothetical scenarios that, incorporating some of the ideas discussed, envision how digital and digital health technology advances can change the delivery of healthcare. The elements depicted herein are currently available or projected to be on the market within

1–3 years. No one has, to date, connected these entities and technologies to create working always available systems to deliver the vision of anytime/anywhere care whenever and wherever the patient needs it.

Case Studies: A "The Asthma Home"

John is a seven-year-old boy with moderate chronic asthma requiring the use of a rescue inhaler approximately once per week. His family recently moved to a new Smart Community in the city that has been optimized for families with seniors or children with chronic diseases. John's new home has multiple sensors and technologies built into the home that work automatically and which are "always on". These sensors can detect any number of issues, concerns and medical conditions commonly affecting seniors and children, including asthma. Over time, the Smart Home "learns" the habits and behaviors of each family member and optimizes the care that it provides them. When an issue arises, the home can, in many cases, accurately and automatically determine the existence of a medical problem (such as an exacerbation of asthma) and correctly initiate a course of action that would address the issue.

One night, after bedtime, John begins to have to work harder to breathe. Before he wakes up, the Smart Home detects that this is happening and recognizes it as an early sign of an asthma attack. His parents are asleep in the next room and unaware of his changing condition. Before John fully wakes up, the Smart Home raises the humidity level in his room and releases an appropriate amount of prescribed nebulized medication, into his room where it reaches him. As John breathes the warm, moist, medicated air, his asthma attack is prevented without human intervention, his parents unaware of the incident until they receive a mobile phone alert detailing what happened. His parents quickly go to his room to check on him, and find him sleeping comfortably and soundly in his bed.

Case Studies: B "Auto-Ambulance"

It is 6 pm and Alex, an overweight, 50-year-old business executive is fighting rush hour traffic to get to his 5-year-old daughter's school Christmas program after an intense 12-hour day at work. While driving, Alex begins to experience numbness in his left hand and facial drooping. His Smart Car detects that Alex is now responding inappropriately to road and traffic conditions and that his speech is slurred, making it impossible to understand his verbal commands. The Car immediately switches to autopilot and relays this information, including his vital signs to the Cloud-Based Artificial Intelligence Emergency Analytics & Response System. (CAEARS) which immediately attempts unsuccessfully to make audio contact with Alex. The Car also notes that Alex has suddenly become totally unresponsive determines that this likely represents a medical emergency. CAEARS immediately relays this information, along with an estimated time of arrival (ETA) to the nearest Hospital Emergency Department (ED). CAERS then commands the car to navigate to the Hospital. The Car sends an electronic signal to the Smart Traffic Light grid designating Alex's vehicle as an emergency transport. The Traffic Light grid communicates with Alex's on-board navigation system to provide the most direct route to the Hospital. Alex arrives at the Hospital ED where the waiting medical team is quickly resuscitates him and diagnoses an impending stroke, and is able to administer life-saving treatment by which Alex experiences complete recovery.

22.6 Conclusions

A vision of what healthcare delivery will look like in the future requires changes in definitions:

- Changes in the definition and recognition of what "healthcare" is, to include non-traditional services, some of which may be mediated through technology and that may not involve a human provider, such as patient monitoring and data collection.
- Changes in the definition and recognition of what a "care provider" is, to include formal and informal caregivers, as well as autonomous technologies, providing care and information about patients.
- Changes in the definition and recognition of where "healthcare encounters" occur, outside of hospital, emergency, or clinic settings, to include community, home and other non-office settings, using mobile and online technologies to support on-demand care.

Barriers to changes, largely driven by traditional healthcare payments, are being overcome by ongoing realities and trends, many of which have been driven by the ubiquitous and disruptive opportunities offered by digital, mobile, and broadband technologies. Compelling innovations in service delivery, supported by consumer/patient acceptance and demand, are gaining traction and pushing changes.

Question/Answer

1. What is the major shift in point-of-care in the digital age?
   (a) The shift in care with mobile and cloud-based technologies and services is away from hospitals and more to ambulatory and home-based care, with measurable improvements in outcomes, delivery and patient safety.

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Informatics and Clinical Workforce Competencies and Education

23

William Hersh

Abstract

A critical factor in the successful implementation of healthcare information management systems is the people, including not only those who develop, implement, and evaluate systems but also those who use them to deliver healthcare. This chapter describes the competencies and education required for all such individuals, including a description of current jobs and certifications that they hold and how they are trained for them.

Keywords

Informatics · Competency · Education and training · Workforce

Learning Objectives

- Describe the competencies in informatics required for informatics and health care professions
- Discuss the various certifications available in informatics
- Describe the different types of education available to train informatics professions
- Discuss what is known about the informatics workforce

W. Hersh (✉)
Oregon Health & Science University,
Portland, OR, USA
e-mail: hersh@ohsu.edu

23.1 Introduction

The discipline that focuses on all aspects of the application of data, information, and knowledge to health-related activity is called *informatics*, and its application in health-related disciplines goes by a variety of names that place various adjectives in front of the word, including *biomedical informatics*, *clinical informatics*, *health informatics*, and others [1]. Informatics is a core skill for all modern healthcare professionals, who must have competence in the use of key applications for patient care, such as the electronic health record and its critical functions, such as clinical decision support and order entry [2, 3].

There are others in the healthcare setting who manage information systems beyond informatics, most notably those who work in information technology (IT) and health information management (HIM) [4]. The former provide IT expertise more generically in areas like networking, security, and non-clinical applications while the latter have historically managed the patient record.

In this chapter, we will begin by discussing the competencies in informatics, first those required of informatics professionals and then of healthcare professionals. Next, we will characterize the certifications of informatics professionals. This will be followed by an overview of

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education in informatics. We will close with a further elaboration of informatics and IT workforce.

23.2 Competencies for Informatics Professionals

There have been a number of efforts in the last decade to characterize competencies of those work in informatics. One early effort defined the core content of clinical informatics, with an aim to discern the required knowledge of physicians in preparation for board certification [5]. Another was an update of educational recommendations by the International Medical Informatics Association [6]. A couple years later, the American Medical Informatics Association (AMIA) published core competencies for graduate education in the field [7]. More recently, AMIA published a core competency framework for applied health informatics that has been adopted for use in the accreditation of master's degrees program by the Commission on the Accreditation of Health Informatics and Information Management (CAHIIM) [8]. As shown in Fig. 23.1, this framework recognizes that base and overlapping domains of knowledge and skills required in such programs.

In an attempt to elaborate the work of informatics professionals for professional certification, AMIA commissioned two workforce analyses that interviewed those working in the field to catalog the knowledge, skills, and tasks applied in their work. This was done for both physicians in the clinical informatics subspecialty (CIS) [9] as well as others working in health informatics (HI) [10]. The goal of the former was to update the competencies for physician board certification and of the latter was to define them in anticipation of advanced health informatics certification being led by AMIA. [11, 12] One interesting finding of these independent analyses was a comparable set of high-level domains of work, which are shown in Table 23.1.

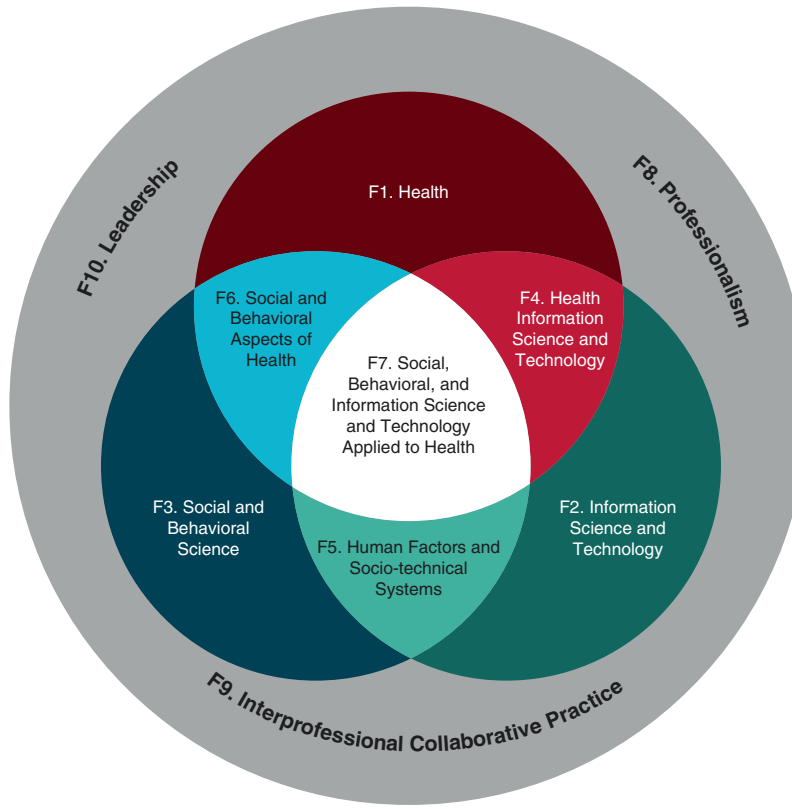

Fig. 23.1 Core competencies for health informatics master's-trained informatics professionals [8]. (Figure reproduced with the permission of AMIA from the Journal of the American Medical Informatics Association, Volume 25, Issue 12, December 2018, Pages 1657–1668, https://doi.org/10.1093/jamia/ocy132)

Table 23.1 Domains of practice for health informatics [10] and the clinical informatics subspecialty [9]

Domain	Health informatics	Clinical informatics subspecialty
1	Foundational knowledge	Fundamental knowledge and skills
2	Enhancing health decision-making, processes, and outcomes tasks	Improving care delivery and outcomes
3	Health information systems (HIS) tasks	Enterprise information systems
4	Data governance, management, and analytics tasks	Data governance and data analytics
5	Leadership, professionalism, strategy, and transformation tasks	Leadership and professionalism

Both analyses describe the first domain of fundamental knowledge and skills, which include a common vocabulary, basic knowledge across all informatics domains, and understanding of the environment(s) in which the workforce functions. Depending on where an individual works, this may include consumer health, health care, public health, or research settings.

The second domain of both analyses focuses on enhancing health decision-making and improving health care delivery and outcomes. Informatics practice should support and enhance decision-making by clinicians, patients, policy makers, researchers, and public health professionals. It must also analyze existing health processes and identify ways that health data and health information systems (HIS) can enable improved outcomes. Informatics work should also evaluate the impact of HIS on professional practice as well as pursue discovery and innovation. More clinically, informatics practice should be able to develop, implement, evaluate, monitor, and maintain clinical decision support while also supporting innovation in the health system through informatics tools and processes.

The third domain comprises health and enterprise information systems. Informatics practice should include planning, developing or acquiring, implementing, maintaining, and evaluating HIS that are integrated with existing information technology systems across the continuum of care. This should include the clinical, consumer, and public health domains and address security, privacy, and safety considerations. This domain should also include the development, curation, and maintenance of institutional knowledge repositories, also while addressing security, privacy, and safety considerations.

The fourth domain is an addition to the original four domains of the Gardner et al. analysis, which focuses on all issues related to data, most prominently governance, management, and analytics. Practice should include establishing and maintaining data governance structures, policies, and processes. The workforce should be able to acquire and manage health-related data to ensure their quality and meaning across settings and to utilize them for analysis that supports individual and population health while driving innovation. It is also critical to incorporate information from emerging data sources and derive insights to optimize clinical and business decision-making. Although not explicitly mentioned in the overall descriptions of this domain (but covered in the details of practice) are the ability to identify and minimize biases in data and mitigate their impact as well as to implement and evaluate machine learning and artificial intelligence applications in all health-related settings.

The fifth domain reflects the sociotechnical aspects of informatics, with required abilities in leadership, professionalism, and transformation. Informatics practice should be able to build support and create alignment for informatics best practices as well as lead informatics initiatives and innovation through collaboration and stakeholder engagement across organizations and systems.

23.3 Informatics Competencies for Healthcare Professionals

As noted above, competence in informatics is required not only of those work in the field professionally, but pretty much every healthcare

Table 23.2 Competencies in clinical informatics for medical education [3]

1.	Find, search, and apply knowledge-based information to patient care and other clinical tasks
2.	Effectively read from, and write to, the electronic health record for patient care and other clinical activities
3.	Use and guide implementation of clinical decision support (CDS)
4.	Provide care using population health management approaches
5.	Protect patient privacy and security
6.	Use information technology to improve patient safety
7.	Engage in quality measurement selection and improvement
8.	Use health information exchange (HIE) to identify and access patient information across clinical settings
9.	Engage patients to improve their health and care delivery though personal health records and patient portals
10.	Maintain professionalism through use of information technology tools
11.	Provide clinical care via telemedicine and refer patients as indicated
12.	Apply personalized/precision medicine
13.	Participate in practice-based clinical and translational research
14.	Apply machine learning applications in clinical care

professional. The informatics competence of healthcare professionals is more related to the ability to use such systems to deliver and improve care than those who develop, implement, and evaluate systems. Such individuals may be engaged in activities with a substantial informatics component, such as clinical decision support, quality improvement, clinical research, and more. This requires that healthcare professionals have informatics education as part of their training.

Hersh et al. defined competencies in clinical informatics for medical students, although they noted they really applied to all health care professionals [3]. Table 23.2 lists the high-level competencies for medical students. Another effort to define competencies for the health care workforce is the TIGER Initiative, which had its origins in nursing but has expanded to include all health care professions.[1]

23.4 Certification of Informatics Professionals

Despite the lack of measurement of the workforce, there is one development in the US that point to its relevance, which is professional certification. The first formal certification was developed for physicians, with clinical informatics designated as a subspecialty of all specialties [13]. This was done through the formal board-certification mechanism. The core content of the subspecialty was outlined in an analysis by Gardner et al. organized around four domains of fundamentals, clinical decision making and care process improvement, health information systems, and leading and managing change [5]. After more than a half-decade, there were more than 2000 physicians board-certified in clinical informatics distributed across the US [14].

The American Medical Informatics Association (AMIA) is also developing an Advanced Health Informatics Certification (AHIC),[2] which will certify other professionals who work in health informatics [11, 12]. AMIA has also developed a set of master's-level competencies for health informatics professionals based on a foundation of health science, social and behavioral sciences, and information science and technology [8]. These competencies are used in master's-level program accreditation being spearheaded by the Council on Accreditation of Health Informatics & Information Management (CAHIIM).[3]

There are other certifications related to health information and technology. The Healthcare Information Management Systems Society (HIMSS) has offered two certifications designed

[1] https://www.himss.org/what-we-do-technology-informatics-guiding-education-reform-tiger.

[2] https://www.amia.org/ahic.

[3] https://www.cahiim.org/accreditation/health-informatics.

for those who work in IT roles, the Certified Professional in Healthcare Information and Management Systems (CPHIMS) and the entry-level Certified Associate in Healthcare Information and Management Systems (CAHIMS).[4] The health information management profession has a variety of certifications, including the top-level Registered Health Information Administrator (RHIA).[5]

23.5 Education in Informatics

There have been many approaches and innovations in the education of informatics professionals, health care professionals, and others [15]. The education of informatics professionals has historically taken place at the graduate (i.e., post-baccalaureate) level. This is probably due in part to the large number of those who enter the field from healthcare professions, i.e., medicine, nursing, pharmacy, etc. Of course, not everyone who works in the field has a health care background, and others come from a variety of backgrounds, including but not limited to computer science, information technology, business, and others. As with most fields, those desiring academic and/or research careers will often obtain a PhD degree (or pursue a postdoctoral master's degree) while those seeking to work in operational settings pursue a master's degree.

Another avenue to advanced training for the field has been the fellowship, which often also includes completion of a graduate degree. The original funder of fellowships in informatics was the National Library of Medicine (NLM), the National Institutes of Health (NIH) institute devoted to informatics research and training. Using the NIH training grant mechanism, the NLM has offered "pre-doctoral" fellowships leading to the PhD degree and "post-doctoral" fellowships for those with PhD or healthcare doctorates that often included a graduate degree, typically a master's degree since the 1980s[6] [16]. In the 1990s, the Department of Veteran's Affairs (VA) started offering post-doctoral fellowships as well.

Another type of fellowship emerged with the launching of the clinical informatics subspecialty for physicians. These fellowships have focused more on the medical model of subspecialty training, although many offer graduate degrees or certificates [17]. The fellowships are accredited by the Accreditation Council for Graduate Medical Education (ACGME).[7] One recent innovation is to blend fellowships in clinical informatics with those of other medical subspecialties [18]. One ongoing concern for clinical informatics fellowships is their financial sustainability, since informatics physicians typically do not "bill" for their services [19]. Clinical informatics fellows did turn out to be important contributors to their institutions during the COVID-19 pandemic [20].

One recent analysis assessed the landscape of master's degree programs [21]. The study identified 75–80 programs in the US, of which about half responded to a survey administered to them. The programs varied in size, with about a third of programs have less than 30 students enrolled and a handful over 90. They were evenly split.

One small trend that may grow in the future is educational programs at the baccalaureate level. At this time, only a handful of programs exist around the US but this could increase as the profession of informatics becomes more established.

There are many people who work in informatics roles, especially in operational settings, who do not have formal degrees in informatics. Many academic programs offer shorter courses of training. One credential that is offered by a number of academic programs is the Graduate Certificate, which provides a smaller concentration of courses but is still at the graduate level.

Another option is single continuing education types of courses. One of the most widely known collection of single courses is the 10 × 10 ("ten

[4] https://www.himss.org/resources-certification/overview.

[5] https://www.ahima.org/certification-careers/certifications-overview/

[6] https://www.nlm.nih.gov/ep/GrantTrainInstitute.html.

[7] https://acgme-i.org/Specialties/Landing-Page/pfcatid/38/Clinical-Informatics.

by ten") program of AMIA and a number of academic partners.[8] The original and still-largest of all 10 × 10 courses, offered by Oregon Health & Science University, has been completed by over 2800 individuals since 2005[9] [22].

23.6 Characterizing the Health Informatics Workforce

There are many jobs and titles in informatics and IT roles in health care organizations. HIMSS has enumerated and described many of these positions.[10] However, the ambiguity of definitions of informatics jobs results in confusion as to who works in the field and what they do. In the US, the Bureau of Labor Statistics maintains statistics about the workforce based on its Standard Occupational Classification (SOC) system. Many in the larger health information technology (HIT) community called for the 2018 update of the SOC to add a code for health informatics.[11] Unfortunately this call was unheeded, and health informatics was lumped into a category of *Health Information Analysts and Medical Registrars*, under which "health informatics specialist" was considered an illustrative example.[12] The lack of a specific SOC code for health informatics makes its workforce less defined and visible. This invisibility has been noted in other countries, such as Australia [23].

One former source of workforce data in the US was the HIMSS Analytics Database,[13] although it was focused on larger HIT employment, a superset of those whose work in health informatics. Mainly a source of self-reported HIT systems usage by healthcare organizations, the HIMSS Analytics Database formerly captured FTE levels overall and for various job categories, such as management, project management, programming, operations, network administration, help desk, PC support, security, and EMR support. Unfortunately, the workforce data of this resource is no longer maintained.

The HIMSS Analytics Database was used for some workforce analyses. An analysis of data from 2007 found that the US HIT workforce size was estimated to be approximately 108,390 [24]. In addition, it was found that as levels of adoption of HIT applications increased within healthcare organizations, so did the amount of FTE. This led to an estimate that the workforce could grow in size to 149,174 if hospitals with lower levels of adoption reached the FTE per bed levels of those at higher levels, such as those incorporating functions such as clinical decision support and order entry. This led to US$118 million in funding for workforce development being included in the US$30B HITECH Act that provided incentives for EHR adoption across the country [25].

The paper analyzing the 2007 data looked at HIT FTE staffing, especially as it related to level of adoption, based on the well-known HIMSS Analytics Electronic Medical Record Adoption Model (EMRAM), a 0–7 scale that measures milestones of EHR adoption.[14] This was, of course, before the HITECH Act, when a much smaller number of hospitals and health systems had adopted EHRs. Also around that time, there had been the publication of the first systematic review of evidence supporting benefit of healthcare IT, showing the value came mainly from use of clinical decision support (CDS) and computerized provider order entry (CPOE) [26]. As such, the paper looked at the level of healthcare IT staffing by EMRAM stage, with a particular focus on what increase might be required to achieve the level of IT use associated with those evidence-based benefits.

Another finding from the study was that if EHR adoption were to increase to the level supported by evidence of improved care, namely EMRAM Stage 4 (use of CDS and CPOE), and

[8] https://www.amia.org/amia10x10.

[9] https://dmice.ohsu.edu/hersh/10x10.html.

[10] https://www.himss.org/resources/health-information-and-technology-job-descriptions.

[11] https://www.amia.org/sites/amia.org/files/Recommendation-for-Health-Informatics-SOC--Proposal-2014-07-21.pdf.

[12] https://www.amia.org/news-and-publications/policy-news-washington-download/121817-government-equates-informatics-registrars-new-occupation.

[13] https://www.himssanalytics.org/.

[14] https://www.himssanalytics.org/emram.

FTE/Bed ratios remained the same for those hospitals, the size of the workforce would need to grow to 149,174. In other words, there was a need to increase the size of the healthcare IT workforce by 40,784 people.

Since 2007, EHR adoption has grown substantially in the US, to 96% of hospitals[15] and 87% of office-based physicians and other clinicians.[16] By 2014, one-quarter of US hospitals had reached EMRAM Stages 6 and 7. An updated study based on 2014 data assessed the impact of increased EHR adoption on the workforce [27]. Although the FTE/Bed ratios in 2014 for different levels of EMRAM are similar to those in 2007 (with the exception of Stage 7, which no hospitals had reached in 2007), because of the advancing of hospitals to higher EMRAM stages beyond Stage 4, the total workforce increased in size from 2007. The study of 2014 data estimated that if all hospitals were to achieve Stage 6, an additional 19,852 healthcare IT FTE would be needed.

There are also well-defined leadership roles in informatics in health care organizations. The role of Chief Medical Information Officer (CMIO – also sometimes called Chief Health Information Officer) has been long-established in the US, and typically represents a physician leadership role in informatics in these organizations [28, 29]. Other Chief Clinical Information Officer roles have been emerging as well [30]. The Chief Nursing Informatics Officer (CNIO) has also been emerging and is noted to be a strategic position in health care orgnizations [31].

23.7 Conclusions/Outlook

Health informatics professionals are at the forefront of applying information to improve individual health, healthcare, research, and public health. A critical aspect of effective application of health informatics is a competent workforce, with such competency demonstrated by certification. Recent studies elaborate the size and required knowledge and skills of this workforce. It is likely that certification will increasingly be a requirement for employment in the future.

Questions to Consider

1. Your health care organization is undertaking a major IT initiative. What education and training are most important for which members of the informatics, IT, clinical, and administrative staff?
2. In maintaining the major IT system that is mission-critical for the organization, what continued education and professional development are most important to keep the project leadership staff engaged in the project and larger organization?

[15] https://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php.

[16] https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php.

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Emerging Need for a New Vision of Multi-Interprofessional Training in Health Informatics

24

Gabriela Mustata Wilson, Patricia Hinton Walker, and Marion J. Ball

Abstract

This chapter provides a very different 'glimpse' of a future for health care education, healthcare delivery/practice and future science driven by technology. While current education systems for interprofessional education (IPE) have grown and are consistently improving, the rapidly changing environment calls for different models of both care and education in the future. This chapter highlights the Multi-Interprofessional Center for Health Informatics's pioneering vision at The University of Texas at Arlington for a **multi-interprofessional model of education** to prepare for this rapidly changing future. This future promises: (1) more person/patient-driven use and integration of mobile health devices; (2) increased telehealth and other tele-driven interventions (including health coaching); (3) positive impact of Artificial-Intelligence (A.I.); (4) attention to cost and cost-savings for individuals, businesses and healthcare organizations; and as always (5) impact on outcomes and satisfaction of personal, profession and system interventions. In a healthcare delivery environment that is increasingly driven by the interface of person/patient, provider and technology at the individual, group/community and system(s) level, it is important to plan for these changes in educational systems. Consequently, the authors of this chapter identify a need for and propose a new multi-interprofessional system of education which will provide the ground-work for a more complex multi-interprofessionally driven healthcare delivery system in the future.

Keywords

Interprofessional · Interprofessional education · Multi-interprofessional Multi-interprofessional education · Health informatics

Learning Objectives

- Discuss current and future needs of healthcare systems
- Define health informatics and multi-interprofessional education (MIPE)
- Describe attributes of traditional interprofessional and multi-interprofessional training in health informatics

G. M. Wilson (✉) · M. J. Ball
Multi-Interprofessional Center for Health Informatics (MICHI), The University of Texas at Arlington, Arlington, TX, USA
e-mail: gabriela.wilson@uta.edu; marion.ball@uta.edu

P. H. Walker
Canton, GA, USA

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- Explain benefits and barriers to working multi-interprofessionally in healthcare settings
- Describe the role of Health Informaticians within multi-interprofessional teams

24.1 Current and Future Needs of Healthcare Systems

We live in an increasingly digitized world, automated and enhanced by technologies ranging from mobile computing riding the internet of things (IoT) to robotics integrating big data and artificial intelligence. Nevertheless, our healthcare system is designed as a reactive 'sick care' model, which relies on data obtained within traditional clinical interactions and settings (i.e., the outpatient clinic, the emergency department, intensive care unit, etc.). These data are often confined within an institution or health system's records and scattered between paper records and electronic medical record systems, which lack interoperability. Even when an engaged patient diligently measures and records their own data at home (i.e., their blood pressures, glucose, or a collection of symptoms), it is often challenging to transmit and share this information with their care providers. These individuals' data leads to our reactive model, where providers all too often rely on waiting for their patients to present with an urgent condition (i.e., chest pain, stroke, or late-stage cancer). As a result, despite spending twice as much as other countries, the U.S. continues to lag behind other countries in most measures of population health. These gaps have been exacerbated even more during the COVID-19 pandemic. Its dramatic effects on all segments of the health and public health landscapes, from research to hospitals, clinics, and homes, showed us the need for better tools better collaborations at the community, national and global levels. Traditional health service systems have been overwhelmed with an incredible number of patients and sustained significant revenue losses despite the rapid expansion of telehealth services. Surviving in such an environment and preparing better for the "next normal" requires innovative approaches that can reshape how care is delivered. This can only be accomplished by placing the citizen and person/patient at the core of the connected health ecosystem (Fig. 24.1), so health information can be extracted in real-time from multiple data streams, such as individual health and wellness data (versus sick-care-focused data), patient home monitoring, rapid, at-home, and at-clinic diagnostic test data, social media, the health of communities including public and population health, schools, and campus-based clinics, and within that new context, social determinants of health (SDOH) data, the Internet of Things (IoT), etc.

The impact of the COVID-19 pandemic exposed the gaps within our healthcare system because we are operating as a **reactive** rather than a **proactive** healthcare system. Our immediate response to the pandemic was to focus on preparing hospitals for the onslaught of COVID-19 cases by making sure there were enough hospital beds, ventilators, PPEs. These measures were critical to providing treatment to those in need. However, equally important was to understand what contributed to the spread of the virus, identifying communities at-risk, sharing health and citizen information, and promoting health education needed at the community level to prevent the spread of the virus. The disproportionate effects of the pandemic on vulnerable and marginalized populations demonstrated the need to address this crisis through collaborative efforts among health agencies, local communities, community health centers, academic institutions, and industry. Only through such actions and a coordinated approach involving multi-interprofessional collaborations will we be able to have a response equal to the challenges we are facing and transition towards proactive healthcare delivery models.

At the same time, telehealth and telemedicine capabilities, which have become the mainstay of health care service delivery during the initial phases of the response to COVID-19, are going to continue to be employed in the out-of-hospital setting as well as for the direct medical oversight and management of selected patients, including critical care patients [1]. Just like online learning has been embraced by many schools and higher

Fig. 24.1 Connected health ecosystem focused on the individual and data streams contributing to this system. (Figure created with Sketchbubble (www.sketchbubble.com))

education institutions, in the same way, persons seeking health care or a follow-up will request that appointments with a specialist be made via virtual care for faster diagnosis and all from the comfort of home [2]. Equally important, wearables and other digital health technologies have the potential to support persons at home who may not need hospitalization but still require close medical monitoring [1]. The challenge is going to be data integration, as well as adequate security and privacy protections for underlying telehealth data and systems. The recent approval by the Food and Drug Administration (FDA) of some mobile health (mHealth) technologies, specifically those related to tracking blood sugar, atrial fibrillation, are already incorporated into some telehealth delivery systems. Also, it is anticipated that additional FDA approval of more of these systems in the future will create more even better opportunities for improved 'mHealth monitoring' related to chronic care management.

As a result of the COVID-19 pandemic and the emerging digital advances and data integration, the current and future healthcare workforce needs to be prepared to meet additional challenges such as the aging population, better care coordination, and integrating behavioral and physical health care and citizen self-care [3]. Equally important are digital and health literacy and understanding the Health Information Technology (Health I.T.) system from the perspective of health information exchanges, data sharing, and agile technology platforms that provide access to various data streams. Altogether, it contributes to translating into better health outcomes, tracking health-related costs at the individual/corporate and community levels. As shown in Fig. 24.2, the **multi-interprofessional** approach enables the transition from the "business of health care" to the 'service' to the community via enhanced person/patient/family engagement.

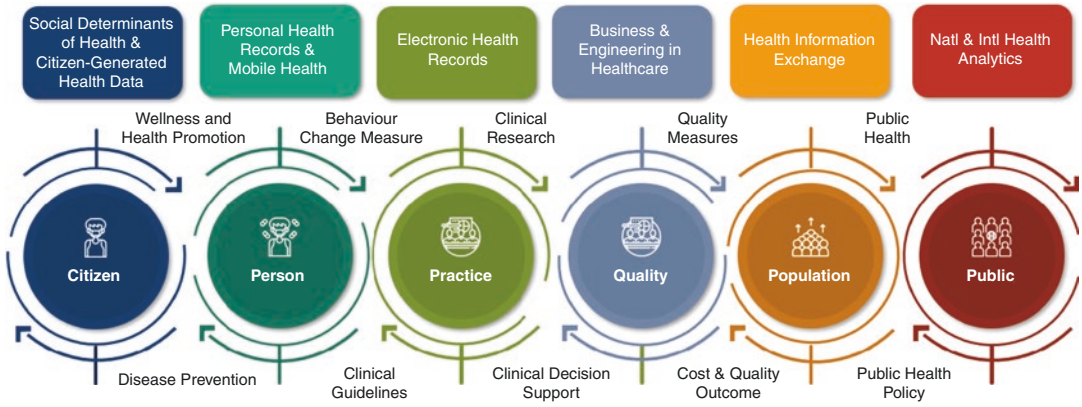

Fig. 24.2 Vision of the Health I.T. Ecosystem. (Figure created with Sketchbubble (www.sketchbubble.com))

This is a significant undertaking but not an impossible one if we do the following:

1. Focus on personal health, wellness, and well-being with an emphasis on healthy lifestyles and health-behavior change to increase resiliency and effective stress management.
2. Focus on preventing disease enabled by individual behavior change and community participation and introducing the enabling tools into all aspects of living and learning.
3. Build informative, intuitive, user-cordial, and flexible health information systems that support health professionals during everyday activities. These health information systems must scale up automatically to counter catastrophic situations/disasters.
4. Formulate creative approaches to public health/population health research linked to health practices and maximize and empower existing resources.
5. Build on established knowledge and accelerate broad multidisciplinary and interprofessional community participation across local, regional, national, and global organizations.

Research, teaching, and learning strategies need to integrate a **multi-interprofessional** view that nurtures equitable access to services and community participation. Strong partnerships with schools, libraries, faith-based organizations, local public health departments, and industry are quintessential for future generations of health professionals to be better prepared and shape a positive future for our connected healthcare ecosystem.

24.2 Health Informatics and Multi-Interprofessional Education (MIPE)

24.2.1 What Is Health Informatics?

Various definitions have been established since the 1960s when **Health Informatics** began to standardize as a field of study [4–6]. One definition worth noting describes Health Informatics as an evolving discipline at the intersection of data science, health information technology, health information management, and data analytics, focused on improving health and healthcare by bringing theory into practice through enabling technologies [7]. In a nutshell, **Health Informatics is** the science of combining healthcare **data** into **information** to derive **knowledge** and create **wisdom**.

With the generation of tremendous amounts of data and the expansion of technology and innovations, informatics has become an integral part of healthcare, incorporating healthcare sciences, computer science, information science, and cognitive science with one primary goal: to improve society's health, wellbeing, and economic functioning. Health Informatics can meet this need by collaborating with scholars and

knowledgeable practitioners from medicine, nursing, pharmacy, population and public and population health, social work, dentistry, library science, engineers, occupational and physical therapy, members of the larger business community, and psychologists/social work/coaches involved in health behavior science and behavior change, etc. (Fig. 24.3).

24.2.2 What Is Multi-Interprofessional Education?

To be able to define Multi-Interprofessional Education, we need to understand what Interprofessional Education means and build on the historical strengths this type of education provides. As most health care professionals know, Interprofessional education (IPE) refers to training or teaching that includes two or more professions in collaborative, interactive learning. The working definition of IPE most often used is that of the World Health Organization, which puts forth that "*interprofessional education occurs when students from two or more professions learn about, from, and with each other to enable effective collaboration and improve health outcomes*" [8].

Transformed practice environments have emerged under health reform, and the economics of quality care for a growing population, health care practice demands that all practitioners be skilled in working collaboratively with other disciplines. The marketplace requires these skills in addition to professions-specific skills, creating the urgent need for educators to preparing students for the realities of communicating and working together with other professions in practice. Even today, a very real and substantial gap exists between health professions education and health care delivery in the United States and other countries. The goal of any healthcare system is to bridge this gap by creating a deeply connected, integrated learning system to transform education and care together. Through the integration of traditional interprofessional practice and education systems, we can:

- Improve the quality of experience for people, families, communities, and learners simultaneously
- Share responsibility for achieving health outcomes and improving education at the same time
- Reduce the cost and add value in health care delivery and education

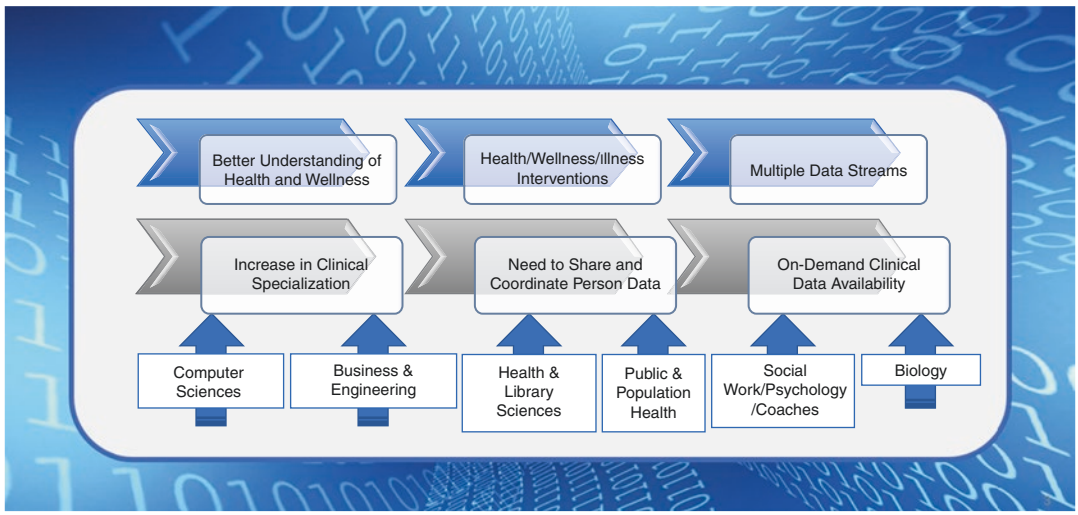

Fig. 24.3 Health/wellness/illness-related Health Informatics data integration

It is critically important to examine current evidence and practices and create practical models that can then be effectively integrated into different clinical and learning environments. Pulling together vastly different stakeholders such as patients, families, and communities; and incorporating faculty, students, and residents into the team can help create better patient experiences, improve health, and reduce costs. Without a doubt, this can be achieved through Interprofessional Education (IPE), which involves more than simply having students from various programs taking classes together; it promotes an understanding, appreciation, and application of the roles, talents, and responsibilities of the members of the healthcare team.

Advances in healthcare have made it essentially impossible for clinicians practicing alone to maintain the knowledge and skills necessary to provide the best care possible. In conjunction with the increasing prevalence of chronic diseases that require care coordination among multiple professionals, this fact has driven the need for an interprofessional approach to provide effective patient-centered care. In recognition of the need for health professionals to learn effective teamwork skills, the standards and guidelines for accreditation of the major professional organizations are now integrating interprofessional education as a standard for accreditation. Six organizations representing medicine (allopathic and osteopathic), nursing, dentistry, pharmacy, and public health, formed a collaborative to train future health professionals in team-based care of patients to improve population health outcomes [9]. These same organizations, known as the Interprofessional Education Collaborative Practice (IPECP), collaborated to develop national core competencies for interprofessional education and practice that were published in May 2011 [9]. In 2016, IPECP welcomed nine new institutional members, expanding the professional representation to 15, and as a result, the IPECP competencies were updated to extend the interprofessional competencies to meet the Triple Aim requirements (i.e., improve the patient experience of care, improve the health of populations, and reduce the per capita cost of health care), with reference to population health [10].

The **multi-interprofessional** approach goes beyond health professionals working together in collaboration by integrating services, utilizing teamwork concepts, incorporating collective decision-making, and allowing for transformation to occur [11–14]. It involves a team-based approach that draws from strengths and knowledge of multiple professions and disciplines, focusing on personal health, wellness, and well-being of the individual and population health. The ultimate goal of the multi-interprofessional approach is to prevent disease through individual behavior change, community participation, and introducing the enabling tools into all aspects of living and learning.

This new approach builds on established knowledge and enables the transition from the "business of health care" to the 'service' to the community via enhanced person/patient engagement. Also, with the anticipated expansion of the use of mHealth devices to focus on healthy lifestyle management, prevention, and better 'home-monitor' chronic conditions, there is an increasing national and international interest in health coaching. It is important to note that over 5000 health and wellness coaches are already nationally certified through the National Board for Health and Wellness Coaching (NBHWC). This National Board has collaborated with the National Board of Medical Examiners (NBME) since 2016 in order to create and provide a robust board certification examination. Currently, over 5000 coaches have become National Board Certified as Health and Wellness Coaches and hold the NBC-HWC credential. It is important to note that the NBC-HWC credential represents an assessment of training, education, demonstration of coaching expertise which facilitates this emerging profession to advance in all aspects of health care and wellness. Below is the most recent initiative of this national certifying body.

"The NBHWC's Healthcare Commission, dedicated to securing payment for coaching services, is pursuing the following aims:

- Establish Category I Codes for Health & Wellness Coaching services
- Establish reimbursement from health plans (payers) and Medicare for health & wellness coaching services
- Collaborate with large healthcare systems committed to the integration of the health and wellness coach onto the healthcare team through the utilization of new and existing CPT codes and collaborating on coaching workflow, referrals, and outcomes data collection.
- Collaborate with the CDC in advancing the Diabetes Prevention Project in clinical settings
- Secure administrative, consulting, and legal counsel where needed" [15].

24.3 Attributes of Traditional Interprofessional and Multi-Interprofessional Training in Health Informatics

24.3.1 Interprofessional Training/ Education in Health Informatics

In 2009, six national educational associations of health professionals formed the *Interprofessional Education Collaborative* (IPEC)[16], "to promote and encourage constituent efforts that would advance interprofessional learning experiences to help prepare future health professionals for enhanced team-based care of patients and improved population health outcomes" [10].

IPEC established four core competencies that are important for a more well-rounded education and necessary to work interprofessionally as a part of a team.

The first Competency: **Values/Ethics for Interprofessional Practice:** Work with individuals of other professions to maintain a climate of mutual respect and shared values.

The second Competency: **Roles and Responsibilities:** Use the knowledge of one's own role and those of other professions to appropriately assess and address the health care needs of patients and to promote and advance the health of populations.

The third Competency: **Interprofessional Communication:** Communicate with patients, families, communities, and professionals in health and other fields responsively and responsibly that supports a team approach to the promotion and maintenance of health and the prevention and treatment of disease.

Competency 4: **Teams and Teamwork:** Apply relationship-building values and the principles of team dynamics to perform effectively in different team roles to plan, deliver, and evaluate patient/population-centered care and population health programs and policies that are safe, timely, efficient, effective, and equitable.

Health Informatics can significantly improve care by developing standardized processes, improved communication, evaluation of performance measures, establishing accountability, and strong care coordination [16]. As a result, there is a need for adaptable training programs with expanded areas of focus and new competencies needed to improve and coordinate care, enhancing more healthy lifestyles incentives and personal chronic care management with a further developed and sustained data infrastructure essential for possible new and improved value-based payment models.

Academic institutions have started to address this need by creating new programs that support this transformation and the demand for higher educational standards. These competencies require knowledge in data and information (information sciences), clinical and health terminologies, data analysis and management, and communication skills, given that the treatment of patients is interprofessional by nature [17]. As depicted in Fig. 24.4, traditional Interprofessional education (IPE) in Health Informatics is a critical approach used to prepare health professions students to learn with each other on how to provide patient care in an *informatics-enabled collaborative team environment* [18]. The preamble is that once learning occurs through IPE, Health I.T. competencies are being acquired, and patient care improves [19–21].

Health Informatics competency-based education and training are necessary to improve patient safety and catalyze collaborative interprofes-

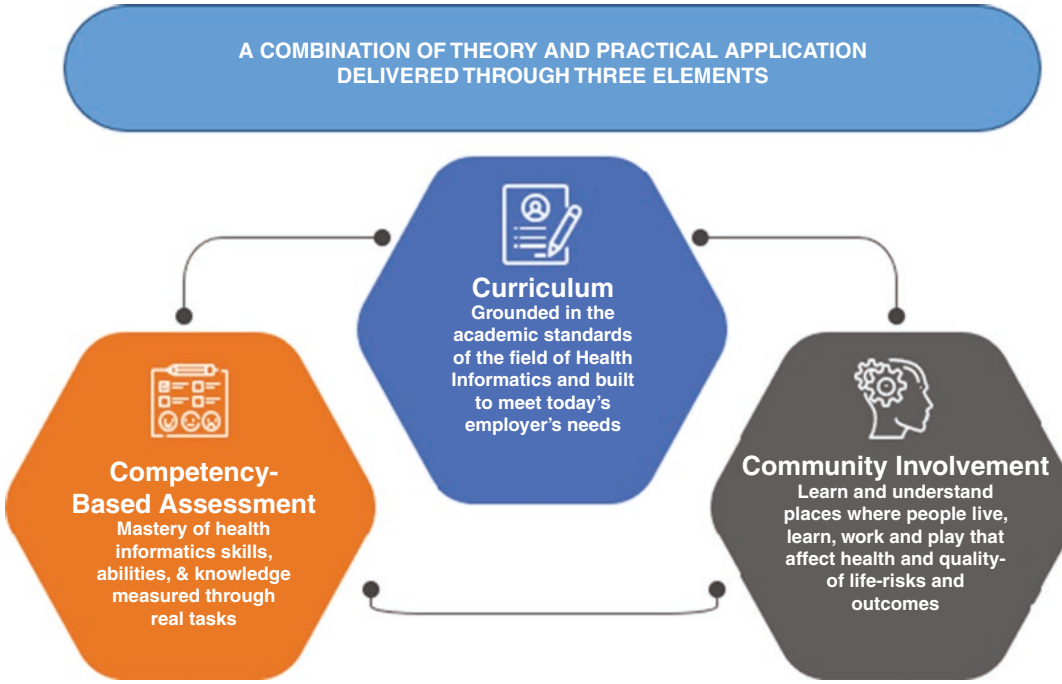

Fig. 24.4 Health Informatics Interprofessional Education Model (Figure created with Sketchbubble (www.sketchbubble.com))

sional research and practice initiatives that will impact healthcare and public health at the local, regional, national, and international domains. Integration of Health Informatics competencies at the very early stages of the academic training offers real-time practice opportunities that will prepare the future workforce in leveraging Health I.T. that supports collaborative patient-centered care and improved health outcomes [22–25].

24.3.2 Multi-Interprofessional Training/Education

As mentioned previously, despite significant health improvements at the individual and population levels through technological advancement, there continues to be an alarming disproportionate burden of illness among persons from racial and ethnic minority and other population groups who experience health disparities. There is also a digital divide between individuals and health providers who have access to technologies and the digital literacy necessary to work with them and those who do not have it. This adds to the SDOH, which from a population health perspective, contributes even more to the health inequities and disparities already existent. Engaging citizens at all levels in developing technologies and products that engage, empower, and motivate individuals and communities, including providers and healthcare institutions, presents a clear path towards sustainable health-promoting activities and interventions that lead to improved health, healthcare delivery, and the elimination of health disparities. As we move into the future, enabling technologies must be affordable, safe, culturally sensitive, and improve the current quality of care for racial and ethnic, and health disparity populations.

As a result, training and education in this newly proposed **multi-interprofessional** context are critical to the future of our health system, and changes need to occur in the way learning/teaching and research need to happen to achieve an interconnected health ecosystem. All disciplines mentioned earlier will be relevant to the emerging new scientists engaged in and developing mod-

els of Implementation Science, Developmental Science, Community-based Participatory Research, and Citizen Science and Outcomes research based on Health I.T. implementation. Therefore, the goal of **multi-interprofessional education/training** is to teach systems-based, holistic decision-making by instilling in learners the knowledge, skills, attitudes, and values necessary for solving complex problems and addressing issues that surpass the scope of any one profession.

As part of the planned initiatives of the Multi-Interprofessional Center for Health Informatics at the University of Texas at Arlington, a framework-driven approach was purposefully designed through which teaching, learning, and research happen through a multi-interprofessional model of learning across platforms, research and idea incubation, nurturing innovation, and outreach and engagement. This approach supports multi-interprofessional collaboration to prepare the next generation of health professionals to meet the challenges of the twenty-first century by catalyzing the transition from today's focus on treating illnesses to preventing and improving health and the human condition.

24.4 Benefits and Challenges to Working Multi-Interprofessionally in Healthcare Settings

24.4.1 Benefits

Common culprits behind medical errors (i.e., ineffective communication, lack of teamwork, and inadequate health informatics competency) [26–29] influenced the need to establish interprofessional teams in healthcare settings. Due to rivalry among professions, poor understanding of individual discipline roles, and undesirable stereotyping are barriers to team efforts in healthcare [30]. Correcting fragmented and disconnected patient care is therefore essential, and evidence supports that team collaboration and communication are vital to improving patient outcomes [31].

Every profession has its own roles, skills, and responsibilities, making for efficient practices in managing patient care. However, as highlighted in the previous sections, these professionals cannot work in isolation to the benefit of the person/patient/service user without the collaboration of professionals outside the health care professionals. The benefits of interprofessional collaboration include fewer medical errors, reduced healthcare costs, and improved relationships across disciplines. Nevertheless, these skills alone are not sufficient as they are factors outside of health care that affect the wellbeing of each individual and population health. A crucial component to training current and future health professionals is to understand the importance of Social Determinants of Health (SDOH) and the digital divide that exists not only at the population level but also within the healthcare ecosystem. These skills need to be learned early on during academic preparation and not wait until graduation or employed in a healthcare setting. Once learners understand how to work with one another, regardless of their profession or discipline, they will be ready to enter the workplace as multi-interprofessional team members. This is a crucial step in moving our health system to a position of strength, in which we can all contribute towards the wellbeing of the individual.

24.4.2 Challenges

Though literature supports traditional IPE activities, the fundamental challenge still exists - healthcare systems are not designed to integrate people, processes, and information [32]. Health care demands require not only collaboration and teamwork among members of various disciplines and informatics competencies. It requires the integration of social and economic data that can contribute to the health of the person. There is no doubt that technology has become a critical part of the healthcare delivery system. It has been demonstrated that the use of information technology in healthcare settings improves patient safety, healthcare quality, efficiency, and data collection and helps save costs. Although hospital systems

have embraced and successfully implemented electronic health records in their institutions, challenges to using these systems and how they impact collaborative practice are still being reported [33, 34]. Nevertheless, the challenge is how do we keep up with the rapid technology advances? The healthcare industry is rapidly approaching a point where integrating wearable sensor data, SmartPhone apps, existing communications, possibly Artificial Intelligence (A.I.), and data security will be far less expensive and far more effective for far more people than ever. Healthcare organizations would need to hire/retain experts knowledgeable in A.I. methods and software and professionals from various disciplines knowledgeable in the health issues of interest. Education models integrating a **multi-interprofessional approach to Health Informatics** are essential to address these challenges.

24.5 Role of Health Informaticians Within Multi-Interprofessional Teams

Every profession has its own roles, skills, and responsibilities, contributing to efficient practices in managing patient care. The Health Informatics team is composed of experts with a variety of backgrounds:

- technical background (e.g., network specialists, database specialists, systems administration, etc.)
- health background (e.g., nurses and physicians, public health specialists)
- data science background (e.g., data analyst, health information manager)
- administrative background (e.g., finance/accounting).

Each member contributes their unique knowledge and experiences to the team, and only through this level of teamwork and collaboration can professionals be successful in the highly complex field of health informatics. Members of Health Informatics teams use their knowledge of healthcare, information systems, databases, and information technology security to gather, store, interpret and manage the massive amount of data generated when care is provided to patients. They are and will be responsible for [28]:

- Selecting and customizing health information systems
- Planning, designing, and defining functional requirements for health information systems
- Managing health I.T. projects
- Interface with the person via mobile health applications
- Integrate and analyze personal health data and citizen-generated data
- Integrate and analyze health-related environmental data
- Analyzing data and processes to help facilitate decisions
- Evaluating the application and impact of information systems in support of health goals
- Developing data-driven solutions to improve patient health
- Using data standards to support interoperability of data between systems
- Ensuring confidentiality, security, and integrity standards
- Creating, supporting, or facilitating new ways for medical facilities and practices to implement and maintain electronic health records (EHRs)
- Improving communication between healthcare providers and facilities to ensure the best patient outcomes
- Being knowledgeable about health data standards, sources, and meaningful use of health data
- Facilitating the communication of regulatory and I.T. requirements between departments

Health informaticians use information technology to process data into information and knowledge through the following direct applications:

- **Biostatistics and Informatics:** translate data into meaningful information that can then be used to make logical and beneficial clinical and public health decisions.

- **Clinical Informatics and Health Quality Assurance:** analyze the application of information technology in clinical settings to improve efficiency and quality (e.g., study the safety and efficacity of a medical device in a hospital setting).
- **Predictive Modeling:** This area of Health Informatics is closely associated with biostatistics. It involves using computer modeling in a predictive fashion, e.g., using predictive modeling to diagnose health conditions in a clinical environment and recognizing common problems related to known drug interactions, prior health conditions, and past injuries or illnesses.
- **Human-Computer Interaction:** e.g., assess current interfaces and propose the development of more efficient and intuitive user interfaces, allowing medical professionals to access relevant information more quickly than they otherwise might. These can be developed in collaboration with computer scientists, etc.
- **Organizational Development:** Examines the various needs, uses, and consequences of information in organizational contexts, such as organizational types and characteristics, functional areas and business processes, information-based products and services, the use of and redefining role of information technology, the changing character of work-life and organizational practices, sociotechnical structures, and the rise and transformation of information-based industries.
- **Process Management:** Defines the healthcare organization's business approach by allowing people, systems, and information to interact with greater consistency. Process Management can essentially change how healthcare functions, with less waste, cost savings, streamlined processes, increased compliance, and better patient care.
- **Health Intelligence:** digital metrics with real-time streams from multiple social media channels analyzed by A.I. algorithms, local adaptation to disease, digital disinformation campaigns, website traffic, human movement through anonymized cell phone data, and anonymized financial transactions. These multiple data streams and SDOH and additional surveillance data incorporated and fused into a single data visualization tool allow us to understand the patterns of movement and behavior that might influence the spread of a virus, disease, etc.

24.6 Conclusions and Outlook

A major theme in the current and increasingly in future healthcare environment(s) is the use of information systems and technologies to enhance the quality and safety of patient care. Although technology holds great promise, the healthcare system's increased complexity challenges educators and providers to think in fresh and pioneering ways about how to prepare students to deliver effective and efficient care. To achieve this ambitious yet not impossible goal, health professions students need to learn how to intentionally work together with the common goal of building a safer and better patient-centered and community-oriented U.S. health care system. Therefore, the goal as future-thinking educators is to provide students with a forum to explore the characteristics and implications of collaborative practice around one or more cross-cutting healthcare challenges while learning more about themselves as team members. Through multi-interprofessional training/education and research, the next generation of health informaticians and all providers who live and work in this new Health IT-driven world will be recognized as trusted and vital partners towards improving healthcare services, patient health outcomes and population health.

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Understanding Disparities in Healthcare: Implications for Health Systems and AI Applications

Eileen Koski, Elisabeth Lee Scheufele, Hema Karunakaram, Morgan A. Foreman, Winnie Felix, and Irene Dankwa-Mullan

Abstract

This goal of this chapter is to describe the origins and impact of health disparities, with particular emphasis on how societal and structural inequities affect both access to care and quality of care. We will begin with definitions, followed by a discussion of contributing factors, including both structural factors and social determinants of health (SDoH). In our discussion of societal inequities on access, use and quality of health care, we will examine the impact of racial injustice, discrimination in research, bias and lack of diversity, as well as organizational and systemic factors, including policy and financing. We will also describe some of the ways the different factors interact to form a web of disparities, using recent experiences with COVID-19 to illustrate how individual factors combine in ways that compound their impact. We will also briefly introduce the ways in which underlying disparities affect healthcare data that are used to develop AI algorithms intended to advance research and improve health care systems and decision-making.

Keywords

Artificial intelligence (AI) · Health disparities Health equity · Healthcare access · Poverty and health · Racial disparities

E. Koski (✉) · M. A. Foreman
IBM T. J. Watson Research Center, Yorktown Heights, NY, USA
e-mail: ekoski@us.ibm.com; Morgan.Foreman@ibm.com

E. L. Scheufele
IBM Watson Health, Boston, MA, USA
e-mail: elisabeth.scheufele@childrens.harvard.edu

H. Karunakaram
IBM Watson Health, Chicago, IL, USA
e-mail: khema@umich.edu

W. Felix · I. Dankwa-Mullan
Merative (formerly IBM Watson Health), Bethesda, MD, USA
e-mail: wfelix@merative.com; Idankwa@merative.com

Learning Objectives

On completion of this chapters, the reader should be able to:

- Define disparity (and equity) in US health and healthcare
- Describe factors that contribute to disparities, including social determinants of health
- Articulate the impact of race, geography, language and literacy, income and wealth, insurance, finance and policy on healthcare disparities (with the COVID 19 pandemic as an example)

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- Discuss challenges in using electronic data and information technology to mitigate health and healthcare disparities

25.1 Introduction

The healthcare system in the United States offers some of the highest quality care available in the world. However, there are deeply entrenched inequities in access to fundamental needs such as basic health care for many people, resulting in significant disparities in outcomes and overall health status [1]. Despite recent large-scale health policy efforts to address such disparities, notably the Affordable Care Act, health disparities continue to persist [2] in terms of access, utilization and quality of care received. While there are many contributing factors, the persistence of race-based inequities in the form of economic and social injustices rooted in a history of discrimination and exclusion, has a profound impact on virtually all aspects of health disparities. While the advent of artificial intelligence (AI) and machine learning is raising hopes of improvements within the health sector, it is also raising serious concerns about the social implications for achieving health equity and addressing existing disparities. There is a growing body of literature urging use of ethical principles for the development and use of AI technologies and machine learning, especially in the health care systems where these models inform decision-making and clinical care practices. As these AI innovations become integrated into healthcare decision-making and management, it is important for stakeholders to understand the context for these disparities. Greater awareness of the social and ethical implications can help inform strategies to debias current AI models, address discrimination and racial biases in training data, question default practices that exacerbate disparities in quality care and ultimately improve health outcomes for all patient populations.

This chapter is intended to provide background on the underlying causes and on-going contributors to health disparities in the United States, highlighted by recent experiences during the COVID-19 pandemic. This chapter will also introduce some of the mechanisms by which both current and past societal racism and discrimination continue to affect healthcare utilization and outcomes in systemic and structural ways. Resulting disparities are reflected in health data, but often in ways that may not be obvious without understanding underlying drivers of the observed behaviors and outcomes. We will discuss how fundamental societal inequities contribute to poorer baseline health, how they manifest in access to healthcare, and finally, how such inequities are reflected in the healthcare data that is used in analytic and AI efforts to understand and address disparities.

As we move into an era when the healthcare system hopes to realize the promise of AI, these challenges become increasingly acute since AI solutions draw inferences from data that may under-represent disadvantaged populations. Health equity frameworks will be necessary to understand how these issues can be addressed both in using the data we already have, and in driving towards more representative data in the future.

25.2 Factors Contributing to Health and Healthcare Disparities

25.2.1 Health Disparities and Health Equity

We define *health disparities* as the preventable differences in the burden of disease, injury or violence, or in opportunities to achieve optimal health that is experienced by socially disadvantaged racial, ethnic, and other population groups and communities [3]. Poorer health status and outcomes observed in an individual's health are often influenced by multiple contributing factors. Healthcare disparities are closely linked with social, economic and environmental disadvantage, and are not explained by variation in health needs or patient preferences. The Agency for

Healthcare Research and Quality defines *healthcare disparities* as the differences in access to or availability of medical facilities and services as well as variation in rates of disease occurrence and disabilities between population groups defined by socioeconomic characteristics such as age, ethnicity, economic resources, or gender and populations identified geographically [4].

At present, calls to address and reduce or eliminate the gaps in prevention, care, treatment and health outcomes within populations require actionable solutions. The work towards addressing health and healthcare disparities is inherently linked to the achievement of *health equity* as the key objective and optimal outcome. Descriptions of health equity can be more action oriented and focused on process when used to address the underlying issues, or philosophical when focused more on the ethical and social justice implications. For our purpose, we will consider the Robert Wood Johnson Foundation's definition which incorporates both themes by defining health equity as a state in which everyone has a fair opportunity to be as healthy as they can be. Achieving this state extends beyond providing fair access to high quality healthcare, and encompasses addressing fundamental obstacles to health in the form of poverty, discrimination, and their consequences, such as inadequate access to good jobs, fair pay, quality education and housing, and safe environments [5].

25.2.2 Factors Contributing to Health and Healthcare Disparities

Health disparities arise from the complex interplay between sociodemographic, environmental, biological, psychosocial and structural factors. Table 25.1 categorizes various social determinants of health that have an impact on individual health. For the most part, the exposures at the environmental or neighborhood level may have a greater influence on population health than individual vulnerabilities, although at an individual level, there are personal characteristics including

Table 25.1 Health Disparities Framework: Domains of health determinants and influence on individual and population health

	Levels of Influence			
	Individual	Interpersonal	Community	Societal
Biological	Biological vulnerability and mechanisms	Caregiver-child interaction; family microbiome	Community illness, exposure, herd immunity	Sanitation, immunization, pathogen exposure
Behavioral	Health behaviors, coping strategies	Family functioning, school/work functioning	Community functioning	Policies and laws
Physical/built environment	Personal environment	Household environment, school and work environment	Residential segregation, neighborhood resources and social capital	Societal structure
Sociocultural Environment	Sociodemographic, limited English, cultural identity, response to discrimination	Social networks, family/peer norms, interpersonal discrimination	Community norms, local policies, local structural discrimination	Social Norms, structural discrimination
Healthcare System	Insurance coverage, health literacy, values, beliefs, treatment preferences, bias and discrimination	Patient-provider relationship, medical decision-making	Availability of health services, public health, safety net clinics and services	Health policies, quality of care, source of evidence for decision-making

Adapted from National Institute on Minority Health and Health Disparities (2017). NIMHD Research Framework. Retrieved from https://www.nimhd.nih.gov/about/overview/research-framework.html. Accessed on 5-26-2021 [6]. NIMHD, a federal agency under the Department of Health and Human Services, does not endorse the content of this text

genetic predispositions that may interact with the environment to produce disease. Healthcare and clinical factors only account for approximately 20% of the contribution of the various determinants of health [7].

Table 25.1 shows a framework for health disparities illustrating the levels of influence of the various determinants that shape population health and influence outcomes over the life span of an individual. Health determinants may have a complex and intricate relationship with patient risk, vulnerabilities and health outcomes.

Given that the goal of this chapter is to understand the determinants of health disparities and implications for healthcare systems and emerging AI technologies, we will focus on the primary interactions within the healthcare system that contribute to them.

Figure 25.1 is a conceptual model illustrating how individuals and groups with different social attributes can experience varying levels of exposure and susceptibility to disease, access to and utilization of care, treatment of disease and outcomes. Each of these factors has a significant individual impact, but the total impact is more than additive, with each layer compounding, reinforcing and magnifying disparities in a highly interrelated and complex web of problematic effects.

Underlying health inequities by race, socioeconomic status and geographic location predispose these socially disadvantaged populations to poorer health status and outcomes than the general population. The influence of multiple determinants can result in increased vulnerability, exposure and susceptibility to disease and injury. These inequities themselves are influenced by patterns of discrimination and unequal allocation of resources that result in financial, logistical and sociological barriers to accessing quality care. Structural inequities result from embedding and hardcoding these barriers into the healthcare ecosystem in the form of policy, law, principles, protocols, standards of practice and research, professional training and licensure and institutional practices.

In its report, the Committee on Community-Based Solutions to Promote Health Equity in the United States identified nine Social Determinants of Health (SDoH) that it considered to be key factors in health disparities [8]—education, employment, health systems and services, housing, income and wealth, physical environment, public safety, social environment, and transportation. They also stressed the interdependent nature of these factors since many of them are highly correlated. Together, these social determinants have an impact on the way that different populations interact with the healthcare system and the quality of those interactions, and ultimately lead to unequal levels of morbidity and mortality.

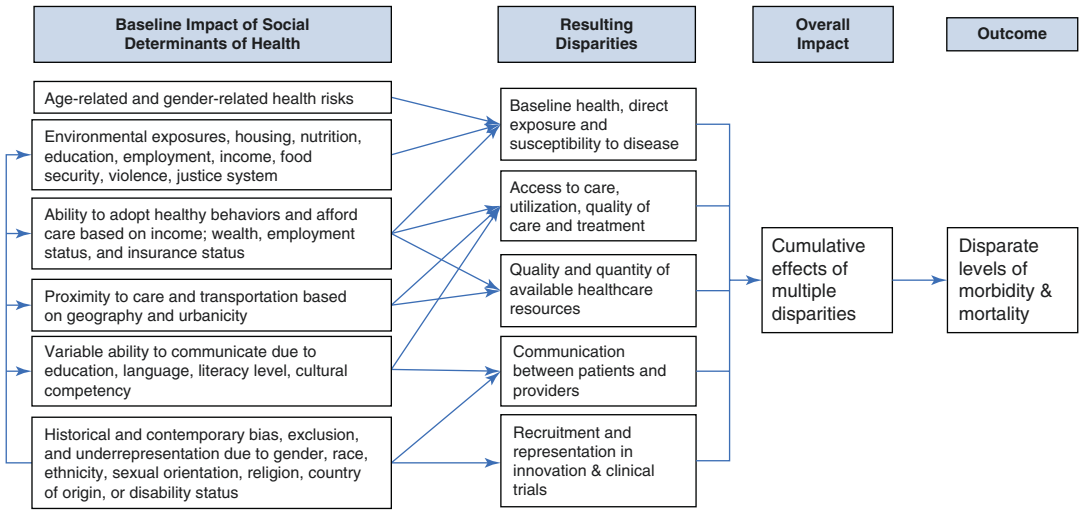

Fig. 25.1 Variables associated with SDoH and resulting health and healthcare disparities

In this section we will focus on a few contributing factors to disparities that occur at individual, interpersonal, and institutional levels including race and racism, geography, language and literacy, income and wealth, insurance coverage and costs of care, and healthcare finance and policy. Many other contributing factors that are not discussed here in depth also intersect with the factors above to amplify health disparities, including age, sex, gender, sexual orientation, disability status, housing status, and more.

25.2.3 The Impact of Race and Racism

Race, as a social classification, is a tool that has been used to subjugate, exclude or marginalize groups of people based on physical, social, or cultural characteristics. In the United States, slavery and forced displacement were used by white colonists centuries ago to maintain superiority over Black and Indigenous peoples, respectively. Over time, inequitable treatment based on race has been reinforced and codified through institutional policies such as segregation, disenfranchisement, redlining, immigration quotas, bans, and mass incarceration. These policies have led to inequities in education, housing and employment opportunities among affected communities. The criminal justice system in particular has disproportionally penalized minorities and other marginalized groups both directly, through the financial impact of unequal application of fines and penalties; and indirectly, through the secondary impact of unequal arrest and incarceration rates, which were 5.8 times as high for Black males as for White males in 2018 [9] leading to both immediate loss of income and worsened long-term employment prospects.

Exposure to racial discrimination can occur at the individual level or at the structural level. The science of population health has demonstrated through multiple studies that racism, discrimination, and exclusion—whether operating at the individual, institutional, or structural level—have adverse effects on mental and physical health [8]. The population health differences or disparities we see in the early onset of illness, chronic disease in racial-ethnic and socially disadvantaged populations, are largely linked with different life experiences, exposure to stressors, and lack of access to coping resources or social determinants [10, 11]. The prolonged psychosocial or physical challenges to stress, discrimination and racism can increase disease susceptibility and promote early onset of chronic conditions—leading to premature illness and death [12, 13].

Studies show that stress, and deeply rooted social processes, can work through biological mechanisms to impact health. Everyday stresses or challenges we face, but especially those shaped by social disadvantage or the experience of racism or discrimination or exclusion, may trigger repeated activation of our body's physiological stress processes and responses.

All people experience stress in one form or the other. However, studies show that the stress resulting from individual experiences with racism and discrimination can have a significant impact on health and health outcomes through physiological mechanisms, allostasis and biological pathways [12, 14, 15]. Chronic stress (as distinct from acute stress) is a dangerous form of stress because if left unchecked, it can contribute to many serious health problems, such as high blood pressure, heart disease, disability and premature death.

Examples of population health disparities can be seen across many settings and with respect to a wide variety of medical problems. For example, infant mortality statistics for 2017 indicate there were 4.63 deaths per 1000 live births for non-Hispanic Whites vs. 10.75 for non-Hispanic Blacks [16]. Prevalence rates, severity indices and death rates for major chronic diseases such as diabetes mellitus, asthma and heart disease all demonstrate a disproportionate impact on peoples of color [17], with a significant part attributable to poorer baseline health and limited access to preventive and basic care. In recent years, the toxic levels of childhood lead exposure during the water crisis in Flint, Michigan beginning in 2014 has been referred to as an example of environmental racism, leading to vast health disparities for the predominantly Black population [18].

Historical policies led to Flint already being economically disadvantaged, and a failure to address the water crisis in a timely and equitable manner compounded the effects of racism, resulting in lasting negative health impacts.

From the perspective of research, systemic racism has had a significant impact on enrollment into clinical trials as well, based on multiple factors ranging from the locations of major medical centers, and the demographics of their patient populations to mistrust in research based on past history or experience. In the case of prevention trials, assumptions about who is at risk have led to under-representation in some cases. As a result, some medical knowledge is built on a foundation of skewed representation of the population [19]. The NIH Revitalization Act of 1993 [20] explicit discussed the need to enroll both women and minorities in sufficient numbers to adequately analyze any variables with specific relevance for them. Nevertheless, a recent survey of majority Black (57.5%) medically underserved individuals as to their willingness to participate in clinical trials indicated that four times as many Black patients as White perceived their care to be worse than that given to other races, and this group had a dramatically lower Likelihood of Participation score with respect to clinical trials [21]. Racism, discrimination and exclusion of population subgroups, either from opportunities, or from clinical trials, drug studies, or any benefits in society continues to exacerbate observed health disparities. In other words, Ignoring the significant impact of structural racism on health, makes it much more difficult to address or reverse the trajectory of health inequities or disparities.

Systemic racism has also long prevented people of color and other minorities from joining the ranks of health care professionals, particularly with respect to higher status roles and decision-making at the administrative and research levels. Lack of concordance in race between patients and providers, due to inequities in access to clinical training, can also have a negative impact on patient trust and satisfaction. Perception of unfavorable treatment by medical providers can contribute to the effects of stress from perceived racism (interpersonal racism), eroding trust in the medical community more broadly, which can deter future patient demand for care, thus further exacerbating poor health outcomes.

The legacy of slavery and segregation, history of medical racism, and scarcity of minority health care providers have resulted in structural dynamics within healthcare institutions that continue to fuel persistent health and healthcare disparities today.

25.2.4 Geography

Access to care, morbidity and mortality can also be significantly affected by location. Area-based socioeconomic capital or deprivation is a strong predictor of health status and outcomes [22]. In the US, neighboring zip codes can exhibit dramatic variations in health. For example, the gap in life expectancy between different zip codes in the city of Chicago is as high as 30 years [23].

There are many environmental and structural factors that result in this variation across geographic locations, including access to essential retail services, such as grocery stores and pharmacies. People who live in food deserts have less access to fresh groceries and healthy food options and a greater concentration of fast-food chains, contributing to poorer nutrition and higher likelihood of hospitalization [24]. Pharmacy deserts are also common in many lower-income neighborhoods even in urban areas, where residents either do not live within 5 miles of a pharmacy or do not have transportation available to get to one. Food and pharmacy deserts are more likely to be found in neighborhoods with larger Black or Hispanic populations [25, 26], underscoring the impact of policies like redlining that historically limited where people of color could live and continue to affect the makeup of different neighborhoods.

Healthcare facilities and providers are often concentrated in larger, urban regions and surrounding affluent suburbs. For the 20% of Americans who reside in rural areas, there may be a severe shortage of providers in reasonable proximity. This includes specialty providers for consultations and second opinions [27], which

poses a challenge to accessing appropriate care regardless of insurance coverage or ability to pay. The limiting factors of available providers and health care facilities typically exacerbate problems of access because of the additional financial and temporal burdens associated with transportation to distant facilities. Reduced provider choice can also mean there is limited representative diversity among providers of care, contributing to barriers with communication and patient comfort.

The combination of inter-related social determinants of health such as low education, low income, insecure housing, reduced access to preventative services and medical care in general, low access to healthy food, lead to poorer health outcomes (higher incidence of chronic diseases, mental health issues).

25.2.5 Literacy and Language Comprehension

Language is a critical barrier to care because it complicates nearly every aspect of the interaction between a patient and the health care system. Patients who either do not speak, read or understand the English language at all, or to only a limited degree, clearly face a major obstacle to thoughtful and purposeful communication between themselves and healthcare providers or representatives.

While many healthcare facilities in the U.S. may have translators available or on call for the more common languages encountered at their facility, this does not completely address the problem. Careful translation and interpretation skills are often required for effective communication. For example, the common Spanish words *intoxicado* and *embarazada* do not translate to the English cognates of "intoxicated" and "embarrassed"; rather they mean "nauseous" and "pregnant" respectively, which can lead to dangerous misunderstandings in clinical settings [28]. Patients with emotionally laden or complex problems, or who require complex explanations of diagnostic or treatment regimens, also risk poor outcomes from inadequate communication.

Even patients with adequate English proficiency—or at least the same language as a provider—may still face barriers to comprehension due to the use of specialized vocabulary in health care or medical settings, particularly from the provider. Patients with low levels of health literacy who are not familiar with the relevant healthcare terminology may misinterpret what they have been told or may feel frustrated by the process or disrespected during their encounter with the provider. Even where language and health literacy are not major obstacles, cultural factors can present communication barriers. Certain topics may be difficult to discuss. Some terms may have different connotations to different people or in different contexts. For example, the words "the clinic" may have a very different connotation in Rochester, Minnesota, than it has in many other communities. The use of idioms and slang can be culturally laden and contribute to negative attitudes on both sides. Shared experiences and concordance can lead to improved understanding, but structural factors may preclude these bridging factors.

25.2.6 Income and Wealth

Rising healthcare costs affect all people, and can bankrupt even wealthy individuals, but increasing costs for routine and preventive care often hit lower income people the hardest, making it more likely that medical conditions will be in a more advanced stage by the time treatment is finally sought or received. Lower levels of education and income also affect baseline health status and are consistently tied to poorer physical and mental health outcomes. Chronic stress resulting from financial instability can also worsen health outcomes over time [29]. People in lower-income or manual jobs are often at higher risk of occupational exposure to disease or injury as well. There are also indirect costs of receiving medical care from contributing factors that generally have a greater impact on people with lower income, such as lack of transportation and lack of paid sick leave with the associated threat of lost income or even job-loss due to health-related absences.

Generational wealth and intergenerational economic mobility can contribute to one's ability to afford necessary healthcare and to access education or neighborhoods that are associated with better health as well. For example, while the income gap between Black and White families has not changed drastically in last few decades, the wealth gap has widened; households with Black children have only 1% of the wealth of households with White children [30]. This wealth gap is driven by socioeconomic factors like home ownership and educational debt and can lead to a cycle of low wealth and poor health across generations. Income and wealth can have an impact on both baseline health as well as access to health services and healthy behaviors over time, but the ability to pay for health care is also mediated by health insurance coverage (or lack thereof).

25.2.7 Insurance Coverage and Costs of Care

In 1965, the US signed into law amendments to the Social Security Act known as Medicare and Medicaid thus creating monumental social programs that have had significant and lasting impacts on healthcare coverage for Americans. Included in its eligibility criteria were citizens 65 years of age and older and those under the age of 65 with long-term disabilities or with End Stage Renal Disease (Medicare); as well as low-income families and individuals, including children, parents, and pregnant women (Medicaid). Administered by the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services, the programs opened the door to health coverage for millions of Americans.

In 2018, approximately 30.1 million people, or 11.1% of the US population, under the age of 65 had no health insurance [31]. Largely as a result of the Affordable Care Act, this has decreased significantly from 2010, when the number was 59.1 million [2]. However, the number is expected to rise again in the wake of widespread job losses due to the COVID-19 pandemic.

Lack of health insurance or adequate insurance coverage is one of the major financial barriers to care, however the situation is more nuanced than the binary distinction between having or not having coverage might imply. For example, patients without insurance may experience a hidden cost in that insured patients often benefit from negotiated rates between payers and hospitals/providers, while un-insured patients may be charged the full "retail" rate for the same services. Effectively, the patients who can afford the least may be charged the most, while also incurring responsibility for the entire cost of their care, not just the deductible or co-payment.

Many people with health coverage may also be effectively underinsured due to the advent of high deductible plans that have become increasingly popular under the guise of encouraging patients to "take responsibility for their own health." These types of plans hit lower-income populations the hardest because the insured have to pay higher amounts out-of-pocket before they can benefit from the coverage [32]. In other cases, insurance coverage may not cover all needed care, such as prescription drugs, or may offer either no coverage or extremely limited coverage for selected types of health care problems, such as mental health services. While lower income populations qualify for government-sponsored coverage through Medicaid, they may also face less choice in providers when accessing care due to reduced acceptance of Medicaid. The cumulative impact of these factors is that needed care is delayed, only partially received or not received at all; often resulting in patients with more advanced disease by the time care is received.

25.2.8 Healthcare Policy and Finance

In addition to financial factors affecting individuals in the form of lack of insurance and general inability to cover the cost of diagnosis, care, treatment and related transportation and time off, there are important financial considerations and

drivers of decisions made at the institutional, governmental and industry levels that have a major impact on accessibility as well.

While healthcare spending at the level of the individual or family, is generally dictated by a combination of need and means, healthcare spending at the level of an institution may also be driven by considerations such as prestige, market share and desired expansion. Healthcare spending at the level of government is heavily influenced by politics, as well as science and perceived need. There are sometimes also perverse incentives in the system that can work against attempts to control costs by differentially rewarding higher cost practices, particularly when health care costs and revenue are not vertically integrated and out-sourcing can reduce one institution's costs, even though it may potentially raise total costs.

A contributing factor in institutional and government spending decisions in particular, is the data used as the basis for decisions, which may not accurately reflect the needs of all communities and is a critical topic to which we will return.

Many government and institutional policies lead to unequal distribution of power, income, goods and services within and across countries thus creating a system of poverty with poor health for many people as a result. Policy in this case can be described as a constructed determinant of health disparities given its inequitable impact within and across populations. Decisions about educational standards, school choice and funding mechanisms for public schools are prime examples of public policies with profound downstream consequences and inequities.

Population-based social and health policy interventions can exacerbate health inequities by failing to address root causes of social and health determinants among the most vulnerable members of a population. Targeted social interventions are ultimately necessary to achieve parity on health equity. Some policies, particularly those related to immigration, can have a potentially devastating impact on people who choose not to seek care at all for fear of being identified and targeted for deportation.

At the same time, government and institutional policies can help to address inequity and offer solutions instead of compounding obstacles. The previously mentioned Affordable Care Act has represented a major effort to expand healthcare coverage nation-wide, and despite strenuous objections, has proven to be very popular with the American public.

The Global Commission on Social Determinates of Health [33] recommendations include: (1) Improving daily living condition and targeting areas for policy driven impact (civil society, national governments and global institutions) with a focus on: (a) Women, girls, and the circumstances into which children are born; (b) Early child development and education for girls and boys; (c) Improved working conditions and social protection policies; (d) Elder care; (2) Tackling inequitable distribution of power, money, and resources with respect to: (a) Gender-based inequities; (b) Private sector accountability; (c) Agreement on and investment in public interest driven needs; (d) Dedicated governance applied equally from community level to global institutions across many aspects of life—education, employment, housing, transportation, health etc. and (3) Measuring and understanding the problem and assessing results of action.

Public health policy is particularly important in addressing health disparities and often focuses on prevention and early detection, thus, reducing morbidity, mortality and risk for the entire population, as well as reducing the cost of care for preventable conditions. This approach is tremendously cost-effective at the population level, but ironically, is the first type of care to be neglected by people with limited funds. It can be hard if not impossible to justify the direct costs or insurance deductible for services and care that are not *immediately* urgent when so many competing demands are more pressing. While there are sources of free screening, and many insurance plans completely cover at least selected screening with no deductible, these efforts do not address all barriers to preventive care. For example, lack of paid sick time or reasonable geographic access to needed services can be a major barrier, even if direct costs of care are covered.

25.3 The Interconnected Web of Health Disparities: COVID-19

While each source and form of inequity described above exerts its own unique impact on vulnerable populations, the reality is that the combination of these inequities is not merely additive, because each unique barrier can compound or exacerbate the impact of the others.

The interplay and compounding effect of the different factors associated with healthcare disparities can be illustrated by the way they have contributed to worse morbidity and mortality for many disadvantaged populations during the COVID-19 pandemic [34].

These factors include:

- Higher exposure due to:
  - Crowded living arrangements—inability to practice social distancing or self-quarantine post-exposure within a household
  - Higher use of public or group transportation
  - Differential incarceration rates compounded by higher COVID-19 rates reported in prisons
- Higher occupational exposure:
  - Essential workers—nursing home and hospital workers, agricultural and food service workers, delivery personnel
  - Inadequate PPE
  - Inadequate ability to maintain social distancing in many job locations, e.g., agriculture, meat processing plants
- Less access to care, particularly for incarcerated/migrant/rural populations
- Higher baseline morbidity from chronic diseases
- Greater impact of COVID-19-related job loss
- Greater impact of mistrust in medical care and resulting disparities in demand for coronavirus vaccine between racial groups.

This provides a perfect example of how underlying inequities interact and compound each other, but it is just one example. In the case of chronic diseases such as diabetes and heart disease, the need for on-going treatment, may become a constant strain on a family's resources, with inadequate care sometimes leading to disability, further compounding financial and logistical access to care. While specific details will vary, similar scenarios can be described that apply to many common and chronic diseases where baseline conditions may be compounded by financial and other barriers that reduce the timeliness and efficacy of care.

25.4 Implications for Health Systems, Data and AI

This chapter has focused primarily on how disparities occur within population groups, how social and environmental determinants of health interact with biological pathways and persist in health and healthcare. While issues related to data, information system, and artificial intelligence will be covered in other chapters, this section will briefly highlight the broad social and ethical implications of data and AI for health systems and management.

Structural discrimination, racism, societal biases and resulting disparities in health access, utilization, processes and outcomes should motivate health systems to consider principles of ethics, social justice and equity in AI and machine learning models that operate on data [35]. An overarching factor which is also a social justice issue, is the inequity in research funding and publications that drive evidence and decision-making in health care settings. Social inequities, gender and racial bias have had a major impact on how research funding is prioritized and supported. To address these longstanding issues, the National Institutes of Health has developed an initiative called UNITE, to ensure transparency, accountability and sustainability in directing resource funding for minority health and health disparities research [36].

The other basic problem is that data typically collected in healthcare settings don't traditionally include many of the relevant factors related to Social Determinants of Health (SDoH). As the importance of SDoH in both assessing and addressing patients' needs is more widely under-

stood, this may change, but the challenges involved in collecting, storing, managing, protecting and interpreting ever larger and more complex amounts of data in healthcare are daunting.

Some of the barriers to getting accurate data relate to the complex nature of some of the data needed. The means by which race and ethnicity data in particular are collected and categorized in the US are highly variable and imprecise. For example:

- Historical context around race data—when, why, how, by whom and for what purpose it is collected
- Variation in the use of one vs. two variables to collect race and ethnicity in different settings
- Variations in the categorical response options available, resulting in inconsistent data collection
- Inconsistency in source of data (not always patient-reported; when supplied by others—e.g., providers, administrative staff, etc.—it may be incorrectly inferred or assumed from other sources, and there is rarely if ever any indication of whether the recorded data is patient-reported or not)
- Privacy concerns leading patients or institutions to withhold or underreport key SDoH data
- Lack of agreement on definitions and categorization, particularly with respect to multiracial individuals

This variability and inconsistency results in difficulty mapping, aggregating and analyzing the data in order to achieve better understanding of the impact of race, or to create benchmarks for improvement.

The problem with data is even more fundamental than the lack of precision, consistency or validity of how it is coded, but rather whether or not representative data is even available. The primary sources of data that are essential to studying or defining disease, treatments, protocols, guidelines and standards of practice often come from clinical trials versus "real-world evidence" (RWE) which are derived from actual practice and outcomes as documented in electronic health records, claims data and other data reflecting clinical practice. The essential problem with both of these data types is that populations affected by health disparities are often under-represented, primarily due to the same factors that have caused the disparities in the first place.

Effective AI and analytical models are crucial to improving health care, but they depend on accurate and comprehensive data that captures the factors discussed in this chapter. As we chart a path forward, we must address the causes of this imbalance in practice, as well as identifying ways to understand how we can address these imbalances when analyzing RWE while simultaneously finding ways to assure adequate representation in the future.

25.5 Conclusions

Disparities pervade our health care system, stemming from factors including race, income, insurance coverage, literacy and language, and policies that impact exposure and susceptibility to disease as well as access to high-quality care. This multitude of factors leads to both significantly poorer baseline health and poorer outcomes.

While advances have been made in professional inclusion and patient representation in research, the legacy of race-based practices, fueled by continued disparities in all walks of life, contribute to clear, on-going disparities in the health of Black, indigenous and other people of color in the United States. Addressing health disparities reflected in the healthcare system requires that we find ways to address barriers to access and care, to foster inclusion in research, to improve healthcare data and analytic techniques, to personalize care to the unique needs of minority populations, and in so doing, to finally deliver quality care to all people.

As we look to AI to solve complex problems in healthcare, we must also understand how the legacy of societal inequities is reflected in healthcare data. If biased data is used to develop and train AI systems, then such systems may simply perpetuate, or even exacerbate, healthcare inequi-

ties. There are mechanisms to mitigate this bias, but we must first understand how the underlying inequities in our society translate into healthcare disparities before we can address them.

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Addressing Health Equity: Sources, Impact and Mitigation of Biased Data

26

Eileen Koski, Fernando Suarez Saiz, Yoonyoung Park, Brett R. South, Elisabeth Lee Scheufele, and Irene Dankwa-Mullan

Abstract

The use of Artificial Intelligence (AI), Machine Learning (ML) and advanced analytics can yield important contributions to our understanding of how current systems and practices contribute to health disparities. They can also inform the development of equitable interventions, policies and decision-making in clinical care. This can only happen if we understand and address the biases in our healthcare system today, and how they are reflected in the data we use to develop and train AI systems. In this chapter, we will provide an overview of healthcare data sources and describe the ways in which the different types of data can be biased. We will discuss the impact of biased data, citing specific examples of how biased data has led to erroneous results or decisions, with particular focus on health equity and disparities. We will then describe strategies and techniques to both improve data prospectively, and to mitigate biases in how we use and interpret existing data to inform decision-making in healthcare.

Keywords

Artificial intelligence (AI) · Machine learning (ML) · Data bias · Health equity · Real world data (RWD) · Real world evidence (RWE)

E. Koski (✉)
IBM T. J. Watson Research Center, Yorktown Heights, NY, USA
e-mail: ekoski@us.ibm.com

F. S. Saiz
IBM Watson Health, Toronto, ON, Canada

Y. Park
IBM T. J. Watson Research Center, Cambridge, MA, USA
e-mail: yoonyoung.park@modernatx.com

B. R. South
IBM Watson Health, Salt Lake City, UT, USA
e-mail: Brett.South@ibm.com

E. L. Scheufele
IBM Watson Health, Boston, MA, USA
e-mail: elisabeth.scheufele@childrens.harvard.edu

I. Dankwa-Mullan
Merative (formerly IBM Watson Health), Bethesda, MD, USA
e-mail: Idankwa@merative.com

Learning Objectives

On completion of this chapters, the reader should be able to:

- Define bias. Describe types and sources of bias in healthcare data that impact decision making
- Describe bias in clinical trials data and factors that contribute to them
- Describe claims data, electronic health records and their content

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- Describe the impact of bias in healthcare data and challenges in developing AI healthcare applications

26.1 Introduction

Artificial intelligence (AI) and machine learning (ML) technologies and applications in the era of big data are poised to generate new insights that could advance health care in many ways. AI has the potential to transform many aspects of health care delivery and to enable research breakthroughs that improve outcomes. This includes uncovering new knowledge into disease pathways to identify potential treatments; improving patient and provider access to credible and relevant evidence; addressing unwarranted geographic variations in quality care; and ultimately delivering on the promise of personalized medicine and precision healthcare.

Unfortunately, the application of AI tools also has the potential to deepen the digital divide, potentially exacerbating already existing health disparities. This can happen in various ways including benefiting those with greater access to new technologies or by promulgating erroneous or biased solutions based on algorithms and data that may not account for relevant social and cultural contexts or characteristics of diverse populations and geographies.

In order to implement and adopt AI in healthcare, we must first understand how the impact of deeply entrenched structural racism, systemic bias and exclusion is reflected in the data generated in the healthcare system, including research, population health assessment and clinical care. In order to use AI to advance health equity, we must build and deploy systems in ways that actively seek to identify, explain and address the impact of systemic biases on the delivery of health care. In this context, advancing health equity includes identifying and addressing the avoidable differences in health and outcomes among groups that are defined socially, demographically, economically or geographically (WHO Health Equity 2019). Ideally every person should have a fair opportunity to attain their full health potential, and no one should be disadvantaged from achieving this potential. The groups that experience health inequities include racial and ethnic populations, groups experiencing poverty or financial hardships, persons with disabilities and other social groups that have historically experienced barriers to achieving optimal health through discrimination and/or exclusion. Healthcare AI cannot eliminate societal inequities at their root, but it can help us better identify, understand, and mitigate the ways in which such inequities influence health care access, delivery, and outcomes to reduce health disparities.

26.2 Sources of Bias in Healthcare

While many disparities in healthcare reflect the influence of societal inequities on health, access to care and quality of care, we must recognize that there are other sources of bias that arise from more subtle practices. Our current healthcare system is the product of centuries of beliefs, theories, research, and practice that in turn reflect every aspect of culture and society. While modern medicine is extensively rooted in science, evidence and practice, questions regarding what research evidence is important, how—and for whom—to develop new treatments, and how the healthcare system is configured to deliver care are more deeply rooted in fundamental societal constructs and beliefs—and, as a result, reflect societal inequities.

Table 26.1 summarizes some of the types and sources of bias that have an impact on decision-making in healthcare. Societal, historical and educational biases, for example, affect the data that is used to develop and train AI applications in healthcare. It is important to remember, however, that these same data biases affect all uses of healthcare data to make decisions, particularly those at a level that will have an impact on large numbers of patients by contributing to research conclusions, policy decisions, institutional practices, protocols, guidelines and healthcare system design.

Table 26.1 Types and Sources of Bias in AI Datasets that influence health care decisions and management

Type of bias		Source of bias
Explicit	Historical bias	Existing historical and institutional bias in research, clinical trials, medical knowledge that is reflected in health beliefs and data
		Research methods, outcomes and interpretation that may reflect scientific bias and societal inequities
		Scientific evidence for clinical practice that is based on trials may have limitations to general applicability if the trials are not diverse or inclusive
	Educational bias	Academic and training programs that are limited in evidence from all population groups
		Learning Health systems and knowledge generation and reapplication that is often used in the health care delivery process for continuous improvement in patient outcomes and institutional performance for quality care may constitute possible source of bias if data quality and diversity are compromised
	Human bias—includes measurement bias, representation bias, cultural and population bias	Building and analyzing datasets without a health equity lens
		Making judgments or stereotypes of what is right or wrong based on one's culture and background
		Linguistic interpretation of patient's illness
		Intentional or unintentional cultural bias and discrimination against one's race, ethnicity, ancestry, country of origin, religious beliefs or understanding
		Misuse of health data that disproportionately impacts socially disadvantaged or marginalized communities
	Embedded data bias	Gaps in health data e.g. missing data or incomplete data in the electronic health record, favoring groups with more robust health data profiles
		Patient medical or EHR data, and administrative claims data are increasingly being used to generate algorithms for decision support, generate quality care indicators and performance benchmarks for health systems.
		These data sources may not accurately reflect care utilization and outcomes for all patients, due to limitations or errors in recording, extraction and translation for medical management, as well as EHR and other healthcare data used for healthcare tracking, reporting and management may not be complete, precise and align with the needs of the patient. In some instances, higher quality data and completeness is seen in instances where reimbursement or pay-for-performance parameters are dependent on it.
	Dataset bias—includes data aggregation bias, sampling bias	Labeling, handling, sample selection, modeling structure
	Algorithmic bias	Lack of cohort diversity
		Training data is not representative
Implicit	Data invisibility	Lack of data on certain important populations or outcomes that can trigger discriminatory results
	Data empathy	Lack of knowledge and experience about the people, places, and other socio-demographic factors that comprise the data
		Inability to recognize bias and optimize analysis due to inadequate knowledge of factors, data source and real-world evidence or implication
	Observer bias	Subconsciously or consciously projecting one's own expectations and prejudices into the AI-ML data building process

This chapter will focus primarily on two overarching sources of bias in healthcare—educational and experiential bias, and data-related bias. As will become clear, the sources of bias listed above are deeply inter-related, so the next sections will touch on many, although not all of them.

26.2.1 Educational and Experiential Bias

Clinicians and researchers learn from a combination of where they are trained, what they are taught, and what they observe. These practices result in educational and experiential biases that are absorbed as knowledge and beliefs about the best way to treat patients. The problem arises when such knowledge and beliefs include faulty assumptions about how they apply to different populations or in different circumstances, whether due to discriminatory attitudes or lack of experience. This can produce a harmful cycle in which faulty notions, based on conscious or unconscious biases, lead to incorrect treatment decisions that result in negative or poor outcomes, thereby perpetuating the original bias.

For example, a study was performed by Schulman et al. [1] in which physicians were asked to estimate the probability of coronary heart disease and appropriate management of chest pain based on age, presenting symptoms and exercise stress test results provided in a videotaped interview with a patient. The "patients" were actually actors who were given identical scripts reflecting one of three different types of chest pain, as well as identical occupations, insurance coverage, other salient medical history and demographic characteristics other than race and gender. The results demonstrated clear bias on the part of clinicians in terms of estimating the likelihood of coronary heart disease, which was lower for women, and for referring suspected patients with chest pain for cardiac catheterization, which was lower for both women and Blacks. Black women in particular, had significantly lower rates of referral for cardiac catheterization than White men even with similar clinical profiles. While this study did not involve real patients, the findings reflected prevailing attitudes that influenced decisions made in the course of routine practice, in which faulty assumptions about the level of disease present—based on gender and race—led to reduced diagnostic testing, delayed or reduced care and ultimately worse outcomes. This type of cycle of harm was more fully described in the landmark IOM publication *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare* [2].

Since the delivery of clinical care is not simply a matter of generating provisional and differential diagnoses to inform treatment recommendations, educational and experiential biases that may be reflected in aspects of care coordination and management can impact outcomes and contribute to disparities. This can include provider attitudes towards patients of different races and socioeconomic status [3]. Assumptions about patients' ability to understand what they are told, and whether they can comply with their treatment, may be based on inherent stereotypes and prejudices including limited understanding or exposure to patients with varying socio-economic circumstances or cultural practices and beliefs.

As we discuss both how biases in healthcare are reflected in data used to train AI systems and how professionals view such systems, we must always consider the societal structures, practice patterns and the scientific evidence or context in which they are embedded. The logic behind specific conclusions or recommendations made by AI systems will need to be explainable in terms appropriate to the intended end-users of such systems so that any underlying biases may be understood. AI applications also have stakeholders and users with highly varied backgrounds ranging from clinicians and researchers, to patients and consumers, as well as policy makers, operational and administrative staff. Each group will have different requirements for explainability, that will also vary by context, e.g., during system selection, evaluation or testing vs. day-to-day use. While the hope is that the use of AI in healthcare will illuminate new discoveries and possibilities that can transform various aspects of healthcare, for

truly transformative ideas to emerge, we must be sure we recognize the influence of the assumptions—and biases—on which they are built and the data on which they are trained.

26.2.2 Data

Healthcare AI, like most AI, is trained on data that is available in machine-readable form, such as numeric, categorical and text-based data, as well as images, audio, and other formats. Before considering how to use AI specifically to promote health equity, it is first necessary to understand how both past and present inequities in our society are reflected in our health care system and the resulting data, and how that affects AI. Understanding both the context of use and the foundational data itself is critical to understanding how AI applications in healthcare should be developed and deployed.

Historically, digital health data included electronic medical data such as clinical trials data, administrative claims, imaging, prescription data and laboratory results. While such data is often carefully curated and validated, it typically covers only narrow subsets of information about selected aspects of a patient's health. Clinical trials data, for example, are focused on specific scientific questions and typically only cover limited populations for predefined time frames. This section will describe specific concerns related to various major data sources in healthcare.

26.2.2.1 Clinical Trials Data

Clinical trials are research studies conducted in order to answer a specific question and thus generate new knowledge. Clinical trials always involve a carefully defined protocol intended to assure consistency of the intervention delivered and the data collected in the course of the trial. Large-scale randomized controlled clinical trials are often viewed as the gold standard in generating medical evidence, particularly with respect to intervention efficacy. Clinical trials datasets are generally well curated and relatively complete and consistent over the course of the trial and long-term follow-up.

Eligibility for clinical trials involves a detailed and complex set of inclusion and exclusion criteria. Recruited patients must have the appropriate demographic and medical requirements to participate, but not have attributes that would interfere with their participation or make it difficult to evaluate the outcome for the trial. For example, many trials exclude patients with serious or multiple co-morbidities in order to reduce potential confounding effects of other diseases on outcomes.

While extensive efforts are generally made to assure that a trial can produce scientifically valid results, both systemic and individual biases historically have had a significant impact on enrollment into clinical trials by minorities and other marginalized groups. The NIH Revitalization Act of 1993 [4] explicitly discussed the need to enroll both women and minorities in sufficient numbers to adequately analyze any variables with specific relevance for them. Nevertheless, a recent survey of majority Black (57.5%) medically underserved individuals as to their willingness to participate in clinical trials indicated that four times as many Black patients as White perceived their care to be worse than that given to other races, and this group had a dramatically lower *Likelihood of Participation Score* with respect to clinical trials [5]. As a result, medical knowledge has often advanced based on studying potentially skewed subsets of the population. When such knowledge is subsequently applied to under-represented populations, it is sometimes found to be biased and to have overlooked factors with important implications for those populations.

It is important to understand that such structural sources of bias are often deeply embedded in how research is conducted, and many people may not be consciously aware of how they represent sources of bias. Major academic research centers, for example, often serve more affluent populations who are more likely to have the resources to both learn about clinical trials and enable their participation. Mistrust engendered by both historical abuses and negative personal experiences may contribute to reluctance to participate in clinical trials on the part of Blacks in particular. In the case of researchers, their learned

Table 26.2 Factors contributing to bias in clinical trial participation rates

Factor category	Source	Examples
Structural	Trial Design	Inclusion and exclusion criteria
	Enrollment	Selection of enrollment sites and enrollees
	Awareness	Where, how, by and to whom information is made available
		Resources that might be lacking for under-served groups to learn about trials, e.g. limited computer access
		Community care vs. care at academic medical center
	Logistical Barriers	Transportation challenges, lack of paid sick time for required visits
Attitudinal	Communication Barriers	Communication barriers to understanding the potential benefits to trial participation
	Mistrust	Mistrust due to negative experiences or historical abuses

trust in statistical methodologies surrounding eligibility for and analysis of clinical trials data may confer a false sense of security, confidence, or conviction about how widely their findings may be applicable, despite inadequate diversity in study populations. Table 26.2 summarizes some of the factors that contribute to lack of representation in clinical trials.

The impact of inadequate diversity in enrollment is that site and enrollee selection bias may result in medically related uncertainties from lack of evidence on the impact of a specific treatment on particular populations. While this may arise from physiological factors or may be secondary to structural factors influencing baseline health or the ability to comply with all aspects of a study protocol, health beliefs or other factors can also have a negative impact on outcomes for a given treatment.

26.2.2.2 Real-World Data

Unlike clinical trials data, "Real-World Data" (RWD) or "Real-World Evidence" (RWE) reflects data and evidence collected in the course of routine medical interactions and many assume that it represents how medicine is actually practiced and how patients actually receive care, as opposed to theoretical constructs of care delivery. There are practice guidelines and standards of care intended to assure that a certain level of care is delivered, however there are many factors contributing to widespread variability of care. Data reflect when, where and how patients choose to present for care; patient characteristics (e.g. demographics, comorbidities, ability to pay); provider characteristics (e.g. training, experience, specialty); and care setting (e.g. clinic, office, hospital). As a result, there is tremendous variability in "routine care" that is reflected in all aspects of RWD/RWE.

While there are additional sources of real-world data that are becoming increasingly important, such as genomic data, sensor data from devices (e.g. pacemakers, insulin pumps, smart watches) and patient sentiment data from surveys and chat rooms, administrative claims data and electronic health/medical records represent the major sources of RWD available today for use in developing AI algorithms.

26.2.2.3 Administrative Claims Data

A significant percentage of administrative claims data has been in electronic form for well over 20 years and some large data sets contain literally decades of data on hundreds of millions of patients. There are well-known limitations to the interpretability of claims data, primarily because they only contain a limited set of information about a clinical encounter, but also with respect to how precisely, completely, consistently and accurately diagnoses and services have been coded over time. When discussing health disparities, however, one of the most important attributes of claims data is that they reflect medical expenses incurred by patients who are covered by insurance, which means that uninsured patients will generally not be represented, and underinsured patients may be under-represented, potentially leading to erroneous conclusions about their health status and health care needs.

26.2.2.4 Electronic Health/Medical Record Data

Since the recent widespread adoption of electronic health/medical records (EHRs/EMRs) by providers and health centers, clinical care records have become more readily available sources of more comprehensive, longitudinal patient data. While there are often technical problems using EHR/EMR data due to inconsistent coding, free-text clinical notes and other issues, the fundamental problem is that, like virtually all healthcare data sources, they reflect the biases inherent in both the purpose and environment for which they were created and implemented.

Socio-economic data that may be needed to understand factors contributing to a patient's condition or behavior are often unavailable or imprecise. In particular, social determinants of health such as access to care as well as food, housing quality, social support, household composition and dependent/elder care responsibilities, transportation, etc. are generally not available for consideration.

This means that such systems reflect several major biases and assumptions, such as:

- Utilization reflects medical need, which assumes:
  - People who need care have the financial resources to obtain it
  - People who need care have accessible care options
- All relevant diagnostic and treatment data from the time period of interest are reflected in the electronic health records, which assumes some measure of Continuity of Care:
  - No major gaps in care
  - Same physician, group, clinic, or hospital, such that all care is reflected in the same EHR
- Sufficient information about a patient is available in the record to recognize structural barriers to care

In addition, decisions about what data are collected and described, must involve consultation with experts who understand the complex interplays of environment and health, and the nuances of social constructs of identity. For example, when race, gender or ethnicity is recorded, the most fundamental question about the validity of the data may be whether the information was provided by the patient or the observer. This is particularly true when the reality is more complex than the limited choices on a form may allow.

26.3 The Impact of Biased Data

It is not enough to recognize how data sources can be biased. We must also understand why it matters. In particular, it is important to understand the impact that embedded bias has on research, on clinical care, on how data is used in developing and deploying AI systems in healthcare, and ultimately, on patients. In the context of disparities in care, much of the bias in healthcare data stems from underrepresentation of marginalized groups. The underlying and immediate causes of underrepresentation vary, and include poverty, location, reduced access, mistrust, selective recruitment, discriminatory practices as well as complex interactions among these and other factors. The impact on the resulting data, however, is similar—the specific circumstances, underlying health status, needs, experiences, and differential outcomes are simply not adequately or accurately reflected, which can lead to poorly informed decisions with a negative impact on affected groups.

Influential work by Obermeyer et al. [6] describes the impact of an algorithm that used health costs as a proxy for health needs and subsequently recommended resource allocations to reduce future costs. In this case, the bias occurred as a result of the algorithm training label to identify costs predictors. While cost predictions were accurate and unbiased, it turned out that cost was a poor proxy for the desired outcome of assessing medical need, because of underlying racial bias in the data. The algorithm concluded that higher healthcare utilization reflected greater need. While this may seem entirely logical, it does not account for the fact that actual utilization inferred uniform ability to both afford and access needed care across all groups. Since the goal was to allo-

cate resources based on need, this bias meant that patients who could afford higher levels of access to care—primarily White—would be likely to receive such resources at a lower level of disease burden than patients who could not, and who were more likely to be Black. In other words, for any given level of need, this algorithm would have allocated the most assistance to the people who may have needed it the least.

Research location is another potential source of underrepresentation. The Framingham Heart Study is a major, longitudinal study that has contributed significantly to the understanding of risk factors for cardiovascular disease. The study was conducted in Framingham, Massachusetts primarily because of the enthusiastic response of local area physicians and its proximity to cardiologists at the Massachusetts General Hospital and Harvard Medical School [7]. Framingham was a middle-class community that was predominantly White of European descent. The study enrolled its first patient in 1948 and continues to follow enrollees, their offspring [7], and a third cohort of offspring children that began recruitment in 2002 [8]. In order to address the fact that the study had originally been predominantly White, the Omni 1 cohort in 1994 and the Omni 2 cohort 10 years later recruited minority residents of Framingham. Despite this, the Framingham Heart Score, a scoring system used to predict the risk of cardiovascular events in practice was later shown not to perform as well among Black patients as it does among White patients, exhibiting both over and underestimations of risk [9].

Biased clinical trials data have an impact on treatment recommendations in that they may not reflect the nuances of a population that can, in turn, affect outcomes. The implications for the efficacy of the treatment in those populations or the risk of adverse events may only become apparent during post-market surveillance long after many patients have been exposed.

An important consideration may be whether or not to use race-based variables or algorithms in research at all. A recent NEJM paper described a variety of examples in which the use of the variable "race" in clinical prediction models proved to be problematic. In many cases, other variables that were highly correlated with race may have been the true predictors, not race per se [10]. As long as underlying disparities and other sources of exclusion are reflected in healthcare data, there may not be a perfect solution that can eliminate all sources of bias in the data itself. There are, however, approaches and techniques that can generate less biased data in the future, and address bias in the data we already have.

26.4 Addressing Data Bias

Many technical challenges exist in using both clinical trials and real-world data for analytic purposes for which they were not originally intended (secondary data use) due to lack of interoperability or common data models, lack of common patient identifiers, variable application of coding standards and general data quality. While we recognize that such aspects of data quality may be affected by social inequities since institutions serving wealthier populations may be able to afford better data management tools, we will not be focusing on these aspects of data quality specifically. Our focus is on the more fundamental bias inherent in using data that underrepresents, or misrepresents, minority populations in algorithms and thus adversely impacting the decision-making outcomes affecting them.

Three distinct components have been described to aid in the process of addressing data bias:

1. *Understanding bias*—processes by which we can recognize the presence of bias in a dataset, identify the source of the bias, determine how the bias reflects societal or systemic conditions that may affect the validity, applicability and efficacy of programs based on resulting AI algorithms.
2. *Mitigating bias*—approaches and techniques designed to eliminate or reduce the impact of bias in all stages and processes involved in AI and analytics algorithms. These include collection, pre-processing, processing and particularly interpretation of the methods used in AI development.

3. *Accounting for bias*—this set of methodologies refers to strategies that account for known biases, particularly those that cannot be mitigated or eliminated, and is therefore highly dependent on the result of efforts to understand and mitigate the bias. This encompasses bias-aware data collection, describing the potential biases of the AI models and supporting explainable AI "decisions" or outputs [11].

In order to fully address bias in data modeling in the context of analytics and AI, it is necessary to define in detail the expectations and outcomes of the systems in which the algorithms will be used. This is partly to inform the building and analysis of the datasets, and ultimately to understand how identifying and addressing any explicit and implicit bias in the underlying data could affect the outcome. There are also implications for the definition of fairness in data collection. Several definitions have been proposed in recent years but what is important is for system developers to be aware of the need to identify and address sources of bias; to clearly define what is expected from AI algorithms; and more importantly, to understand and address the expectations and needs of users and consumers of such processes from a socially aware perspective.

In a clinical setting the consequences of bias in data, algorithms and interpretations are of particular importance. Historically, it has been shown that some models and outcomes that are widely known and accepted in clinical practice were biased from their inception either by gender or race. The sources of bias in clinical practice have been well studied by Fitgerald, et al. [12] In this systematic review, the authors describe how implicit biases are pervasive in clinical care and are simply reflective of the biases that exist in society at large. They go further to describe a correlation between biases with diagnoses and treatment decisions. Their research also suggests that there is no standard norm of impartiality and the extent to which any such norm is applied in healthcare is neither consistent nor sufficiently broad.

Leavy et al. [13] provide more insight on sources of bias in AI training data. They argue that data is simply a reflection of the biases existing in society and that eliminating bias completely is not possible. They further describe how awareness and transparency will require technical, social and data governance solutions. Ironically, acknowledging the impossibility of objectivity can positively affect our efforts to control and mitigate bias by a variety of methods. Methods that involve data-augmentation, re-weighing, re-sampling and re-balancing of the data are only possible because of our awareness of the lack of objectivity in data generation and collection. Such approaches have been shown to reduce algorithmic bias by incorporating concepts of race, gender and social justice into the creation of AI algorithms.

Even if perfectly representative data is not an unattainable goal, it is nevertheless important that we strive to address those underlying issues causing data bias that can be addressed. For example, to increase minority representation in clinical trials, future trials must be structured to require, or at least foster, such participation. Several mechanisms have already been used to address recruiting for other reasons, and can be adapted to increase minority representation, for example:

1. Enrollment diversity targets similar to gender targets
2. Support for potential enrollees with financial or logistical barriers to participation, e.g. funding for transportation to visits, mobile/local follow-up locations, follow-up visits outside of typical working hours for patients with no paid sick time
3. More extensive and thoughtful outreach to underrepresented communities

Such strategies must be carefully thought out, however, to avoid accidentally introducing new sources of bias. For example, telehealth might be a cost and time effective mechanism to enable follow-up visits for patients with financial and temporal barriers to participation. However, it could also introduce a new source of bias if applied preferentially to a specific group of patients, particularly if the quality of the follow-up interaction had implications for the outcome.

26.5 Broader Perspectives

Biases in data, analytics and artificial intelligence do not exist independent of the underlying biases present in the socio-historical context in which the data is generated, or where the algorithms are designed and tested. The impact of bias in healthcare delivery have been well-documented in both physicians' and nurses' behavior with respect to a range of patient attributes including race/ethnicity, socioeconomic status, gender, weight, HIV status and disability [12]. Even though there have been questions raised about the impact of interpersonal bias, there is ample evidence that biases influence clinical behavior and decision-making.

A prerequisite for addressing and mitigating bias is awareness of the data sources, content, historical context, and how outcomes are aligned with advancing health equity. In general, awareness must occur at the level of both the individual and the organization or institution. This requires an intentional, multidisciplinary and cross functional approach, integrated with broader efforts to increase diversity, inclusion, and equity. High level strategies to mitigate bias include: commitment to culture change and training at the organization level; reflection, introspection and counter-stereotype thinking at the individual level; and intentional diversity, cultural curiosity, humility, mentorship and sponsorship that require involvement of both individuals and organizations. In AI and Machine Learning, we must also recognize that biases in data collection and algorithm design may have short, middle and long-term consequences, each requiring different solutions. Challen et al. [14] detail each of these aspects.

26.5.1 Short-Term Solutions

In the short-term, practitioners should consider *Distributional Shift*, which is understood as situations where previous experience cannot be applied or is considered inadequate in the present. This shift includes both the data and the context of the data. Ultimately there is a misalignment between the training data and the operational data. This has particular relevance in a rapidly moving healthcare space particularly in the context of changing practice or clinical paradigm shifts in our understanding of disease. Practically, this is evident in the case of new and ever evolving targeted therapies and immunotherapy in cancer or a change in the context of healthcare practice and delivery more recently seen with the COVID-19 pandemic.

Secondly there is *Insensitivity to Impact*. In brief, AI/ML systems do not apply a measure of impact to the decisions or answers provided by such systems. For example, it has been shown that both AI systems and clinicians have trouble diagnosing skin lesions. However, in general, human evaluators tend to be "over-cautious" and more often suspect malignancy. While overall it could be said that clinicians are more inaccurate, we should not discount the calculation that clinicians are making when taking the impact of their decisions into account. ML models are often measured in regard to an accuracy metric that does not account for the individual or social impact of its decisions in real world scenarios.

Another short-term source of potential bias is what is known as *Black Box Decision-Making*. One potential limitation of more modern and sophisticated AI techniques is that the answers provided by those algorithms, by their very nature, cannot be easily explained in the context of the input data. In most systems this problem is hard to manage and requires careful design and analysis of the models, particularly when inputs are not stable, as is generally the case in clinical settings. Lastly, in the short-term category, we have *Unsafe Failure Mode*, which is understood in the context of the previously described short-term consequences like *Distributional Shift* and *Insensitivity to Impact* and which refers to those situations where the system should avoid making a prediction altogether based on low confidence in the input data, the algorithm, or the answer being provided.

26.5.2 Medium-Term Solutions

In the medium-term, clinicians, data scientists, system designers, algorithm developers and others involved at all levels of collecting, curating and managing data to be used in AI should take *Automation Complacency* into consideration. Particular attention should be placed on "confirmation bias" scenarios where the answers provided by AI systems that tend to agree with practitioners' own perspectives are adopted and trusted, to the exclusion of those that refute their preconceived notions. In the context of automation, there is a risk that clinicians might become desensitized to other sources of information and come to accept predictions or guidance without question, thereby precluding continued pursuit of confirmatory or contradictory evidence, and in the extreme case, transferring decision-making responsibility to the system. As with all forms of automated communication to clinicians, there is also the risk of AI becoming just one more contributor to alert fatigue.

Another medium-term consequence to consider is the *Risk of Reinforcement* of outdated practices and self-fulfilling predictions, as mentioned earlier. For example, a sudden change in clinical practice resulting from drug recalls or new drug approvals may invalidate therapy recommendations made by systems trained on earlier data that no longer represents best practices.

26.5.3 Long-Term Solutions

Long-term solutions have been primarily described in continuous learning, adaptive or completely autonomous systems in the clinical setting, but such systems are difficult to deploy [15]. There are some closed-loop devices that have already been used successfully for some time, such as insulin pumps, which have the potential to dramatically improve care for patients with type 1 diabetes mellitus. However, when looking at many potential applications, there is an extraordinary amount of continuous oversight that would be necessary to adjust for potentially dangerous decisions or recommendations that could result from unanticipated variations in the amount, source or quality of new data received.

For example, continuous learning modules would require constant updating of the training data to take into account new findings that could either validate or call into question observed patterns of diagnoses or recommendations, thus requiring close oversight that would likely make them impractical. Currently most of the AI/ML algorithms approved by the FDA are "locked," given a set of input data, so the expected output is known. The FDA has only recently begun to consider continuously learning or adaptive algorithms that are designed to do real time optimization [16], meaning that FDA approval for continuous learning models may not be practical or feasible in the near term [17].

As a result of these challenges, it may be premature to consider the long-term implications of potential bias associated with continuous learning or adaptive AI. However, as with many issues described earlier, if such devices are initially only available to narrow groups of patients, such as patients with better insurance coverage, the data gleaned from their experience may not reflect all of the issues that will be encountered in their use by other groups and thus may be biased as a result.

26.6 Conclusions

The application of AI to challenges in healthcare is based on the development and use of tools, such as algorithms, that analyze data to identify patterns and derive meaning from them. This may lead to hypotheses about causation or treatment effects that can then be tested via clinical trials, or to a better understanding of how different populations or individuals may respond to specific treatments or environmental exposures. In some cases, it may be used to improve the accuracy of diagnostic and treatment decisions by augmenting human decision-making or reducing human error.

It may also be used to inform policy decisions with potentially far-reaching effects.

However, AI systems are built on data, and healthcare data reflect the underlying biases in our society. In the case of health disparities, bias arises from many interrelated causes, in particular, underrepresentation of minority populations in clinical trials and other sources of data used to develop and train AI systems. Bias can also result from faulty assumptions about how data, particularly "real-world" data, can be interpreted, or how concepts of interest can be derived or inferred from the data that is available. Such faulty assumptions can lead to conclusions and decisions that don't properly address the needs and circumstances of all populations.

In order to mitigate bias, attention must be paid to all aspects of data collection, AI algorithm design and deployment. This starts with awareness of sources and drivers of bias, but also requires an understanding of the technology to be used and the social context in which it is to be deployed. Each implementation will need to be reviewed holistically to assure that the most appropriate set of solutions is identified for each situation.

One of the most promising aspects of advanced analytics and AI is the potential to reveal patterns that might not be evident to researchers and clinicians, whether due to the inherent complexity of the data itself or to deeply held assumptions. This is particularly critical in the context of addressing healthcare disparities where underrepresentation has contributed to a historical lack of understanding. However, when awareness and understanding of bias is achieved and mitigation strategies applied, it can facilitate recognition of new insights across all populations that can move medical knowledge, clinician practice and the entire health care system towards more inclusive and equitable practice.

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A Future Health Care Analytic System: Part 1—What the Destination Looks Like

27

Stephen Bandeian, Christopher P. Tompkins, and Ashwini Davison

Abstract

This chapter and the next propose a collaborative initiative to develop a comprehensive analytic system as a shared national resource to help improve health and health care. To provide greatest benefit, analytics should be fully integrated into the delivery of care across tens of thousands of settings ranging from small rural practices to large regional health care systems.

Such a system must be comprehensive for the simple reason that an individual may have any number or combination of illnesses and treatments. The chapters present a simple conceptual framework that fully encapsulates the diversity and complexity of health and health care. By doing so, the framework radically simplifies the task of building a comprehensive system and ensures that the system provides key information in a manner that is consistent, understandable, transparent, trusted, efficient, and sustainable.

This chapter addresses three basic questions. Why is such a system needed? Why is a national collaborative effort the best way forward? And how would the system work? The next chapter provides addition detail as to system components and sketches a roadmap for development.

Learning Objectives

- To understand how a comprehensive analytic system can help improve health care,
- To understand and evaluate the high-level conceptual model of health and health care that is proposed here,
- To understand the capabilities, concepts, and building blocks needed,
- To consider how the concepts discussed here may be relevant to the reader's own work.

27.1 Introduction

27.1.1 Overview

With near universal capture of clinical data in electronic form, increased availability of self-reported patient data, and advances in large-scale use of observational data for analytics, the stage is set for a health care analytics 'revolution'—one that can transform health care. The '**future analytic system**' described here reflects the logical culmination of these trends and is truly transformative.

S. Bandeian (✉)
Elevance Health, Bethesda, MD, USA

C. P. Tompkins
Brandeis University, Waltham, MA, USA
e-mail: tompkins@brandeis.edu

A. Davison
Johns Hopkins University, Baltimore, MD, USA

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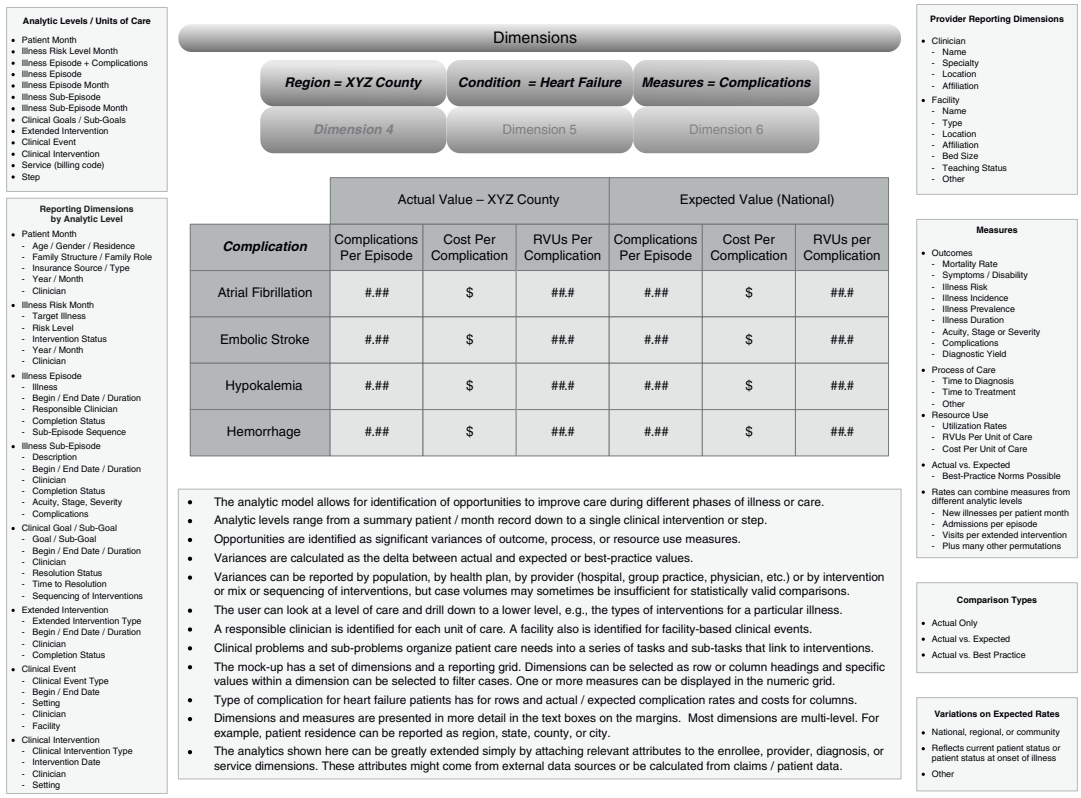


Fig. 27.1 Mock-up of a future analytic system

This chapter reflects work begun at the Agency for Healthcare Research and Quality (AHRQ) as presented to an advisory panel of Institute of Medicine commissioned by Carolyn Clancy MD, then AHRQ director in 2010.[1] Figure 27.1 is from the 2010 presentation and still serves as a model for what is possible. Figure 27.2, also dating back to work at AHRQ, shows how integrated components of the future analytic system would be sourced from a core 'analytic patient history.' The key enabling insight is that a high-level conceptual model of health and health care along with a well-designed 'analytic patient history' can support and simplify development of a comprehensive analytic system.

In recent years, great progress has been made in collecting and organizing clinical data. The value of such data has been proven during the COVID-19 pandemic. Initiatives such as the National COVID Cohort Collaborative (N3C) and OMOP and PCORnet common data models are helping to lay the foundation for the analytic infrastructure of the future.[2]

While this progress is impressive, we may have an important message that may help to accelerate progress. We say this with a sense of humility. There are thousands of extremely bright and dedicated people in diverse settings making

[1] Bandeian S, Clinical Analytic Model, Council on Health Care Economics and Policy, Princeton Conference XV, 2008. https://heller.brandeis.edu/council/pdfs/2008/Steve-Bandeian.pdf; Bandeian, S, Clinical analytic model – project overview, 2014, unpublished paper presented to an informal Institute of Medicine advisory panel. Papers related to the Clinical Analytic Model are available upon request.

[2] National COVID Cohort Collaborative (N3C), https://covid.cd2h.org/n3c; OMOP Common Data Model, https://www.ohdsi.org/data-standardization/the-common-data-model/; PCORnet Common Data Model, https://www.pcornet.org.

Fig. 27.2 Analytic patient history at center of an integrated future analytic system

important contributions to the health care analytics revolution. It is hard for us to have a comprehensive and detailed view of this activity. However, we believe that many of the ideas presented here may help us to reach our shared goal faster than otherwise possible.

This chapter suggests an approach for building a system that supports **research** to develop new clinical knowledge and capabilities and **applied clinical analytics** to improve use of existing knowledge and capabilities. While complementary, these use cases are different in a key respect. Research does not require an ongoing system and often is conducted through one-time projects. In contrast, for greatest benefit, applied clinical analytics must be closely integrated with day-to-day delivery of care, and **this requires an ongoing system**.

There are a number of important questions we do not answer. Should the system be centralized, decentralized, or federated? Should there be data requirements? We think that such questions should not delay work on developing a prototype system. As such work proceeds, those involved in development as well as the larger community of stakeholders will gain new insights and will be better able to assess tradeoffs objectively. To use a legal phrase, such questions are not yet 'ripe for decision'.

27.1.2 The Context

We have a novel problem in the history of medicine: how best to use the vast torrent of newly available patient-specific data. Over the past half-century, the paradigm for progress has been carefully designed clinical studies with specialized data collection, definitions, and methods aimed at generating new knowledge to be disseminated via journal articles, textbooks, conferences, and guidelines. This work has built the foundations of today's **evidence-based medicine**. The opportunity now is to build a new paradigm—***an***

evidence-based health care delivery system—where scientific evidence is more tightly integrated with daily the processes of care than previously possible.

To succeed, we must build on the rich set of methods, insights, and knowledge and on important values of peer-review and transparency developed in health-related research. At the same time, to achieve the scale and scope needed for operational analytics—we must transform health care analytics from a set of separate teams working on disparate projects often with different methods and definitions, to a *shared enterprise built collaboratively* by the same community. Collaborative work would be organized around an agreed-upon plan with shared terminology, definitions, concepts, models, and methods. There already is encouraging movement in this direction.

In our vision, the fields of research, and applied clinical analytics are complementary and mutually reinforcing. Integration of disparate data sources, standardization of data, definitions, and methodologies as needed for applied clinical analytics will facilitate research analytics, and the findings of such research can be used to inform and direct clinical care analytics.

27.2 Why Is a Comprehensive Health Care Analytic System Needed?

The United States has lower life expectancy and much higher health care costs than other advanced societies.[3] These outcomes are determined by a myriad of local decisions and processes of care. To have an impact, reform must somehow touch upon and improve these decisions and processes. While other reforms will also be needed, patients, doctors, nurses, payers, public health officials, and other government agencies all need better and more timely **operational information** if we are to improve. To make a measurable impact, **applied clinical analytics** must inform these decisions and processes on a mass scale whenever and wherever needed. ***That is why we need an ongoing health care analytic system***.

The chapter proposes an approach to constructing a **health care analytic system** that anticipates the myriad of specific questions that must be answered to optimize health care and systematically answers such questions. The system does so in an organized (and automatable) manner that would be transparent and trusted and compliant with accepted norms for methodologic rigor and information security. Such an approach is enabled by the conceptual framework proposed in this chapter.

Most of the necessary methodologies and technologies exist, and the costs of developing and deploying a health care analytics system are small relative to financial and human costs resulting from suboptimal health and health care. Moreover, as discussed in Sect. 27.2.2, success is more likely, sooner, and at lower cost if development is based on a comprehensive understanding what a fully developed health care analytic system would look like.

The suggestions made in this chapter and the next are illustrative, not prescriptive. For an initiative of this type to be successful, functionality, design, and methodology must reflect a rough consensus among relevant experts and leaders in the field. Here, we suggest a basis for discussion designed to reach such a consensus—offering some detail to help make our vision concrete and understandable. In the next chapter, we provide additional detail on the building blocks of a future analytic system and a realistic and achievable roadmap as to how to proceed incrementally from current state to future state.

27.2.1 How a Comprehensive Health Care Analytic System Would Help

A ***comprehensive*** system is needed because there are limits as to what dedicated clinicians can

[3]Commonwealth Fund, U.S. Health care from a global perspective, 2019: higher spending, worse outcomes?, January 2020.

without analytic support and because patient-related issues cut across narrow discipline-based boundaries. Analytics can support professional experience and judgement in several ways as described here.

Systematic improvement of care—First, traditionally, clinicians have had only a limited view of their patients' experience, a view limited to the information that can be gleaned during an office visit or hospital stay. This view can be made more complete by integrating data from all encounters, whether in-person or via telehealth, regardless of practice or health system, with pharmacy data and self-reported data gathered by smart phone apps. Again, there is encouraging progress along these lines.[4]

But detailed patient information, even if captured via EHRs, is insufficient. Even the most experienced clinician has only a limited ability to integrate numerous data points into precise probabilities of potential outcomes. This is simply a limitation of human cognition. In contrast, analytics can be developed to do just that. The results can then support initiatives to improve care.

Clinical managers also could use analytics to identify and correct patient care problems. Such problems are difficult to detect without formal analysis because poor outcomes or high costs can result from random chance, patient case mix, or hidden problems in care. Sorting this out is only possible through analytics based on patient data.

Analytic systems should identify opportunities for improvement at each step in the process of care from primary prevention through acute care and rehabilitation for all illnesses. Consider hip fracture. Can fractures be prevented? Can surgical complications be reduced? Can rehabilitation be more effective? At each step in the process of care, are persons from diverse backgrounds receiving similar care? Are there opportunities for cost-savings? Information that answers these types of questions should be available for all phases of care for all types of illness or injury. Local, regional, national, and best-practice benchmarks should be available to spotlight potential improvements. Moreover, metrics should be consistent across illnesses, settings, and treatments to avoid inconsistent results that simply reflect differences in data and methods rather than true differences in health care.

Different end-users would be provided different views of the analytics that they can use to help improve the care they provide. For example, primary care, emergency, surgical, oncology and rehabilitation teams each see relevant data. Public health officials, consumers, and payers would also have access to relevant summary data. Each role-based view would be a subset of a larger, comprehensive set of internally consistent analytics.

Individualized care and advice for patients—Second, it is difficult for a physician, no matter how knowledgeable, experienced, and skilled, to integrate a large number of data elements concerning a patient's clinical and social circumstance as well as known risks and benefits of treatment into a comprehensive assessment of the risks and challenges facing the patient.

In a future analytic system, relevant aspects of a patient's medical and social history and details of a forthcoming treatment can be integrated in predictive models to identify patients at high-risk of treatment complications for care management; models also could identify and assess treatment alternatives or supportive care to mitigate these risks. Or ambulatory patients at high risk of gaps in care or adverse outcomes can be identified from analytics and flagged for a follow-up contact.

Over time, with increasing sophistication, the same architecture could support statistically valid and reliable estimates of likely short- and long-term outcomes of diagnostic or therapeutic options for individual matched patients based on a patient's presenting clinical problem, comorbidities, health-related behaviors, and family and social support. One example is a surgical risk calculator developed by the American College of Surgeons.[5] A major goal of the future

[4] See for example, initiatives by the regional health information exchange for Maryland and the District of Columbia at https://www.crisphealth.org.

[5] American College of Surgeons, Surgical Risk Calculator, https://riskcalculator.facs.org/RiskCalculator/.

analytic system would be to extend such predictions to a comprehensive range of conditions and treatments and make this information available on demand in the office or at the bedside to assist patients and clinicians select the best option for the patient based on the patient's clinical characteristics (including risks) and expressed preferences.

Clinical effectiveness research and other health-related research—Third and finally, it is difficult for clinicians to judge the relative effectiveness of tests or treatment (or of the sequencing thereof). Such issues can, in theory, be addressed through randomized clinical trials, but such studies are only suitable for a small subset of issues because of the logistics, cost, time, and ethical issues involved. The Patient Centered Outcomes Research Institute has fostered a successful clinical effectiveness research initiative using observational data.[6] Some of the suggestions made here might help to facilitate and extend this effort. Findings from other health-related research, such as epidemiology, also can help to inform a clinician's understanding of the probabilities and causal chains that underpin daily clinical work.

27.2.2 Why We Need a Planned, Collaborative Effort Based on an Overarching Conceptual Model

Collectively, we are on new journey. So, where is the road map? How do we get there without getting lost? In this case, the road map flows directly from our shared understanding of health and health care. There are no mysteries. The landmarks are simple and well known. This chapter and the next will provide a draft road map based on these landmarks, subject to review, revision, and consensus within the health care and health care analytic communities.

[6]Patient-Centered Outcomes Research Institute, https://www.pcori.org.

For understandable reasons, analysts sometimes focus on solving a narrowly defined question without attempting to solve a larger family of questions within which the specific question fits. As a result, if many different groups tackle the same question (or set of questions) in ways that narrowly make sense, we can end up with many overlapping partial solutions with inconsistent terminology, methods, and categories that cannot be combined to form a comprehensive whole. Wasteful duplication of effort also is likely. Moreover, it is important to remember that an individual patient may have many medical problems and may need many different types of care. As a result, compartmentalized efforts cannot work if the goal is to build a comprehensive system that is closely integrated with ongoing patient care.

It is far better to start with a plan—a comprehensive understanding of what we need to help improve health care though analytics. That is why this chapter is subtitled '*What the destination looks like*'. We believe that the destination—a future health can analytic system—is well within our grasp given current technology and current understanding of the fundamentals of health and health care. We also believe that the high human and economic costs of suboptimal health and health care, coupled with enabling technology means that the vision we set forth will become a reality somewhere, sometime in the next decade. All that is needed is shared understand, resolve, a plan, and resources.

27.3 What Is Needed for a Successful System?

The overarching goal of the future analytic system is to help improve health and health care through research and applied clinical analytics to improve daily use of existing knowledge and methods. Logically, to improve care, the system must first be able to identify **problems in prevention or care** that result in poorer health than otherwise possible. In addition, observed problems in care must be traced back to potentially remediable causes in order to help improve care.

Table 27.1 System building blocks

Conceptual Framework
• **Patients, clinicians, and other participants**
• **Health, health problems, and health outcomes**
• **Choice of care, units of care, and process of care**
• **Suboptimal care and root and mediating causes**
Analytic Patient History
Health Problems and Health Outcomes
• **Risk factors** that may result in illness or injury or impede treatment (genetics, socioeconomics, behaviors, etc.)
• **Conditions** (new or ongoing illnesses and injuries)
• **Condition phase** (a change in control, acuity, or stage)
• **Poor condition control** (symptoms, complications, or intermediate outcomes, such as elevated blood pressure)
Units and Processes of Care (to address health problems)
• **Major clinical task** (a necessary high-level step in care)
• **Multi-day clinical intervention** (a treatment episode)
• **Clinical event** (an inpatient stay or ambulatory encounter)
• **Single-day clinical interventions** (a test or treatment)
• **Service or 'micro-step'** (components of an intervention)
Clinical Logic, Methodologies and Data
• Curated clinical categories and proven causal relationships
• Look up tables and algorithms to populate the analytic patient history from source data
• Generic conceptual and analytic models that are 'localized' to answer fully specified questions
• Computed measures to quantify mediating causes and predictors of suboptimal outcomes and care
• Clinician, patient, local health system, and community characteristics that may be possible root causes of suboptimal outcomes and suboptimal care
• Automated statistical and data science algorithms to answer fully specified questions using generic analytic models and the analytic patient history as input

To do so, the system must start with an accurate representation of health and health care at a person-level and must be capable of identifying need for care, instances of suboptimal outcomes and care, and root and mediating causes.

Section 27.3.1 describes logical requirements and Sect. 27.3.2 describes requirements for an integrated system. Table 27.1 outlines these building blocks.

27.3.1 High-Level Logical Requirements

27.3.1.1 Patients, Clinicians, and Other Participants

Patients and clinicians are the primary 'actors' in health and health care. As a result, their actions and decisions are central to a comprehensive system. At the same time, both are influenced by larger contexts: family and community for patients and practices and local delivery systems within which clinicians work. And both are influenced by payers and government.

27.3.1.2 Health, Health Problems, Health Outcomes

The system must be able to measure health and the health outcomes of care. **Health** can be defined and measured as the 'ultimate' impact of a person's set of **health problems** on longevity and daily well-being.[7] A '**health problem**' can be defined as an identifiable risk of onset of a new condition or an ongoing condition or a risk that an ongoing condition may be unduly prolonged, may worsen, or may result in complications. High-level categories of health problems are listed in Table 27.1. Health adjusted life expectancy (HALE) is a standard measure of health that integrates the full set of a person's set of health problems into a single estimate of life expectancy and daily well-being.[8] This is an important component of the analytic system and will be discussed further in the next chapter. Health problems also serve as the basis of measuring health and health outcomes at granular level.

Health care may be defined as any intervention to address a health problem through

[7] World Health Organization (WHO), Definition of Health, https://www.who.int/about/who-we-are/frequently-asked-questions. The definition of health proposed for analytic purposes does not include the WHO's phrase '…a state of complete physical, mental and social well-being…' for the immediate future due to practical issues of measurement. However, in keeping with WHO's Global Burden of Disease, the phrase disability in the proposed definition includes functional disabilities caused by emotional or behavioral symptoms.

[8] WHO defines HALE as the "… average number of years that a person can expect to live in 'full health'… taking into account years lived in less than full health due to disease and/or injury". https://www.who.int/healthinfo/statistics/indhale/en/.

public health [1], health care providers, care management, or self-care.[9] Health care itself has several outcome domains of broad and universal interest (Table 27.2). A **problem in care** can be defined as a situation where one or more of high-level outcomes could be improved through better use of existing clinical knowledge and capabilities. For example, outreach to a disadvantaged population with low cancer screening rates could improve health outcomes, resource use, and health equity (Table 27.3).

Health outcomes of care can be defined and measured as changes in a person's set of health problems. The overall or 'ultimate' effect of care on a person's set of health problems can be measured as the resulting change in the person's health adjusted life expectancy.

Clinicians typically think in more granular terms. A **penultimate** or **clinical outcome** corresponds to a new condition or significant change in an existing condition. An **intermediate health outcome** is a test or other markers of condition control or disease activity, such as blood pressure or lipid levels, that cause or correlate with onset of new conditions or changes in existing conditions. For example, a penultimate health outcome, such as a stroke might be triggered by a failure to control an intermediate outcome, such as hypertension.

Table 27.2 Outcomes of health care

- **Health outcomes** – the impact ofhealth care on health problems that threatenlongevity and well-being
- **Resource use** – utilization and cost of units of care
- **Burdens of care for patient and family**
- **Equity** – comparable outcomes and resource use a cross sub-populations for the same set of clinical problems
- **Respect** for the autonomy and dignity of patients

Table 27.3 Measures of the impact of care on health (This categorization is similar to a framework used to categorize recommendations of the United States Preventative Services Task Force. See Jonas, D, et al., Evaluating evidence on intermediate outcomes: considerations for groups making healthcare recommendations, American journal of preventive medicine, 54. S38-S52, 2018; https://doi.org/10.1016/j.amepre.2017.08.033)

The impact of care on health can be measured by changes in -

- **Ultimate health outcomes** – changes in a person's expected longevity and daily well-being (HALE or similar measure)
- **Penultimate or clinical outcomes** – new conditions or changes in existing conditionsthat directly affect longevity or well-being
- **Intermediate health outcomes** – favorable or unfavorable changes in tests and other markers of condition control that correlate with clinicaloutcomes

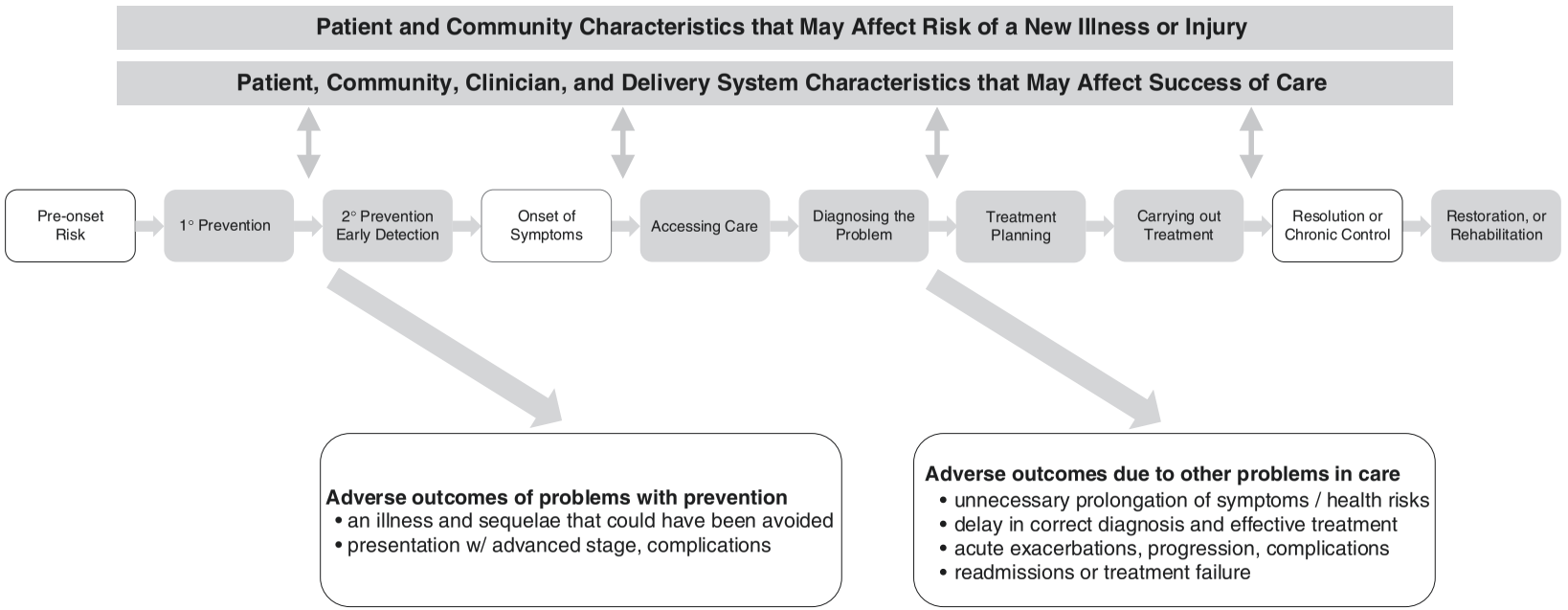
27.3.1.3 Major Clinical Tasks, Units of Care, Choice of Care, and Processes of Care

Health problems typically require successful completion of a set of generic high-level **major clinical tasks** or steps in care, such as initial diagnosis, or one-time or ongoing treatment (Figs. 27.3 and 27.4). A major task specifies what must be accomplished for successful care, not how it is to be accomplished. Major tasks include initial diagnosis, treatment planning, acute or chronic treatment, and supportive or rehabilitative care.

Specific **units of care** are provided to complete such tasks or steps[10] Sometimes, different units of care may be used to accomplish a task. If so, clinicians and patients must make a **choice of care**. After that decision, a **process of care** is initiated to produce the selected units of care. Each unit of care, in turn has a set of processes for each subcomponent of the unit of care; these then are completed. If the completed unit of care success-

[9] AHRQ, Care management: implications for medical practice, health policy, and health services research, https://www.ahrq.gov/ncepcr/care/coordination/mgmt.html.

[10] A unit of care is a service or medication or set of related services and medications provided for its own value in accomplishing a task, not as a supporting component of another unit. For example, a glucose test to monitor care for a diabetic patient is a distinct unit of care, while a routine pre-operative glucose test may be thought of as a supporting component of the surgery.



- This diagram summarizes the 'life-cycle' of a condition and its treatment as well as adverse outcomes resulting from problems at any major step care.
  - **Condition phases** correspond to phases in the life cycle of a condition and are shown in clear boxes (See next chapter for further detail)
  - **Major clinical tasks** correspond to major steps in care and are shown in shaded boxes.
- The downward sloping arrows correspond to problems in care and point to avoidable adverse health outcomes that may result from such problems
- The straight-line path from onset to resolution or control corresponds to a best-case scenario without problems in care and resulting adverse outcomes.
- The two shaded bars at the top correspond to 'root causes' of avoidable adverse outcomes
  - The first bar shows root causes that may result in a new illness or injury that could have been avoided
  - The second bar shows root causes of problems in the care that may result in suboptimal outcomes
- The bi-directional arrows indicate the disruption involved in an illness or care can also affect a person's personal and socioeconomic circumstance

Fig. 27.3 Suboptimal outcomes and care, context, and high-level causes

Major Tasks in Care	Roles and Responsibilities in Care	
	Patient	Clinician
Accessing care	• Make appointment or contact clinician promptly for new problems • Keep scheduled appointments	• Make practice accessible • Provide staff to triage patient phone calls
Diagnosing the problem	• Engage with clinician on a timely basis as to new or changing symptoms or problems in care	• Engage with patient to elicit information and develop trust • Recommend tests or consultation if needed • Identify new illnesses or new problems in care promptly and accurately
Choosing the 'right' treatment	• Ask questions and express concerns about proposed clinical plan to help clinician develop a mutually agreed upon treatment plan	• Recommend referral or consultation if needed • Recommend a treatment plan based on detailed understanding of the patient and of clinical best practices
Carrying out treatment successfully	• Understand and follow the treatment plan, especially self-care at home • Keep follow-up visits, tests, and referrals • Take medications as prescribed • Promptly communicate problems with medications or self-care or changing symptoms or other new problems	• Successfully execute services, such as surgery or therapy, according to applicable clinical norms • Be attentive to issues arising between scheduled encounters, including patient communications, test result, and consultant reports • Communicate and coordinate with other clinical team members involved in the patient's care

Fig. 27.4 Patient and clinician roles and responsibilities for major tasks of care

fully addresses the need defined by the health problem and task, then the next step in care can be addressed; otherwise, a different unit of care may be used, before moving on to the next step.

For example, consider a person with a new **health problem**—mild chest pain. The new problem 'triggers' a necessary **major clinical task** (initial diagnosis). Several tests may be available to accomplish this task. Of these, a specific test, or **unit of care** is chosen. Once chosen, a **process of care** is initiated to produce the test. If the test confirms a diagnosis of coronary disease, the next step is to choose and then implement treatment; if the test is negative, then another test may be provided, and so forth.

Thus, health problems, major tasks, and choice, units, and processes of care are inextricably linked and are represented as such in this chapter and the next. A process of care is an explicit or implicit 'recipe' for providing a unit of care (or a component thereof). An **explicit process** may be a best-practice guideline, a protocol, or a treatment plan recorded in the patient's chart. An **implicit process** is the set, sequence, and timing of services provided to produce a unit of care. Variances between an explicit process and an implicit process (based on care actually provided) may suggest a **process of care problem**. And a variance from a best practice shown to result in better outcomes is strong evidence of an opportunity to improve outcomes.

Table 27.4 Nested framework for organizing care

1. **Health problem** (a health risk, symptom, or condition) 2. **Major clinical task** (needed to address a health problem) 3. **Choice, unit, & process of care** (to accomplish a task) 4. **Actual service / expected step in process**
Example
1. **Chest pain** (a new health problem) 2. **Diagnostic evaluation** (a major clinical task) 3. **Nuclear stress test** (a choice, unit, and process of care) 4. **Image interpretation** (actual service / expected step)

These elements are shown in Table 27.4. A new or ongoing **health problem** is at the top of a nested framework. This problem 'triggers' the need for some type of intervention to maintain or improve a person's health. The second level is a **major clinical task** or high-level step that must be accomplished successfully without needless delays or costs. The third level is a '**unit of care**' that is chosen to address a specific task and is provided through a '**process of care**'. The fourth level in the framework includes records for each service or step actually provided and each service or step required under an explicit process, whether provided or not with actual service dates and expected dates based on the explicit process.

This framework and data structure supports identification of deviations from pre-defined processes and analysis of the impact of such deviations on health outcomes and resource use. Moreover, in cases where no established process exists, the structure enables clinical effectiveness research to identify a best practice that then could be incorporated into the analytic system as a recognized best practice.

This framework mirrors the 'problem oriented medical record' (POMR). A **health problem** corresponds to a POMR 'problem'. Major tasks and units of care correspond to a '**treatment plan**' within the POMR framework [2]. Because the framework proposed here is generic, it supports a comprehensive analytic system that can be automated.

27.3.1.4 Suboptimal Care

As noted, *problems in health care correspond to situations where outcomes could be improved through better use of existing clinical knowledge or methods*. This entails two corollaries. First, suboptimal care relates to the type of care provided (**choice**) and how it is carried out (**process**). Health care is suboptimal if the 'wrong' care is chosen or the 'right' care is poorly carried out. The 'right' care is the care best suited to the patient's health problems and personal circumstance as jointly understood by the patient and treating clinician. The second corollary is that root and mediating causes of problems in care can generally be traced back to actions or characteristics of patients and clinicians (or their social or health care context) because health care primarily involves these participants.

Figure 27.3 shows how problems in care can result in suboptimal outcomes at any step in the prevention or care of a condition. Figure 27.4 shows clinician and patient roles and responsibilities for these steps in care, and Fig. 27.5

Broad Category	Suboptimal Outcome
Suboptimal health and cost outcome (with potential health and cost impacts)	• onset of preventable illness • late presentation of illness (with preventable adverse occurrences) • acute exacerbations (requiring emergency care) or disease progression • illness and treatment complications • readmissions / treatment failures
Potentially avoidable excess unit costs (use of more costly care when a similar lower-cost alternative is available)	• use of a costlier setting when a less costly setting is equally safe / effective • **use of a costlier service or medication when an alternative is equally safe / effective** • use of a costlier provider when less costly provider equally accessible / safe
Potentially avoidable units of care (cost impacts only)	• use of care that has little expected net benefit

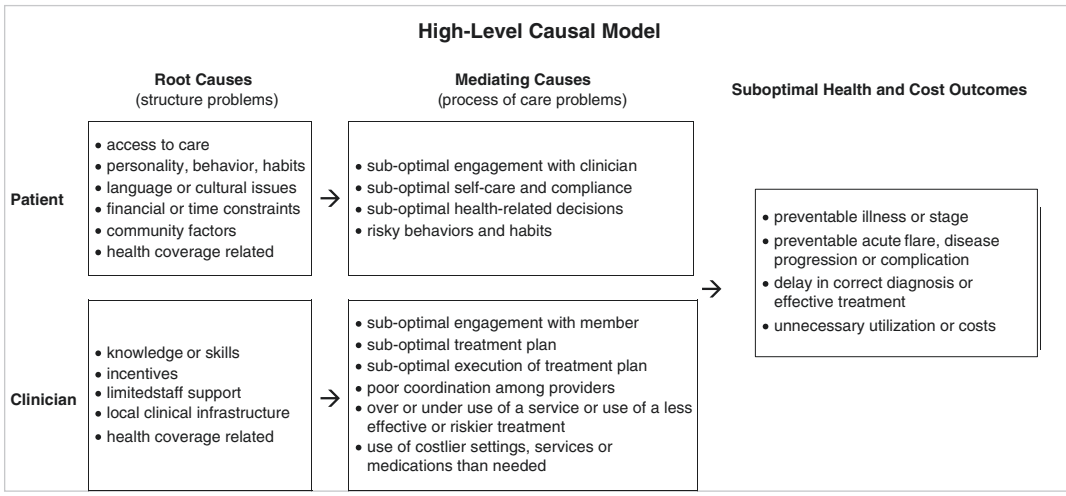


Fig. 27.5 Types of suboptimal outcomes and root and mediating causes

shows root and mediating causes of suboptimal outcomes related to these responsibilities. With that background, how can problems in care be identified? Such problems can be identified through comparisons among subgroups of patients who are comparable (except with respect to choice or process of care). Three main types of comparisons can be made.

First, clinical outcomes can be compared. This approach directly identifies subgroups with poorer outcomes but may be impractical for routine operational (non-research) use, if adverse outcomes are rare or develop slowly over a multi-year period during which multiple providers and types of care might be involved. Moreover, such comparisons provide little or no insight as to how outcomes could be improved (Table 27.5).

The second approach is to compare intermediate outcomes that predict or are correlated with clinical outcomes. This approach does not have the disadvantages just discussed, and provides a target for corrective actions, but has two limitations of its own. First, intermediate outcomes similar to blood pressure levels do not exist for all conditions. Second, there should ideally be evidence from a well-controlled study that the intermediate marker is causally related to an important clinical outcome or alternatively a very strong clinical basis for such belief.

The third approach is to compare process of care. If process differs in ways that are *thought to be clinically important*, then again, a problem in care is possible. Process comparisons have the strong advantage of being able to target specific problems for corrective interventions, but process measures need to be validated as predictive of clinical outcomes through research or compelling clinical logic. For process comparisons, an explicit or implicit norm is used to compare actual and expected care. This norm can be in the form of a recognized best practice, or a calculated statistical norm, or the intended treatment plan for the patient as recorded by the patient's physician or (other authorized clinical staff) in the patient's EHR.

Perhaps unfairly, it seems that the current set of commonly used process measures, while helpful, do not appear to fit into a systematic framework, which thereby adds complexity to their maintenance and implementation [3]. The conceptual framework of major tasks related to sub-tasks presented in this chapter and the next can be used to systematize process of care measures. Indeed, systematization, validation, and creation of a comprehensive set of process measures would itself be a major goal and major contribution of a future analytic system. For such process measures to be embraced and used daily, they must be seen by the provider community as important and helpful aids for improvement, rather as than rote items on a punch list performed only to meet an administrative requirement.

Table 27.5 Three ways to identify suboptimal care

Comparison of --
• **Clinical or 'penultimate' outcomes**, such asneed for emergency care, symptoms, or complications • **Intermediate health outcomes**, such as elevated blood pressure or glycated hemoglobinlevelsthat cause (or correlate with) adverse clinical outcomes • **Process of care**, such as delays in diagnosis or treatment, poor compliance, etc. that correlate with clinical outcomes
Three Ways to Identify Problems in Diabetes Care
Comparison of--
• **Diabetes complication rates** (penultimate outcomes) • **Glycated hemoglobin levels** (intermediate outcomes) • **Medication compliancerates (**process of care**)**

27.3.1.5 Root and Mediating Causes of Suboptimal Care and Outcomes

Figures 27.3 and 27.5 together sketch a high-level taxonomy of suboptimal outcomes and a high-level model of root and mediating causes. *Root causes of a preventable conditions* can be traced back to environmental, occupational, community factors, as well as personal or family factors, behaviors, habits, and attitudes. *Root causes of suboptimal care for ongoing conditions* can be traced back to a partially overlapping set of patient, clinician, community, and local delivery factors. Social determinants and other root causes at a census tract level can be sourced from pub-

licly available data and can be collected at a patient level, if relevant to care, in EHR systems. Mediating causes of suboptimal health outcomes correspond to choices, behaviors, or processes by patients and clinicians that directly affect health care and outcomes. These in turn are influenced by root causes as described above. Figure 27.4 summarizes patient and clinician roles and responsibilities in care while Fig. 27.5 shows how joint patient and clinician choices and processes affect outcomes as mediating causes.

Computed measures based on EHR data can be used to characterize these mediating causes and analyze their impact on outcomes. As an example, consider ambulatory management of a chronic condition such as asthma. To avoid acute flares or disease progression, patients and clinicians need to work closely together on a long-term basis. Choosing right medications, using them daily, keeping scheduled follow-up visits, and communicating and responding to at-home problems are all important for successful care. Computed measures for each of these would be important predictors and mediating causes of adverse outcomes.

Understanding root and mediating causes of suboptimal care has been a traditional focus of health service research. But the key difference proposed here is that now, research-based insights and methods could be embedded in an ongoing, continuously updated system that could help improve care in thousands of settings across the country. A systematic approach would organize, curate, validate, and use causal information to help improve care across a comprehensive range of problems. Moreover, ongoing analysis would guide and prioritize iterative improvements in causal logic. Such improvements can then be incorporated into new versions of the system. Concisely stated, to make significant progress in this domain, all analytic elements including, root and mediating causes, health problems and outcomes, utilization and process measures must be available for analysis within an integrated system. Fragmented or siloed approaches simply cannot capture the full value that is there.

27.3.2 High-Level *System* Requirements

An ***analytic system*** has additional requirements beyond those needed for a single project. Table 27.1 summarizes system building blocks with details provided in the next chapter.

27.3.2.1 An Integrated, Comprehensive System

The system must have a consistent conceptual framework and terminology that fits naturally and comfortably with well-established public health and clinical concepts across all aspects of health and health care. This is fundamental if the system is to provide internally consistent answers to a broad range of important questions in a manner that is trusted, sustainable, and understandable.

Moreover, to provide greatest benefit, the system must be comprehensive in range and in scope—covering all threats to health and all interventions to improve or maintain health and as well as all factors that may blunt the impact of an otherwise effective and appropriate interventions in individual cases. The idea is to develop first a logical structure that works well across the full range of questions, and then to populate the structure incrementally in successive versions of the system.

27.3.2.2 A Generalized Conceptual and Causal Model That Can Be 'Localized' to Specific Health Problems

To support a comprehensive range of analytics, the system must be based on a generalized conceptual and causal model of health and health care using generalized concepts, definitions, and methods that can be 'localized' to specific issues and problems defined in highly specific, clinically meaningful terms. When used with a standardized analytic patient history, this approach can be automated to answer a myriad of important questions even before these questions are asked by specific end-users.

For example, a high-level conceptual framework for identifying factors that increase the likelihood of complications of an illness or injury or its treatment can then be applied to all illnesses, injuries, treatments with suitably structured input data and algorithms. The results can then be used to expand clinical knowledge of causative factors, support retrospective analysis of complications and their causes for quality improvement at any organizational level of care, from micro to macro, and support predictive models to target preventive interventions for individual patients. Through this approach, what seems like a myriad of analyses can be reduced to a single set of high-level analyses that can be automated.

27.3.3 Questions the Analytic System Will Answer

While there are many specific questions that need to be answered to improve health and health care, such questions are specific instances of the small set of high-level 'meta' questions listed in Table 27.6. This helps to explain how a well-designed system can answer important questions in a manner that is consistent, understandable, sustainable, and efficient.

Table 27.6 Analytic use cases and related high-level questions

A.General health and health-care related research[14] • **What happened and how does it compare?**(*description*) • **What are the causal effects?** (*causal inference*) • **Can we predict what will happen?** *(patient level prediction)*
B.Identifying opportunities for systematic improvement • How do outcomes compare? Do results suggest a problem? • Can a *possible* cause of an adverse outcome be identified? • Can the causal effect be confirmed and quantified? • Are any of the causes of such differences correctable? • What is the likely effect on outcomes of such correction?
C.Providing individualized patient support and advice • Is this patient at high-risk of an adverse outcome? If so, how can such risk be avoided or mitigated? • What are the short- and long- term effects on outcomes and burden of care for this patient of a specific clinical options?

One way to understand this approach is to sketch the components of an analytic modeling file that would be used to answer a specific question. The basic components are analytic records or 'observations' for members of a study cohort or unit of analysis of interest with accompanying variables that define an outcome of interest, a factor whose effect is being studied, and covariates or confounders. The next sections show how the analytic use cases and questions in Table 27.6b, c can be addressed.[11]

27.3.3.1 Identifying Actionable Opportunities for Systematic Improvement (Table 27.6b)

The first step for identification is to compare outcomes for 'comparable' cases. For example, a difference in readmission rates between hospitals may suggest a process of care problem, if hospital admissions are fully comparable in terms of 'biologic' factors likely to affect complications. Such 'biologic' factors include characteristics of the illness or injury being treated, the treatment provided, and ongoing comorbidities (including genetics) that might affect outcomes but would exclude process of care markers that might contribute to readmission rates. Thus, any variation in outcomes not explained by biologic factors would be due to process of care, or unobserved biologic factors, or chance.

The next step in the analysis is to add process of care variables that might affect outcomes. If these added variables reduce unexplained variation in outcomes, then process issues likely contribute to differences in readmission rates. Further analysis can quantify the effect of specific processes on outcomes and put a limit on the extent to which unobserved confounders might result in a spurious causative effect.[12]

[11] Research questions in Table 27.6a can be answered in a similar manner, but with greater customization. Lessons from research then can be used to expand the set of questions that are answered in a more structured manner in Table 27.6b, c.

[12] See references at Footnote 16.

If a process problem has a significant causal effect on outcomes, then the next step is to identify possible root causes of the identified problem. For example, consider a study focused on preventing acute flares of asthma; a process analysis might identify medication compliance as an important mediating cause. In this case, the next question would be to identify factors that might cause poor medication compliance in asthma. Similar methods would be used to identify the root causes of identified process of care problems.

Figures 27.3 and 27.5 provide a sketch of a high-level causal model applicable that could be used for systematic identification of mediating and root causes for any avoidable adverse health outcome or costs. Systematic identification of possible corrective interventions by practices, hospitals, and health systems to improve health outcomes or costs would be supported by the causal analysis described here.

Each such process or mediating cause can be traced back to one or more structural issues or 'root causes' that may compromise the ability of a patient or clinician to do what is needed.[13] Root causes for patients include financial barriers, work and family pressures, language barriers, or other social or behavioral factors. Root causes for clinicians include training, knowledge, skills, incentives, clinical support or organizational issues, or gaps in the local health care delivery system. Figure 27.5 defines categories of avoidable adverse outcomes and costs and presents a high-level causal model that traces suboptimal outcomes to mediating causes and root causes (e.g., to process and structure).

27.3.3.2 Providing Individualized Patient Support and Advice (Table 27.6c)

Identifying high-risk patients—Analytics can identify patients at high risk of adverse outcomes. Physicians and care managers can then focus special attention on these patients. Analytics could also identify the most important causes of risk for each identified patient. Patient-focused interventions could then be focused on these causes. Details of the analytics involved will not be provided here. The key take-away point is that such analysis would be facilitated by the proposed future analytic system.

Advanced clinical decision support—A future analytic system also would support advanced patient-centric clinical decision support (CDS) systems.[14] An advanced system would predict both short- and long-term impacts of treatment options in contexts that involve 'serious' or 'critical' risks for the patient. Consequently, such systems must be held to the highest possible standards of accuracy, validation, peer review, and transparency.[15]

The approach suggested here *would not* substitute artificial intelligence for clinical judgement. Today, we rely on clinical judgment informed by well-designed studies. This is what evidence-based medicine is all about. The only change is that a future analytic system could greatly expand the number and range of well-designed studies that serve as the basis of

[13] This framework is consistent with Donabedian's well-known 'structure – process – outcomes' paradigm, Donabedian A, The quality of care: How can it be assessed? JAMA. 260 (12): 1743–8, 1988. The framework also is consistent with a more general causal inference methodology and framework, developed a statistical and data science perspective. *See* Imbens GW, Rubin DB, Causal Inference for Statistics, Social, and Biomedical Sciences: An Introduction, 2015; Rosenbaum P, Observation and Experiment: An Introduction to Causal Inference, 2019; and Pearl J, et al., Causal Inference in Statistics, 2016.

[14] Office of the National Coordinator (ONC) for health information technology, Clinical Decision Support, https://www.healthit.gov/topic/safety/clinical-decision-support; National Academy of Sciences, Clinical Decision Support, 2018; Sutton RT, et al. An overview of clinical decision support systems: benefits, risks, and strategies for success, npj Digit. Med. 3, 17 (2020). https://doi.org/10.1038/s41746-020-0221-y.

[15] The Food and Drug Administration intends to regulate some categories of CDS because of potential risks to patients. *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software. *Also see* International Medical Device Regulators Forum, IMDR Software as a Medical Device, Possible Framework for Risk Categorization, and Corresponding Considerations, 2014, which the FDA cites, http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf.

evidence-based medicine in the future and that the system would support individualized predictions of patient outcomes for treatment based on matching patient and clinician characteristics to observed outcomes for comparable patients.

It also is crucial that such analytics be fully transparent and understandable. The language and concepts of medicine must be central components so that clinicians fully understand and are fluent and comfortable with the underlying studies and associated on-demand predictions, just as they are today after reading results of a study published in a well-regarded peer reviewed journal. This is important to ensure that both the clinician and the patient understand the issues involved.

27.4 Conclusion

Today, the technology exists to transform clinical data into information necessary to help improve health care systematically and for individual patients. Secured web-enabled tools would simultaneously meet the needs of diverse audiences with a set of consistent metrics. Access to different levels of detail and summarization would be controlled to ensure that individual users can only see that slice of the information that they need to know about. Users could range from patients and front-line doctors and nurses to clinical managers and medical directors in hospitals, medical practices, and health plans, to purchasers and health plans, and to local, regional, or national officials. For example, patients with diabetes, doctors and nurses who care for patients with diabetes, and appropriate managers and public health officials could all view the same metrics that detail the cost and quality of care provided for diabetes focused to be relevant to each user's needs and restricted to ensure confidentiality. Tools of this sort could facilitate enormous improvement.

The simple conceptual framework and accompanying analytic patient history presented in this chapter and the next together encapsulate the diversity and complexity of health and health care. As a result, the work involved in developing a comprehensive analytic system can be completed successfully more easily, more rapidly, and at a much lower cost than might otherwise be expected. And such an approach ensures that the resulting system provides key information in a manner that is consistent, understandable, transparent, trusted, and sustainable.

The more difficult task is reaching agreement as to how to organize and provide these resources and under what terms. Another difficult question is how to obtain and pool the data needed for more advanced implementations. A good start has been made by one of us (Bandeian) using health insurance claims data to power the analytics. But clinical data will be needed if doctors and patients are to be able to rely on the information for critical decision-making. Moreover, for many questions, millions of patient records will need to be pooled to support robust estimates across the spectrum of illnesses and treatments. How can this be done?

Imagine a future when you and your physician can discuss treatment options with the benefit of statistically valid estimates of likely options. Isn't this something that everyone would want for a family member with a serious illness?

It can be said that we face many possible futures and that we have many possible paths to the future. In this case, the future seems clear. Analytics will become embedded into the daily fabric of health care. Fifty years ago, this would have been impossible. If we collectively have the will, as soon as 5–10 years from now it will be difficult for doctors and nurses to imagine how health care could be provided without ready access to data. The stakes in health care are simply too great for continued reliance on informal means of identifying and resolving problems. At the same time, with the cost of data capture dropping and with the range of data capture growing due to technology, widespread implementation of analytics will be possible for the first time in history.

What remains uncertain is the path whereby we get to the future and how long it will take. There are many cultural and social issues involved. Perhaps we in the United States will get to the future state first, perhaps not. It is hard to

see how we will be able to attain national goals regarding health care quality and cost without moving forward with a strategy for health care analytics.

As a nation, we face major challenges with respect to health care. An analytic system could help give all participants in our health care system from front-line clinicians to national policymakers a shared understanding and a detailed, comprehensive, and consistent view of the way forward.

Ideally, the policy community should consider the national value of a shared and comprehensive analytic infrastructure. If there is consensus as to the benefits, then stakeholders and the policy community should work together to accelerate realization of this vision.

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28 A Future Health Care Analytic System (Part 2): What is Needed and 'Getting It Done'

Stephen Bandeian, Christopher P. Tompkins, and Ashwini Davison

Abstract

This and the preceding chapter propose a collaborative initiative to develop a comprehensive analytic system as a shared national resource to help improve our nation's health and health care. This chapter provides further detail on requirements and building blocks of the system and a high-level summary of steps to move from concept to completion of an initial version that would be iteratively enhanced.

A central 'building block' of the system is an '**analytic patient history**' that faithfully mirrors the actual course of prevention, illness, diagnosis, and treatment at a patient level, but organizes concepts and interrelationships needed for analytics. This approach supports comprehensive and systematic measurement of health outcomes, resource use, equity, and supports identification of problems in care and their root and mediating causes.

The key initial step needed to build the proposed system is to secure consensus from stakeholders and funding agencies as to the general approach proposed here and the likely benefits of such a system. The next step would be a proof-of-concept prototype, followed by an initial version that would be ready for use, and then followed by iterative enhancements that extend and improve the analytics supported.

Learning Objectives

- To understand the building blocks for a future system to support research and applied analytics to improve care on an ongoing basis
- To understand the need for broad collaboration and buy-in for success, consensus on elements of the future analytic system, and planned, coordinated, and phased development

28.1 Introduction

28.1.1 Overview of This Chapter

In the preceding chapter we laid out the rationale for a collaborative initiative to build a comprehensive analytic system and provided a sketch of benefits and high-level requirements. In Sect. 28.2 of this chapter ('Building Blocks'), we provide additional detail on requirements to emphasize that the proposed future system is well-thought out and can serve as the basis for collaborative discussion leading to an-agreed

S. Bandeian (✉)
Elevance Health, Bethesda, MD, USA

C. P. Tompkins
Brandeis University, Waltham, MA, USA
e-mail: tompkins@brandeis.edu

A. Davison
Johns Hopkins University, Baltimore, MD, USA

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upon plan. In Sect. 28.3 ('Getting it done') we lay out a step-by-step road map for building an initial prototype followed by a working system.

28.1.2 Recap from Previous Chapter

For many years, studies have identified problems in quality or cost of care in the United States.[1] Our system seems almost unable to respond to these findings. While structural reforms and new incentives may be needed, doctors, nurses, administrators, patients, employers, payers, public health officials and policy makers *all need ready access to better information to optimize costs and outcomes*.[2] Research is important, but *what is essential for 'bending the curve' on national trends is to make actionable information readily accessible in local settings of care. Only there, where care is delivered, can care be improved. To do this, an ongoing analytic system is needed.*

To help improve care to the greatest extent possible, a future analytic system should be:

- Tightly integrated with daily processes of care to provide 'on-line' support for process improvement, for care management, and for joint clinician—patient decision making,
- Provide access to information relevant for a broad range of decisions and processes of care, whether at the level of a patient, a practice, a hospital, or a health system, or a locality, state, or nation,
- Implemented in an ongoing, sustainable system capable of answering a broad range of questions in a methodologically sound, trusted, peer-reviewed, transparent, and understandable manner,
- Comprehensive, integrated, and internally consistent across the full range of health care problems and treatments, because patients often have multiple problems and treatments at the same time.

The system should progressively be able to:

- Measure health outcomes, resource use, equity, and other outcomes of care at the level of an individual or a population or at different loci of health care delivery ranging from micro to macro
- Identify and measure instances of suboptimal care and opportunities for improvement, the causes of any associated problems, and the likely impact of possible corrective interventions
- Identify high-risk patients for care management or other risk mitigation
- Provide trusted estimates of expected health outcomes for treatment options that reflect characteristics of the patient and the patient's clinical history to assist joint clinician—patient decision making
- Support research to expand the evidence base of medicine

Three high-level requirements follow logically from these principles:

- *Source data and building blocks should be sufficient in scale, scope, and type such that well-known sources of bias that compromise validity or generalizability of analytic inferences can be minimized*
- *Building blocks should be use-case independent to be able to support a broad range of analytics*
- *Unifying definitions, conceptual and causal models, and analytic methods* are essential if the system is to produce a consistent and comprehensive results that are understandable and sustainable

Without a unifying framework, a plan, and a nationwide collaborative process, health care analytics could easily become a complex, 'unknowable' and costly 'Tower of Babel'.

[1] See e.g., E. A. McGlynn, S. M. Asch, J. Adams, et al. The quality of health care delivered to adults in the United States. N Engl J Med 2003; 348:2635–2645.

[2] One commonly discussed reform, pay-for-performance, cannot succeed without a new generation of information tools both to rank performance and to help providers identify the steps they need to take to improve.

28.2 Building Blocks

The building blocks described here are intended to serve as a basis for discussion and consensus and subsequently, with revision, as a roadmap for development of the future analytic system.

28.2.1 Outcomes of Health Care

To help improve care, the future analytic system must be able to define and measure outcomes of health care that are of universal interest and importance (Table 28.1).[3]

28.2.1.1 Health Outcomes

'Optimal' health for a person can be defined as the absence of markers, such as health risks, symptoms, conditions, or complications likely to result in premature death or disability. So, aspects of health (but not health itself) can be measured by identifying and counting such 'health markers' at the level of an individual, cohort, or population.

The health impact of a health risk, symptom, condition, or complication depends on its detailed characteristics (which may vary over time). For example, an ankle facture can range from simple and easy to complex and difficult to treat depending on specifics. And a single patient condition, such as heart failure, may have acute reversible flares and may worsen progressively over time. Impact also depends on duration. All other things equal, a risk, a symptom, or a condition of longer duration will have greater health impact than a similar one with shorter duration.

Counting and characterizing risks, symptoms, or conditions (such as counting the number of persons with heart failure in a population) is important for many purposes. However, this approach is incomplete. There are thousands of 'health markers,' each with a different health impact. So, for measurement and comparisons, it is helpful to map each marker onto a common yardstick of impact on the longevity and well-being.

Health adjusted life expectancy (HALE) provides this yardstick by combining the longevity and well-being impacts of multiple health problems into a single measure of health.[4] HALE therefore allows one to characterize a person or population as 'healthier' or 'sicker' than another; something that cannot otherwise be done. For this reason, HALE should eventually be included in a future analytic system to measure and help improve the health of a population[5] or to measure the impact of an illness or a treatment on longevity and well-being. (Provider organizations also could use HALE to prioritize opportunities for improvement.)

28.2.1.2 Clinical Resource Use

Resource use for an illness or injury can be measured simply by counting related units of care,

Table 28.1 Outcomes of health and health care

- **Health outcomes** – the impact of risks, conditions, and sequelaeon longevity and well-being
- **Resource use** – utilization and cost of units of care
- **Financial and other burdens of care** for patientsand family
- **Equity** – comparable outcomes and resource use across sub-populations for the same set of clinical problems
- **Respect** for the autonomy and dignity of patients

[3]The set of five health care related outcomes presented here overlap with the 'triple aim' of the Institute for Healthcare Improvement, http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx.

[4]The World Health Organization (WHO) defines HALE as the "… average number of years that a person can expect to live in 'full health'… taking into account years lived in less than full health due to disease and/or injury". https://www.who.int/healthinfo/statistics/indhale/en/; A related approach, the 'global burden of disease is used by the Institute for Health Metrics and Evaluation (IHME) for yearly surveys of disease burden by country; http://www.healthdata.org/gbd/about.

[5]Bushnik T, Tjepkema M, and Martel L, Health-adjusted life expectancy in Canada, 2018. https://www150.statcan.gc.ca/n1/pub/82-003-x/2018004/article/54950-eng.htm. A HALE measure also has been implemented in the US on person/year basis including all symptoms and conditions reported for each person/year with claims data as input; Blue Cross Blue Shield Health Index, https://www.bcbs.com/the-health-of-america/health-index.

such as hospital stays. A unit of care can be defined as an individual service or set of related services intended to address a specific diagnostic or therapeutic need. As such, a unit of care can range from a fasting glucose to screen for diabetes to a multi-week course of chemotherapy with all supporting components. Depending on the question being addressed, the appropriate unit of care might range from 'micro' to 'macro' as discussed in Sect. 28.2.2.3.

Counting units of care is important and helpful, but units vary widely in resources used. So, once again, a method is needed to map units of care to a common yardstick. The obvious choice is cost. Perhaps the best way measure cost is to use a 'standardized' cost that is independent of the unit price or 'allowed' charge for the service as recognized by a payer [1].

28.2.1.3 Burden of Care on Patient, Family, or Caregivers

Such burdens are an important outcome of care and should be included in a future analytic system that would measure and predict such burden over a wide range of clinical contexts both because burden of care is important *per se*, and because a mismatch between ability and burden may result in process failures and adverse outcomes. Out-of-pocket health care cost for patients can be measured (perhaps incompletely) with claims data. Other measures of time and burden should be surveyed, and development of new measures (if needed) should be incorporated into plans for the analytic system.[6]

28.2.1.4 Equity

Equity can be measured by comparing health outcomes or resource use between a potentially disadvantaged subpopulation and the general population. This can be done if the data set includes elements that can reliably and usefully identify potentially disadvantaged subpopulations and has adequate controls for confounders. Such elements are currently captured to some extent in clinical data, but improvement is a priority.

28.2.1.5 Respect for the Dignity and Autonomy of Patients

This fifth measure domain of health care requires specialized data collection to measure. AHRQ's Consumer Assessment of Healthcare Providers and Systems (CAHPS) includes well-designed and validated questions directly on point.[7] This approach should be extended to a greater range of clinical encounters and included in the future analytic system to identify problems related to respect on an ongoing basis and identify potentially correctible causes of adverse outcomes resulting from problems with doctor-patient communication, as discussed below.

28.2.2 A Standardized Longitudinal Patient History as the Primary Input for Analytics

The central element of a future analytic system is a standardized and privacy-protected patient history optimized for analytics (Table 28.2). This **analytic patient history** faithfully represents details of a person's history of health and health care in clinically meaningful terms that does not focus too narrowly on any specific use case. Multifunctionality is not otherwise possible because each analytic use case has its own distinctive requirements.

The analytic patient record would be sourced from granular clinical data, such as that based on OMOP common data model,[8] and would synthesize such data into an easy to understand and easy to analyze patient history. Supporting algorithms

[6]Burden of care questionnaires have been developed. See for example Eton D, et al., Development and Validation of the Patient Experience with Treatment and Self-Management (PETS): A Patient-Reported Measure of Treatment Burden, Qual Life Res. 2017; 26(2): 489–503. Published online 2016 Aug 26. https://doi.org/10.1007/s11136-016-1397-0.

[7]https://www.ahrq.gov/cahps/index.html.

[8]Observational Medical Outcomes Partnership (OMOP) Common Data Model, https://www.ohdsi.org/data-standardization/the-common-data-model/.

Table 28.2 Analytic patient history

Health Problems and Health Outcomes (Figure 1)
- **Health summary** – health adjusted life expectancy reflecting a person's set of health problems during a defined period
- **Risk factors** that may result in illness or injury or impede treatment (genetics, socioeconomics, behaviors, etc.)
- **Pre-onset risk** of a condition
- **Conditions** (new or ongoing illnesses and injuries)
  - **Working diagnoses** for a condition
- **Condition status** (a change in control, acuity, or stage)
- **Symptoms, findings, and complications** of a condition

Units and Processes of Care (Figure 2)
- **Major clinical task** (a necessary high-level step in care)
- **Multi-day clinical intervention** (a treatment episode)
- **Clinical event** (an inpatient stay or ambulatory encounter)
- **Single-day clinical interventions**(a test or treatment)
- **Service or 'micro-step'**(a component of an intervention)

would organize source data into a set of '**analytic constructs**' that mirrors real events as observed by clinicians and patients. Such constructs can then be queried to answer a comprehensive set of questions.

As noted, optimal health can be defined as the absence of risks, symptoms, or conditions likely to result in premature death or disability. Thus, a person's health can be assessed in these terms. Health care, in turn, is the intersection of a person's set of risks, symptoms, and conditions with units of care and processes of care to prevent, diagnose, or treat this set.

28.2.2.1 Tracking a Person's Health Problems

The first component of the analytic patient history (shown in Fig. 28.1) is a set of tables that capture health problems that are determinants of a person's health as they change over time. *A new or changing health problem typically triggers a need for care or a need to change care*.

The '**person**' table includes one record for each person in the data set with an encrypted

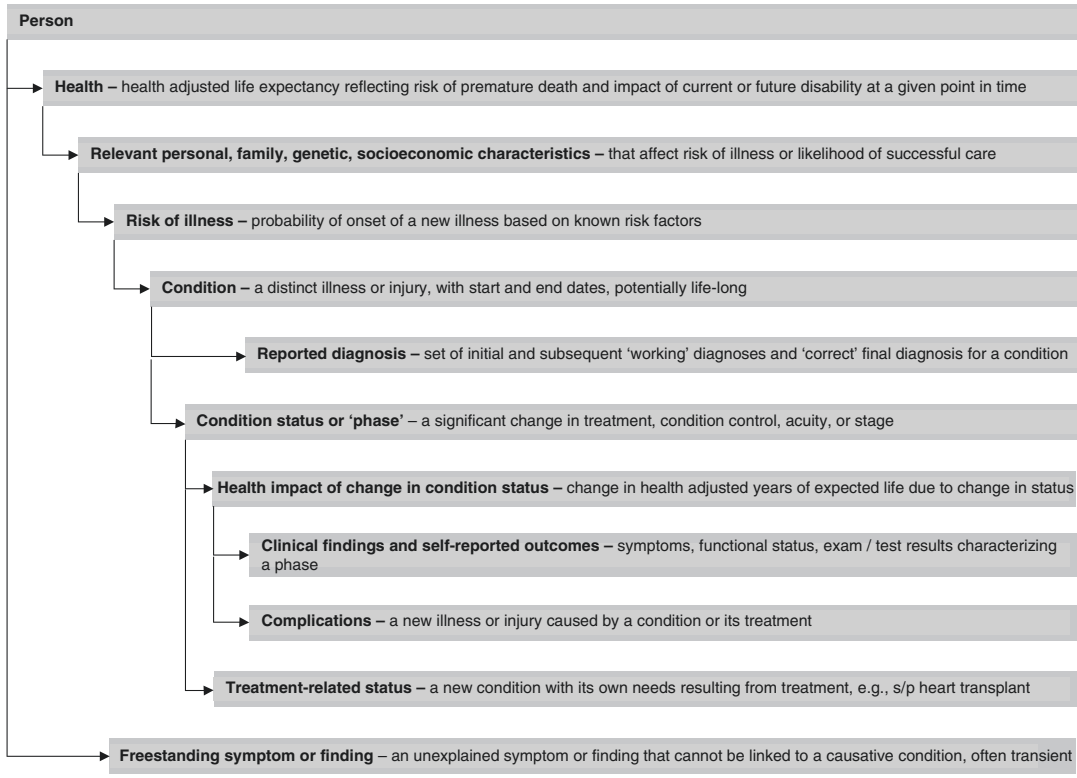


Fig. 28.1 Tracking a person's health and health problems

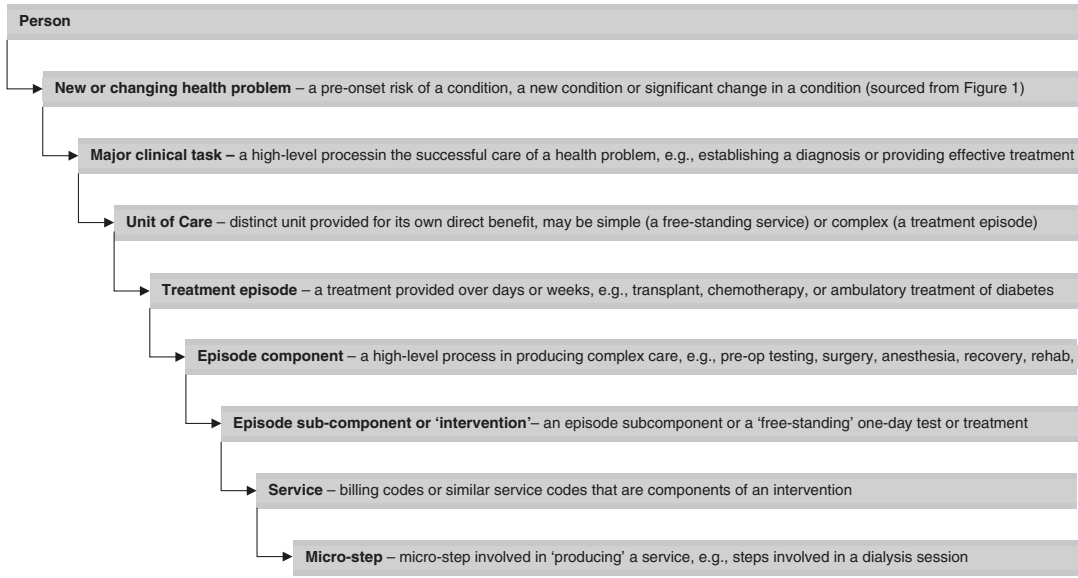


Fig. 28.2 Organizing services into clinical meaningful units of care suitable for analysis

identifier, date of birth (and date of death). The encrypted identifier allows linkage of all other tables in the analytic patient history. The '**heath summary**' record includes one record per person per time-period with the person's estimated health adjusted life expectancy (HALE) during the period. The calculation of a person's HALE is dependent on many of the elements in Fig. 28.1.[9] A new record for the person is added upon change of any of factors involved in the person's HALE calculation. For example, a person's HALE will decrease with poor control of diabetes or with diagnosis of a new cancer and will subsequently increase if such risks are successfully treated.

The '**personal/socioeconomics**' table organizes patient characteristics that *may affect the risk of a new condition* ***or*** *the likelihood of successful care*. Factors that might affect these risks include age, gender, family structure, genetics, family medical history, occupational exposure, socioeconomic factors, and personal behaviors.

The '**risk of illness**' table has a record for each illness for which the person has a calculatable risk, with the probability of illness during a time-period. For example, the system would include each person's risk of coronary disease based on Framingham epidemiologic risk models.[10] Over time, epidemiologic research supported by data tables in the system will itself be used to develop new 'Framingham-type' models for other conditions and to refine existing models.

The '**condition**' table includes one record per patient/condition. Each record corresponds to a distinct instance of an illness or injury. Both fully resolved and ongoing conditions are included. Each record would carry a set of attributes, such as the specific condition diagnosis (using ICD10 or other coding), flags indicating whether the condition is resolved or ongoing, onset and resolution dates and first and most recent encounter dates.

The '**condition status**' table reflects the fact that the status of an illness or injury may change over time and subdivides each condition episode

[9]Full discussion of the calculations needed for granular and personalized HALE estimates are beyond the scope of this chapter.

[10]Framingham Heart Study, https://framinghamheartstudy.org. Framingham prediction models were integrated into the prototype analytic system that one author of this paper (Bandeian) developed while at AHRQ; documentation available upon request.

into sequential **condition phases** or time periods that correspond to such changes. Changes in status may reflect treatment, for example, a fracture before or after repair. For chronic conditions, changes in status may reflect treatment or significant changes in condition control, acuity, or stage. Each such change in status has a distinct impact on health (and therefore HALE) and also has distinct treatment or resource needs. Accordingly, a change in condition status may trigger a need to reassess and potentially change the care being provided.

The '**clinical findings**' table includes a record for each symptom, test result, or other findings relevant for a condition on the date observed. Significant changes in such findings would be the basis for 'triggering' a new condition phase and would be reflected as a new record in the condition status table. For example, a new symptom of dyspnea at rest (with supporting findings) would end a previous phase of 'well-controlled' heart failure and start a new 'acute flare' phase.

The '**complications**' table contains one record for each complication and possible cause (a condition or treatment) with a probability for each such cause.[11] For example, deep venous thrombosis (DVT) as a complication might be linked to preceding hip replacement surgery or heart failure as causes. The probabilities for each cause would depend in part on timing. So, hip replacement is more likely as a cause if the DVT occurs soon after surgery and less likely 6 or 12 months thereafter. By this means, a most likely cause of the DVT can be identified. Because of this architecture, the complications table provides a way to quantify the total direct and indirect impact of a condition or a treatment on health and resource use and therefore is of value to a broad range of analytic questions.

[11]The linkage between causes and complications can be more complex than that presented here. Specifically, a condition or treatment may trigger a chain of complications. For example, pneumonia → sepsis → shock → stroke. Such a chain of complications can be derived from the complications table and can be made part of the analytic history.

The '**working diagnosis**' table has one record for each reported working diagnosis (including the correct final diagnosis) for a presenting set of symptoms and findings. Each reported working diagnosis reflects a point-in-time clinical judgment as to most likely diagnosis. As more data becomes available, the current working diagnoses may change. For example, suppose presenting symptoms of weakness, fatigue, and dyspnea on exertion are reported as heart failure on May 1. Suppose that a month later, on June 1, with additional information, clinicians conclude that the condition is, in fact, constrictive pericarditis. The working diagnosis table would have two records for the condition, one from May 1 through May 31 for heart failure and the next starting on June 1 for constrictive pericarditis and ending with successful surgery. This allows for identification of instances of delayed or incorrect diagnosis and for measurement of health risks, symptoms, and resource use resulting from such delays or errors.

28.2.2.2 Need, Choice, Units, Process, and Norms of Care

The second major component of the analytic patient history organizes **need**, **choice**, **units**, **process**, and **norms** of care in a consistent and logical framework (Figs. 28.2 and 28.4) that supports a comprehensive range of analytics.

- A **need for care** is a norm or expectation that is triggered by a new or changing health problem or by a new step in the overall process for a health problem
- A **choice of care** is made when a specific unit of care is chosen to address a health problem
- A **unit of care** is a service or medication (or an integrated set thereof) provided to directly address a specific health problem (and not as a supporting component of another unit of care)
- A **process of care** is the set, sequence, and timing of services or steps used to produce the unit of care that is **needed** and or **chosen** to address a health problem.
- **Norms of care** specify need for care and optimal choice and process of care and serve as a basis for comparing actual care to expected care (Table 28.3).

Table 28.3 Norms for assessing choice or process of care

- Formally recognized, evidenced-based normshown to improve outcomes
- Professionally recognizednorms thought to improve outcomes, but with a lesser evidence base
- A benchmark (or model) developed through statistical analysis that may be useful for comparisons,
- A treatment plan for the patient as recorded in the patient's medical history (and as agreed upon by the patient)

As discussed in the preceding chapter, care is suboptimal if no care is provided to address a need, or the 'wrong' care is provided, or the 'right' care is chosen, but is poorly provided due to process of care problems. Evidence-based or professionally endorsed norms provide guidance to as to need, choice, and process. For example, norms established by the United States Preventive Services Task Force specify need, modality of care, and process of for breast cancer screening and for primary prevention of coronary artery disease.[12] Actual care can be then compared to these expectations. In the absence of a recognized evidence-based or professional norm, statistical norms can be used. A treatment plan recorded in a patient's medical history also can serve as a benchmark for comparisons thereby identifying and distinguishing variances attributable to the clinical team or patient.

A major goal of the future analytic system is to characterize choices, units, and processes of care and determine their impact on health outcomes and resource use. This would lead to an ever-increasing set of evidence-based best practices that can be formally recognized as such and incorporated in subsequent iterations of the analytic system. The system architecture proposed here is intended to facilitate this effort.

28.2.2.3 Organizing Units and Processes of Care for Analysis

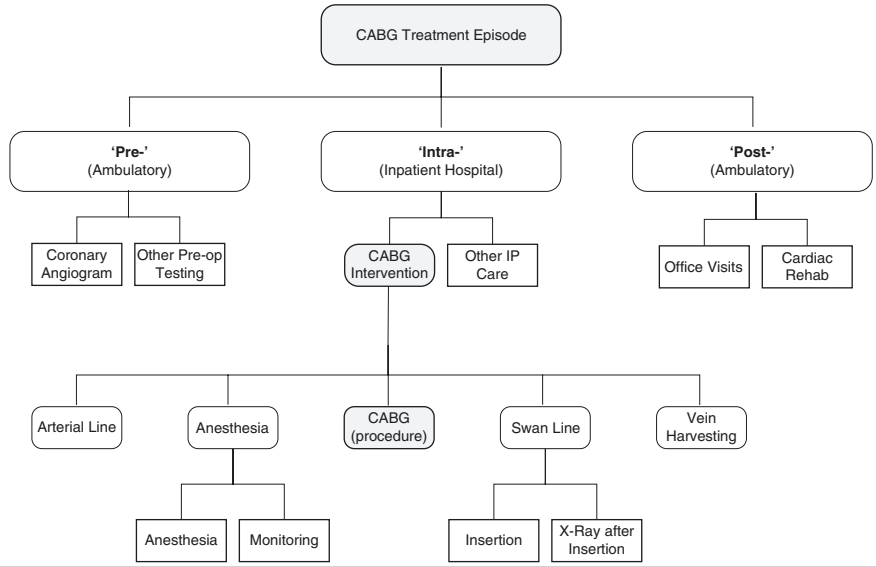
Answering a broad range questions related to choice or process of care requires a well-designed analytic framework. Consider an analysis of adverse outcomes among patients with angina. For analysis of choice of care, medical therapy, percutaneous coronary intervention (PCI) or CABG are relevant options. Depending on patient characteristics, a particular patient would likely have had a better outcome if a CABG had been chosen instead of PCI or vice versa. Outcomes also can be suboptimal if there is a process failure. Thus, to identify possible causes of suboptimal outcomes for an appropriate procedure, subcomponents of the procedure, such as preoperative testing, anesthesia, the surgery itself, or post-operative care need to be assessed. Accordingly, a comprehensive set of units and processes of care are needed from micro- to macro, from simple to complex as shown in Fig. 28.2.

To understand how this can be done, consider an analogy between the process of providing a complex unit of care to the assembly of complex manufactured object, such as an airplane. The tasks involved are simplified by recognizing that the airplane (as a whole) is the final assembly of a set of hierarchically nested sub-assemblies, such as airplane wings, engine nacelles, or landing gear, and each such top-level sub-assembly has multiple levels of successively smaller nested sub-assemblies. The logical data structure used in industry to organize assemblies and their subassemblies and parts is referred to as a 'hierarchical bill of materials.'[13] This same data structure can support assembly of a simple single-component process, such as a pulse oximetry test, as well as assembly of a complex multi-day, multi-component process such as a CABG procedure (Fig. 28.3).

Continuing the analogy, for airplanes, a failure in a sub-assembly can cause a failure of the airplane as whole. Similarly, a process of care problem in a sub-component may impair effectiveness or lead to complications or higher costs. The architecture proposed here will enable the future

[12] https://uspreventiveservicestaskforce.org.

[13] See http://en.wikipedia.org/wiki/Bill_of_materials for an article describing the structure and uses of a 'bill of materials' table.



- The top-level of the service hierarchy (not shown here) is a **major clinical task** ('treatment) for a **condition phase** ('angina') that includes high-level categories of treatments for angina, such as medical therapy, or coronary revascularization, which in turn, includes percutaneous coronary intervention (PCI), and coronary artery bypass surgery (CABG).
- A CABG treatment episode is a final assembly of pre-, intra-, and post-hospital units of care; each of which includes subcomponents, such as a coronary angiogram provided prior to surgery to guide treatment or cardiac rehab after hospital discharge to facilitate recovery
- The CABG intervention itself include the CABG procedure itself as well as supporting components provided during surgery such as anesthesia and a Swan line which in turn also include subcomponents as noted.
- Note that subcomponents such as the Swan line are 'reusable', in the sense that after developing logic to identify a Swan line and its components, the Swan-line intervention can be used in other contexts, either as a free-standing intervention or as a supporting component of other surgical treatments.

Fig. 28.3 Units of care as 'final' assemblies of a set of nested sub-assemblies

analytic system to identify variances between actual and expected process steps for any sub-component of a treatment and analyze the impact of such variances on health outcomes and resource use.

Units and processes of care are organized in a nested, hierarchical, set of data tables shown in Fig. 28.2. The '**new or changing health problem**' table is at the top level in this hierarchy. This table is analogous to a problem list in a medical record and indicates a need for care. A new record is triggered by a new or changing health problem as identified data elements show in Fig. 28.1, and in turn, the addition of this new record triggers the addition of one or more high-level tasks in the **major clinical tasks** table.

The **major clinical task** table contains one record per patient, health problem, and task. A major task is a high-level process norm, applicable across a broad range of health problems. Each record has attributes describing the health problem and task, open and close dates for the task, responsible clinician and facility, and a flag for successful completion. Suggested generic tasks for a wide range of health problems are shown in Table 28.4.

A major task specifies what must be accomplished, not how it is to be accomplished. So, a task provides the context within which units of care must be chosen, and once chosen, a process of care is initiated for that unit. For example, for a patient with angina pectoris, a choice must be made as to treatment (e.g., medical therapy, PCI, or CABG) and once chosen a process of care is started. So, a record in the **major clinical task** table links to records in the **unit of care** table that identifies the units and processes of care used to accomplish the task.

Major clinical tasks also provide a context that helps define the appropriateness or adverse impacts of a service. Consider two otherwise similar patients with pneumonia. Suppose that

Table 28.4 Suggested major tasks in care for health problems

For a Health Risk
• Risk identification
• Risk mitigation (vaccination, education, control of risks)
• Early diagnosis and screening
For a New or Ongoing Condition
• Initial access to care
• Diagnosing the problem (testing and or referral, if needed)
• Recommending and planning treatment, educating patient
• Carrying out treatment (by clinician or patient at home)
• Follow-up, monitoring, and re-evaluation, if needed
• Continuing or revising treatment, if needed
• Rehabilitation or restoration, if needed

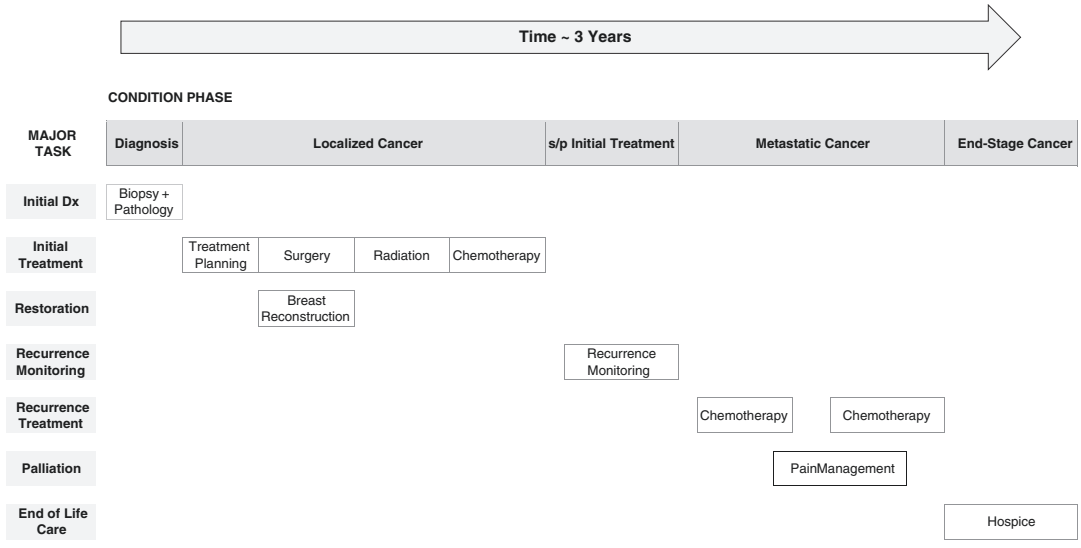
one had a chest X-ray for initial diagnosis while the other had a chest X-ray after antibiotic treatment. The X-ray for the first patient is helpful while the X-ray for the second is less helpful. Putting the X-ray into context is necessary for such a judgment. Similarly, context is critical when identifying causes of suboptimal outcomes. For example, complications of cancer treatment might either be caused by problems in treatment planning or in treatment administration.

The '**unit of care**' table contains a record for each distinct unit of care provided to accomplish a major clinical task for a health problem. *The defining feature of a unit of care is that it is provided for its direct benefit, not as a supporting component of a larger unit of care*. For example, a blood glucose test is a distinct unit of care if provided for care of a patient's diabetes, but not, if provided simply as a routine component of pre-operative testing for surgery; in this latter case, the test would not have been provided *but for* the surgery. A unit of care can range from a complex multi-day episode to a simple single service and supporting components and processes are identified by linkages shown in Fig. 28.2.

The '**treatment episode**' table has one record per patient, condition, major task, and type of care. Such episodes are a useful unit of analysis for any care provided over a multi-day period, such as surgery, therapy, home care, or ambulatory management of a chronic condition. For example, for breast cancer, a major task is initial treatment. This may involve several treatment episodes for surgery, chemotherapy, radiation therapy, and/or hormonal therapy (Fig. 28.4). Records for each episode have attributes identifying the treatment involved, place of service, first and last service dates and responsible clinician and facility. The table also includes links to the condition and major clinical task for which the treatment was provided and to the services included.

Cardiac surgery can be represented as a treatment episode (Fig. 28.3) that includes the operation itself as a 1-day intervention and supporting interventions (or services) provided for several days before and several days or weeks after. Surgical episodes can be 'triggered' by a procedure code for the surgery (in this case CABG). Therapy episodes can be identified by a sequence of recurring 'trigger' services, such a sequence of physical therapy encounters or chemotherapy infusions. Supporting components or subcomponents or an episode are linked to the episode by means of a look-up table that identifies commonly used supporting components within predefined time windows. Process of care issues within an episode can be identified by analyzing the components and subcomponents in the episode and their timing and comparing these components and subcomponents to applicable norms.

The '**major component**' table contains one record per episode and expected component. Expected major components vary by episode type and incorporate process norms where applicable. Record attributes include date and time of first and last included service and flags to indicate whether any related process norms were met. Table 28.5 shows a template for surgical episodes. For example, for hip replacement surgery, prevention of deep venous thrombosis would be included as an expected component of hip replacement surgery and linked to records for such treatment, if provided.



- Health care involves solving specific clinical problems. Such problems can be defined in terms of the condition, condition phase, and major clinical task.
- Clinical needs for a condition change over time as represented by condition phases. With breast cancer, the first phase 'Diagnosis' refers to the time period when cancer is a possibility, but not confirmed. Needs during this phase focused on diagnostic evaluation. Condition phase may change over time, for example, once initial treatment intended for cure has been completed, the patient's status or phase is 's/p treatment', which in turn changes, if the patient develops recurrent disease.
- Major clinical tasks reflect specific care needs based on condition phase and available treatment. Major clinical tasks for breast cancer are shown on left-hand boxes.
- The specific diagnostic or therapeutic interventions needed to accomplish a task, vary based on condition, phase, and the interventions that are potentially suited. These interventions are represented by treatment episodes or by one-day clinical interventions as illustrated above.

Fig. 28.4 Describing breast cancer care: condition phases, major clinical tasks, and treatment episodes

Table 28.5 Major components of a surgical episode

- **Pre-treatment evaluation and planning** -
  - Evaluation and tests to confirm need and identify optimal choice and approach for treatment
  - *Evaluation and tests to assess operative risk due to unrelated co-existing conditions*
- **Intra-treatment care** -
  - The surgery or therapy itself
  - Complementary components of the treatment itself, such as anesthesia, facility services, medications, or supplies
  - *Tests, monitoring, and supportive care to manage* ***expected adverse effects*** *of treatment*
  - *Tests or services to detector prevent treatment complications*
- **Post-treatment care** -
  - Evaluation and tests to monitor and manage recovery
  - *Post-op care of expected adverse effects of treatment, such as care of post-op pain or surgical wounds*
  - *Post-op treatment to prevent complications, such as deep-venous thrombosis after lower-extremity surgery*
- **Rehabilitation for restoration of function.**
- **Care for treatment-related symptoms or complications**

Ambulatory treatment episodes for chronic conditions include major components for ongoing evaluation and monitoring, follow-up visits, education, and medication use and adherence. As summarized in Fig. 28.4 in the preceding chapter, clinicians and patients have shared responsibilities, especially for ongoing ambulatory care of chronic conditions. Accordingly, the patient's treatment plan, as recorded in the patient's EHR can be used as a norm against which actual care is compared. This can be used to identify instances where the patient did or did not follow treatment plan recommendations, such as scheduling follow-up visits, tests, and referrals or filling prescriptions for medications. Adherence rates for each of these items can be calculated and summarized in a corresponding major component of ambulatory care for the condition. The treatment plan and physician orders as written also can be compared to relevant norms of care to assess adequacy of the treatment plan.

The '**clinical event**' table contains one record per hospital admission, emergency department visit, ambulatory procedure, or other ambulatory visit with attributes for characteristics, such as

setting, dates, provider, principal diagnosis, and principal service.[14] Events are a helpful unit of analysis if most of the care provided during the event is related, as is true for a hospital admission for pneumonia, an inpatient or outpatient procedure or emergency department visit. Office visits tend to be more heterogeneous.

The '**sub-component**' or '**clinical intervention**' table contains one record per patient, per intervention, and date. Interventions correspond to distinct tests or treatments and link all supporting services (as provided during on a single day). The key for constructing an intervention is to distinguish between ***primary*** and ***supporting*** services. For example, a cardiac nuclear stress test includes a primary service (the test interpretation) and supporting services (supervision of exercise and technical services). Each intervention record has a set of attributes as well as linkages to other tables in the units of care hierarchy and health problems and major tasks of care for which the intervention was provided.

To illustrate the relationships between treatment episodes, interventions, and services, consider a 'Swan line' (Fig. 28.3). Swan lines are used in two circumstances. By itself, a Swan may be used to monitor and manage patients critically ill patients. In this context, a Swan is a free-standing **clinical intervention**. However, Swan lines are often used as an adjunct to cardiac surgery to monitor the patient during surgery and would most likely not have been provided *but for* the surgery and should therefore be identified a supporting **sub-component** of the surgery.

A Swan line, in turn, also has its own set of supporting services. For example, a chest X-ray often performed after catheter placement to verify proper positioning. In this case, the chest X-ray is a supporting service without an independent clinical benefit. On the other hand, a chest X-ray is a distinct intervention with an independent clinical benefit when provided to help diagnose pneumonia.

The '**service**' table is the next level down in the hierarchy and contains one record per service. With claims data, this corresponds to a unique claim line. A service record includes identifying attributes and a link to the intervention that includes the service and a flag indicating whether the service is the primary component of the intervention (see above).

The '**micro-step**' table includes micro-level components of a distinct service and is useful only for highly granular analysis of processes of care. As an example, a complex dressing change might consist of a series of micro-steps in the overall process. This element is of lower priority and should be deferred.

In summary, the architecture presented in this section systematizes care into a clinically meaningful, standardized structure that integrates need, choice, process, and norms of care. As such, the architecture enables analysis of the impact of variances between actual and expected care on health outcomes and resource use across a comprehensive range of health problems and units of care.

28.2.2.4 Assembly of the Analytic Patient History

At a high-level, the process of assembling the analytic patient history from input data, whether administrative or clinical, involves sorting through all input records for a person and linking those that correspond to a single instance of an illness, injury, or unit of care while keeping records separate if they correspond to different instances thereof. This process is ultimately controlled by a set of look-up tables that specify categories, relationships, and probabilities for relationships.

28.2.2.5 Curated Concepts, Categories, and Relationships

Both for their own value as a reference and as a means for assembling the patient history, important categories and relationships should be curated and validated. Table 28.6 lists some

[14] Special logic, such as a service hierarchy, may be needed to identify the principal intervention. This is particularly true for surgery when multiple surgical procedures are performed during the same operation. Alternatively, the surgery can be labeled as a concatenation of the two procedures, e.g., valve replacement with coronary artery bypass grafts.

Table 28.6 Curated categories and relationships

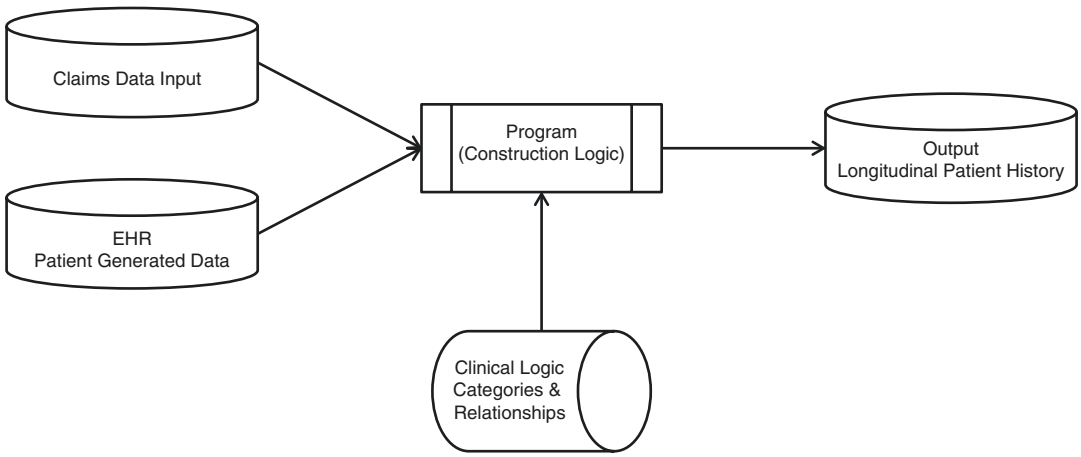
- Multi-level sets of condition and service categories to support analysis at optimal levels of detail
- Service and medication categories commonly used to diagnose, monitor, mitigate, or treat a condition to support linkage to conditions as well as validation of conditions
- Clinical criteria for condition control, acute exacerbations, disease stage, and other possible changes in a condition
- Clinical and patient-reported outcomes to measure impact of illness and success of treatment
- Differential diagnosis for sets of symptoms or findings to link working diagnoses to final diagnoses
- Primary and supporting services for buildingof units of care with time window for linking possible supporting services to primary services, and with specification of the 'subtask' for which the supporting service is provided.
- Clinical criteria for identifying and linking symptoms or complications to causative conditions or treatments with time-dependent probabilities to identify a most likely cause
- Patient and community characteristics potentially related to risk of a new illness or injury
- Clinician and health care organizational characteristics and patient and community characteristics potentially related to risk of suboptimal care

of these. Assembling such look-up tables can be facilitated by data mining to identify 'candidate' relationships for validation by clinicians. While there is an extensive and well-developed starting set of concepts, vocabularies, and measures available,[15] it can be anticipated that additions and modifications will be needed. Further work along these lines may be important for processes of care and for fields such as allied-health professions. An inventory to identify and prioritize gaps will be important. Additions can be incorporated on an incremental basis (Fig. 28.5).

28.2.3 The Range of Analyses Supported

To illustrate how the analytic patient history can answer a comprehensive range of important questions, it is helpful to provide a sketch of the 'typical' analysis for identifying opportunities for improving care. Such analyses generally involve the question '**What are the causal effects of …?**' This question can be answered by

[15] ONC, Interoperability Standards Advisory (ISA), https://www.healthit.gov/isa/about-isa.



- Input data are transformed into a set of data tables that correspond to the core longitudinal patient history. For example, data tables are constructed for condition and treatment episodes and for events and interventions.
- The building of model constructs and relationships is controlled by a program that utilizes a set of clinical logic tables that identify model constructs and possible relationships between constructs. Probability statistics can be used to identify most likely relationship when more than one is potentially valid.

Fig. 28.5 High-level overview of analytic patient history construction process

building and analyzing a data file where each record in the data set corresponds to a member of a study cohort (or other unit of analysis, such as a hospital stay), with variables for the outcome being studied, the 'treatment' (or other factor whose effect is being studied), and confounders that could affect results.

As an example, consider a study of the effects of a medication on complications related to heart failure. The study cohort can be defined as patients with heart failure throughout a 12-month period. Outcomes can be defined as occurrences of heart failure-related complications, such as pulmonary edema. The treatment cohort can be defined as members in the cohort who received the medicine. Confounders could include cardiac function, other medications used, prior history of heart failure flares or complications, comorbidities, demographics, and social determinants. All these variables can be sourced from the analytic patient history. From this framing and from the range and depth of analytic elements presented in this and the preceding chapter, it is clear, that a broad range of important questions can be analyzed in a systematic manner using the analytic patient history as input.

Whether such studies can be completed successfully with valid, and generalizable findings, depends on whether the patient histories used for the study:

- Contain sufficient information to define an analytic record with all necessary elements as described, especially confounders that could have a clinically significant effect
- Include enough observations for statistical inference,
- And include a sufficiently representative set of observations to support generalizability of inferences

While these caveats are valid, they also underscore the importance of a systematic plan and project. All of the issues listed in the preceding set of bullets must be addressed in any effort to use observational data to improve health care. None are unique to the approach proposed here. Data gaps must be addressed to capture the full potential benefit of health care analytics. But we believe that the best way forward is to have a well-funded, well-planned, coordinated, and collaborative effort to build a comprehensive analytic system. There are no fundamental barriers of knowledge that block the way. Having ideal data is not a requirement for beginning the development of a prototype system. Quite the opposite, having a prototype is exactly what is needed to identify priorities for data enhancement and to energize and galvanize such efforts.

28.3 Getting It Done

The health care and health informatics ecosystem are complex and diverse within the United States and beyond. There is enormous activity in local health care delivery systems focused on health care informatics. And formal and informal collaborations are emerging. A starting question then would be: Do some of the ideas presented here resonate with leaders of these initiatives? If, so, do they see value in a developing a shared approach in a planned collaborative manner?

Based on our informal scan of the ecosystem, we believe that current activities are quite rightly focused on extracting and organizing data from local EHR systems and addressing local priorities. Some institutions also are collaborating on research using standard data models for clinical data, such as the OMOP or PCORnet data models. However, the informatics community may be at the early stages of formulating approaches for a comprehensive, operationally oriented, ongoing analytic system as described here.

If so, the very first step is to formulate a coherent vision of a future analytic system as a basis for discussion. That is the purpose of the two chapters we have written here. The next step would be to engage thought leaders in health care informatics and analytics to develop consensus on a conceptual framework. The 'ticket for admission' would be a commitment to help formulate a consensus framework that can serve as a basis for moving forward. There are several

national organizations that could host and facilitate a process of this type.

In a consensus development process, every word, every idea, and every exhibit in these chapters would be subject to revision, so long as at the end we have a consensus framework that can serve as a plan for developing a future analytic system that can identify actionable opportunities to improve outcome of health and health care across all conditions, types of care, and settings of care.

It would, of course, be prudent for a plan to be step wise in nature to build confidence in terms of feasibility and utility prior to proceeding to the next step of the plan. Accordingly, we suggest that a first step would be a prototype to be completed within 3 years. This would require staff, a technical environment, and access to de-identified clinical data in a standard format such as the OMOP data model. The project team would be supported and guided by an advisory panel perhaps drawn from the consensus process described above.

Because of prior collaborative work among the authors using administrative data and similarities between the structure of administrative data and clinical data based on the OPOP and PCORnet models, we are confident that a successful prototype is possible within the proposed 3-year time frame. Simultaneously with prototype development, a second plan for the next 3 years would be developed. Ideally, in less than 5 years an initial version of the future analytic system described here would be available to help improve care throughout the country. Successive iterations would add additional data sources, data elements, and methodologies so within a few years, the complete system as described here would be a reality. This timetable could be accelerated through coordinated parallel development processes depending on the level of confidence and support.

As noted at the start of the preceding chapter, there are many important decisions that we do not attempt to answer here. Should the system be centralized, decentralized, or federated? Should there be data requirements? We think that such questions should not delay work on developing a prototype. As such work proceeds, those involved in development as well as the larger community of stakeholders will gain new insights and will be better able to assess such tradeoffs objectively.

28.4 Summary of a 'Generic' Analytic Framework for a Comprehensive System

Developing a comprehensive system within a few years may seem to be an impossible task. It is not. The key is to recognize that the complexity and diversity of health care can be represented by a simple 'generic' framework that encompasses all conditions and treatments. Here are the major elements:

- A **health problem** is **a risk or condition** that threatens a person's life expectancy or well-being
- **Health care** is any intervention or **unit of care** intended to address a health problem whether through public health, health care providers, care management, or self-care by patient or family
- A **need for health care** is triggered by a new or changing health problem and the **unit of care** needed varies **by problem and major step** in care (e.g., prevention, diagnosis, treatment, etc.)
- A **unit of care** ranges from a simple 'free-standing' service to a complex integrated service (with supporting components), **intended to provide benefit directly** (and not as a supporting component).
- A **process of care** corresponds to the set, sequencing, and timing of components of a unit of care and may be pre-defined or implicit in the care actually provided.
- **Health and health care will be suboptimal:**
  - If a health problem is **not prevented**, **not identified**, or **not resolved or controlled** as safely, quickly, and efficiently as possible given current knowledge and capabilities
  - Or, if no care is provided to address a need (**access**), the 'wrong' care is provided given

the patient's clinical history (**choice**) or the 'right' care is poorly provided (**process**)
- **Causes of suboptimal access, choice, or process** may be traced back to patient, family, or community characteristics or to clinician, practice, or delivery system characteristics or to interactions among these characteristics

Note that this framework is fully generic—no specific health problems, units of care or processes of care, or causes of suboptimal outcomes are listed. As a result, this framework is applicable across the full range of potential opportunities to improve health and health care and radically simplifies the task of developing a comprehensive and integrated analytic system.

28.5 Conclusion

How do we improve health care? How can we improve health care unless doctors and nurses know at a micro-level where the problems are? Who else can improve care? How do we know whether improvement efforts are working? How can we know unless doctors and nurses can readily measure progress? Who else can make sure that improvement efforts stay on track?

The answer to these questions is simple. To provide greatest benefit, analytics should be closely integrated into the delivery of care to help doctors and nurses in tens of thousands of settings ranging from small rural practices to large regional health care systems. Moreover, analytics must be comprehensive for the simple reason that an individual may have any number or combination of illnesses and treatments.

Here are three closing statements. First, the concepts described here reflect the underlying structure and logic of health and health care. While different words may be used in different contexts, any comprehensive analytic system, wherever developed would include substantially the same set of concepts and interrelationships. Certainly, there may be gaps or errors in the structure or concepts articulated here, but these can easily be identified, adjusted, or corrected through dialog and consensus.

Second, the development process is do-able. Many of the elements have been prototyped in previous work by one of the authors while at AHRQ. Moreover, while each illness, injury, test, treatment, or other care has its own characteristics and interrelationships, these can be specified as data entries in a set of clinical logic look-up tables. This enables a generic architecture that applies to all conditions and types of care to be differentiated via these look-up tables. Moreover, the algorithms needed to map clinical data as input into the analytic patient history are relatively simple to program and validate.

Third, because the analytics required to provide actionable insights are also encapsulated in a small set of high-level 'meta questions', it will be possible, using constructs from the analytic patient history as input, for statistical and causal analysis to be 'semi-automated' thereby facilitating valid inferences that answer thousands of important questions across the entire spectrum of health and health care.

The suggestions made in this paper are intended to recognize, support, and facilitate the efforts of the many teams working on health care analytics today. If consensus on a collaborative plan is achieved, if there are sufficient resources available, and if sufficient clinical data are available for development, a working prototype of a comprehensive analytic system could be developed in just a few years' time. At that point, support and progress would follow at an ever-increasing rate.

The type of future analytic system described here will be widely used in varying forms throughout much of the world well before 2050. Technology now makes this possible. And the human benefit involved makes this possibility inevitable.

Reference

1. Centers for Medicare & Medicaid Services. CMS standardization methodology for allowed amount, vol. 7. Baltimore, MD: Centers for Medicare & Medicaid Services; 2018. p. 2006–18.

HIT, Informatics and Ethics

29

David L. Meyers

Abstract

The rapid growth in the scope of health informatics raises ethical questions far beyond those of the historical concentration on the collection, organization, storage, distribution and management of medical records and personal health information. Questions of good and bad or right and wrong actions, the domain of ethics, now arise in relation to a practically endless list of realms where information is the critical influence on policies and enabler of actions to effect goals within the entire arena of health and health care. Each area presents its own ethical challenges, and there will be other challenges related to the various combinations and interactions between and among them. Health informatics is now central to virtually all health- and health care-related activities, and its importance will only grow in the future. Healthcare informatics professionals (HIPs) will be called upon to facilitate the development, use and management of data and its conversion to useful information while being aware of the potential for harm that exists in any enterprise of such breadth. Knowledge of ethics is essential to inform such work.

D. L. Meyers (✉)
Adjunct Faculty, Johns Hopkins University, Baltimore, MD, USA

Emergency Medicine, Sinai Hospital of Baltimore, Baltimore, MD, USA

Keywords

Ethics · Bioethics · Informatics · Morality
Equity · Justice · Maleficence · Beneficence
Autonomy · Code of ethics

Learning Objectives

- Define several considerations for informatics and ethics.
- Explain frameworks used in conducting bioethics evaluations.
- Analyze the role of ehealth within bioethics constructs.

29.1 US Health Care: Background

The COVID-19 pandemic is currently affecting virtually every part of the world, and the United States has been among the hardest hit countries in terms of incidence, morbidity and mortality with more than 600,000 deaths due to the disease. It has exposed vulnerabilities and inefficiencies in the health and health care enterprise which, if not unsuspected, had not been aggressively addressed in the past. Acknowledged problems prior to the pandemic included inadequate public health resources and planning arising from the focus on treatment rather than prevention of disease. Other factors include disparities and inequities in access to health resources, high costs, large numbers of

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uninsured people and poor performance on many measures reflective of individual and societal health. It is hoped and predicted by many that the pandemic will lead to much-needed improvements in the organization and delivery of health services, efforts toward which are expanding and likely to grow in the foreseeable future. Health informatics will play key roles in these changes.

A description of the current state of US health care will be useful as we contemplate the role of informatics and ethics in the health sector of the economy. Data from the US Centers for Disease Control and Prevention (CDC)[1] reflect the massive scope and impact that the health sector has, accounting for nearly $3.5 trillion in 2017 and estimated to be at ~$4 trillion in 2020. This is equivalent to nearly 18% of total US Gross Domestic Product (GDP) and corresponds to an average annual health expenditure of ~$10,700 per person. An estimated $2.96 trillion of the 2017 total (~85%) was spent on health care of individuals, primarily for hospital care, drugs and professional office and clinic visits. These total and per capita expenditures significantly exceed those of other developed countries including the 11 member states of the Organization for Economic Co-operation and Development (OECD), with which we are often compared.[2, 3] In addition, health care accounts for ~12% of total American workforce employment.[4, 5]

While the US can point to historically high rates of preventive measures such as breast cancer screening and flu vaccination in the elderly, many other measures of population health show significantly worse performance. For example, life expectancy, rates of suicide, drug use disorders, obesity, chronic disease burden, physician visits and access to timely appointments are all worse than in comparably developed countries. Similarly, the US has higher rates of avoidable deaths and hospitalizations for preventable illnesses like diabetes and hypertension.[6] Other areas of concern are pregnancy-related maternal illness (morbidity) and death (mortality) and child well-being and death, areas in which the US performs worse than many other developed countries [1].[7] The ongoing COVID-19 pandemic in the US has shown worsening of some of these measures, including the reduction of average life expectancy by a full year after the first 6 months of the pandemic [2].

So, the question must be asked "Given these statistics, what are the causes and solutions to the problems of health and well-being of the people of the United States?" The causes are broad and deep. Systemic and structural injustice, that is, conditions such as the "social determinants of health"—housing, nutrition, education, employment, access to health services—which contribute to poorer health in vulnerable populations undoubtedly play roles.[8] Other important factors are related to how our health care system evolved, especially after World War 2 [3], a focus on disease rather than wellness and prevention, the limited collaboration among various entities providing care, the incentives built into financing models and a host of others. Recent COVID-19 experience has revealed resistance by significant numbers of the population to mask mandates and calls for vac-

[1] Centers for Disease Control and Prevention National Center for Health Statistics, United States, 2018, table 42. Health Expenditures, 2017. https://www.cdc.gov/nchs/fastats/health-expenditures.htm. Accessed 17 Jan 2021.

[2] Tikkanen, R and Abrams, MK. *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?* (Commonwealth Fund, 2020). https://doi.org/10.26099/7avy-fc29. Accessed 15 Jan 2021.

[3] Current OECD member countries as of 01/21.2021. http://www.oecd.org/about/document/list-oecd-member-countries.htm.

[4] Employment by Major Industry Sector, 2019, Table 2.1. Bureau of Labor Statistics, US Department of Labor. https://www.bls.gov/emp/tables/employment-by-major-industry-sector.htm. Accessed 17 Jan 2021.

[5] These data reflect conditions prior to the COVID-19 pandemic which was first identified in the US in January, 2021, and which had a major impact on overall utilization of health services as well as the types of services and health care expenditures.

[6] Cf Footnote 5.

[7] Centers for Disease Control and Prevention (CDC). (2020). *Pregnancy Mortality Surveillance System*. https://www.nichd.nih.gov/health/topics/factsheets/maternal-morbidity-mortality#f1. Accessed 20 Jan 2021.

[8] Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/socialdeterminants/about.html.

cination against the disease; these attitudes have resulted in persisting or worsening incidence of disease. While overall progress is being made, skepticism and mistrust of science-based recommendations in the future may portend worse individual and population health outcomes in the future.

Of course, the quality of the health care itself plays a critical role, and it has been found in need of significant improvements. According to the National Academy of Medicine (NAM), in a landmark series of reports examining the quality and safety of health care in the US beginning with "To Err Is Human" in 1999 [4], errors in the course of receiving health services contribute significantly to patient death and other harms. Mortality from such errors was estimated in that report to cause between 44,000 and 98,000 annual deaths. Some subsequent studies have disputed whether the number is higher or lower, and, while the actual number remains unknown, there is agreement that there is a significant amount of preventable harm. Solutions were proposed in the original and follow-up NAM reports, but progress has been slow in spite of a sense of urgency and strong consensus recommendations to make health care "safe, effective, patient-centered, timely, efficient, and equitable" [5].

Besides the National Academy of Sciences, Engineering, and Medicine, many government agencies and non-government groups have joined in the mission to improve health care and have had important influences in these efforts. Among especially important ones are the federal Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum (NQF), the Institute for Healthcare Improvement (IHI) and the health care accrediting agency, The Joint Commission (TJC).

By now, you may be asking yourself, "What is the point of reviewing all of this information as a preface to a discussion of ethics and health Informatics?" The reason is that the future of our entire approach to health and health care, from the health of individuals living in communities to the points of patient encounters with health care entities to public policy at the national and international levels will depend substantially on the data, tools and methodologies of health informatics.

Ethics, the understanding and evaluation of morality and its influence on conduct, has special significance in health care at least since the time of the ancient Greek physician, Hippocrates, whose oath identified obligations of physicians to their patients and defined certain standards of behavior to fulfill them.[9] Many of the elements of that oath now guide the work of the individuals and institutions who carry out the work of health care, clinicians as well as health information professionals (HIPs), executives as well as health planners, vendors of health care products and services as well as health policy makers, researchers as well as educators. Furthermore, ethics is considered one of the core competencies of health informatics.[10]

29.2 Nexus of Informatics and Ethics

Organizations which provide health-related services, whether for-profit or not-for-profit, are guided by mission, vision and values statements which articulate the reasons for the organizations' existence. In virtually all cases, the statements place patients, ill or potentially ill persons, at the focal point of those intentions. Service to the sick and injured is a, if not THE, primary driving force for the work of these entities. It is not only manifested in direct patient services; research, education, public health and other areas are also influenced by similar values. The same may be said of individuals who pursue work in fields related to health and health care. Most hold values of service to the well, ill and injured, whether in promoting health, providing direct care, participating in research, education, health policy and other related fields. Underlying the

[9] Oath of Hippocrates. http://classics.mit.edu/Hippocrates/hippooath.html. Accessed 28 Jan 2021.

[10] Thye, J. *Health informatics - understanding health informatics core competencies*. HIMSS.org/Resources/Health-InformaticsHIMSS.org/Resources/Health-Informatics. Accessed 10 Feb 2021.

values of all involved in these efforts are certain standards of behavior and expectations that give primacy to the interests of those being served. Ethics is the study of morality and how our understanding of moral concepts of right and wrong translates into behavior.

The American Medical Informatics Association (AMIA) defines medical informatics as "the science of how to use data, information and knowledge to improve human health and the delivery of health care services," and relies on health information technology to focus on computer, cognitive and social sciences to achieve these goals.[11]

It has become clear in recent decades that acquisition and management of information is a critical piece of all health and health care-related activities, but also that the nature of that information has changed and expanded dramatically. No longer the mere repository of the health records of patients, the electronic health record (EHR) is the foundation of what is termed eHealth, which refers to a complex of digital information and communication technologies aimed at facilitating, enhancing and improving the provision of high quality and safe care. eHealth also recognizes that the data of the EHR can be the basis for research and education. With these dramatic changes, the role of the health informatics professional has changed from one primarily of technical support for the clinical electronic record to that of a manager of all facets of that engine of the entire health enterprise, the EHR database.

Further, the field also is also critical to institutional administration and business management, planning and public policy, as well as how various technologies which are used in those activities are designed, developed and applied.[12] A comprehensive but perhaps not exhaustive list of areas of informatics falling under the rubric of eHealth which are ripe for consideration of ethical issues includes the following [6]:

- Clinical assistive resources such as decision support, prognostic scoring systems, artificial intelligence, ePrescribing, digital order entry, image archiving and retrieval
- Structure, content, accessibility, security and privacy of electronic health records
- Government regulation of health informatics and technology tools
- Technology of informatics and communication
- The Internet as a resource for professionals and patients
- Structure and management of laboratory, radiology and other diagnostic and therapeutic resources
- Mobile health resources
- Provider-clinician/patient relationships
- Remote technology for health, wellness and health care (telehealth, wearables and web-enabled medical devices)
- Research and education
- Robotics, digital/virtual companions
- Safety, quality, and evaluation of care
- Professional credentialling
- Social networking
- Patient control of their health information
- Artificial intelligence tools
- Software engineering
- Health information exchanges, collection and use of mega-data,
- The "virtual hospital" and "hospital of the future"
- Computational biology
- Institutional management including financial planning

Additionally, healthcare informatics is expanding to play larger roles in government and public policy, including national security. The current COVID-19 pandemic illustrates the international impact of that disease, and the importance of efforts to determine origin and understand patterns of spread of the SARS-CoV-2 causative agent are on-going. Individual countries have both common and competitive interests in the impact and management of this disease (and oth-

[11] American Medical Informatics Association. *What is Informatics?* https://www.amia.org/fact-sheets/what-informatics. Accessed 5 Feb 2021.

[12] International Medical Informatics Association. *Ethics for Health Informatics Professionals, The IMIA Code, its Meaning and Implications* (2016). https://imia-medinfo.org/wp/wp-content/uploads/2019/08/Handbook-for-revised-Code-of-Ethics.pdf.

ers throughout history). These differing interests contribute to cooperation and lack thereof in efforts to fully understand all aspects of diseases, primarily infectious, with propensity to spread. Meanwhile, the COVID virus is mutating into more virulent and worrisome strains which can have implications for national and world economies as well as national security.

While the COVID pandemic has raged, a serious security breach of information systems of numerous US government agencies and private companies took place and was revealed in December, 2020. Although the extent of the damage has yet to be fully characterized, it has been reported that health information systems at the US National Institutes of Health were penetrated.[13] This breach as well as the rising numbers of "hacks" of health care institutions' information systems point to the vulnerability of and threat to the security and privacy of individuals, groups and societal health information, leading to potentially far-reaching economic and political implications.

29.3 Ethics 101

As previously stated, ethics is a general term encompassing the study of morality and how our understanding of moral concepts of right and wrong translates into behavior. There are a number of sub-categories within the discipline. *Normative ethics* seeks norms, rules and principles to be used to determine what we *ought* to do and why. *Practical or applied ethics* uses the norms, rules and principles to address specific instances or problems in professional, public policy and institutional spheres [7].

Bioethics lives in the realm of practical ethics insofar as it provides guidance toward solving moral problems encountered in fields relating to biology and biologic systems, including health and health care. It arose in the mid-twentieth century in response to growing concerns over the conduct of research on humans, initiated by revelations of the Nazi prisoner experiments at the Nuremburg War Crimes Trials in 1946–1947 and subsequent reports of improper conduct in other research settings in the US and elsewhere [8, 9]. In addition, advances in genetics, molecular biology and neurosciences prompted discussions in religious and public fora on subjects such as abortion, euthanasia, organ transplantation, rights of research subjects and informed consent [10]. It became apparent that the traditional ethical codes and guidelines for physicians did not adequately address those matters and others such as patient rights, equity and injustice, research practice, conflicts of interest, public health matters and, by the late 1970s,[14] the corporatization of health delivery.

There are a number of frameworks or moral theoretical constructs used in conducting bioethics evaluations and making ethical judgements, that is, deciding on a right course of action [11]. Those in most common use today include principlism, consequentialism/utilitarianism, deontology, rights/obligations, virtue ethics and the related ethics of care. Less frequently encountered are communitarianism, casuistry and others. It should be noted that the framework chosen to address a particular problem or situation may lead to a different end point or ethical result compared to another framework. There are obviously nuances in the facts of a particular situation which would influence the application of these frameworks to those facts and the results.

Principlism is one of the predominant approaches to evaluating and resolving ethical dilemmas today. It derives from the work of Beauchamp and Childress [12] who first promulgated this method in the late 1970s and has gained wide acceptance since then. The four ethical principles from which the name of the framework derives and the actions required to fulfill them are as follows:

[13] Geller, Eric; Rayasam, Renuka; Ward, Myah (December 17, 2020). *The big hack: what we know, what we don't*. Politico. Accessed 19 Dec 2020.

[14] Informatics lives in the institutional/corporate world and is subject to considerations not only of bioethics, but also of the ethics of the business world. At times, those realms are in competition, posing challenges to choosing the right action.

1. *Principle of Autonomy*—requires us to avoid impairing individuals' free exercise of actions they deem in their best interest (allowing for certain constraints under special conditions such as for those who lack decision-making capacity) and to treat individuals with respect by appropriately informing, educating, encouraging, and assisting, if needed, to facilitate their decision making.
2. *Principle of Beneficence*—requires that we act to benefit the patient by actively promoting their well-being and doing what is in the patient's best interest.
3. *Principle of Non-maleficence*—requires us to prevent harm directly, minimize risk of harm or remove or remediate potentially harmful conditions.
4. *Principle of Justice*—requires fair and equitable treatment in the provision of benefits and burdens, without discrimination on the basis of non-relevant characteristics—equity not equality.

Consequentialism and utilitarianism are related frameworks which both look to the consequences of an act as determinative of its rightness. Actions are right or wrong depending on the net balance of the resulting good and bad consequences. In these formulations, intentions, history and other concerns have no bearing on the rightness of an act. In its original form as described by JS Mill and others, the good being sought was happiness, often equated with pleasure. The consequentialist framework judges the rightness of an act solely on whether the outcome is better than the available alternatives. If so, then it is right. Utilitarians judge the rightness of an act on whether it achieves the greatest good for the greatest number. These frameworks are applied in many circumstances where pleasure is not the goal. Rather, some other good(s) may be desired when considering the proper course of action. The specification of the desired good can influence the arguments to be made and the outcome to be accomplished. Public health is often seen as reliant on utilitarian theory.

Deontology derives from the Greek word meaning duty or obligation. This framework does not look to consequences to determine the rightness of an act. A rigorous explication of this framework was articulated by the eighteenth century German philosopher, Immanuel Kant. The essence of his approach imputes to us a desire to do the right thing which, in turn, requires that we know what the right thing is. According to Kant's formulation, moral rules or "maxims" are guides to what is right and wrong. These maxims can originate from external forces—religion, government, institutions—or can be derived using our intellect from our intrinsic notions of what is right. Furthermore, one must act according to the rule out of a sense of obligation to respect the moral rightness of the rule, not out of fear of the consequences of acting otherwise. Kant named his concept of the reasons for a required behavior the "categorical imperative." To meet the criterion of a categorical imperative, a rule must be accepted as universal, requiring that **everyone** follow the rule under all circumstances, without exception. For example, "do not lie" qualifies as a universal. We would not want a world where lying was accepted because we would never know whom and when to trust. There are, of course, famous challenges to the maxim of "do not lie." Consider the circumstance where a gunman comes to Mary's door asking if John is home and states "I intend to shoot him." John is home, but Mary answers "no" to protect him. Is such a lie acceptable?

Kant also promulgated another formulation of the categorical imperative which prohibits acting toward another person or persons in a manner that treats them *solely* as a means to our (or others') ends, rather than as deserving respect and dignity in and of themselves. This particular formulation has been interpreted to support a principle of respect for individual autonomy.[15]

[15] Beauchamp, T. Cf footnote 17. P 367. And Beauchamp T.L., Rauprich O. (2015) Principlism. In: ten Have H. (eds) Encyclopedia of Global Bioethics. Springer, Cham. https://doi.org/10.1007/978-3-319-05544-2_348-1.

Another useful framework for ethical decision-making derived from deontology is one based on consideration of **rights and obligations**. The concept of rights is inextricably bound up with the concept of obligations. A right is a claim for which an entitlement exists such that an entity recognizing the claim owes an obligation (or duty) to the claimant or bearer to fulfill it. Rights can originate from a number of sources, including natural law, i.e., be inherent due to some attribute of the rights bearer. For example, being human has been construed to confer rights inherent to that status. The natural law concept has been articulated by thinkers from Aristotle to Aquinas to Kant and more recent thinkers. A feature of this theory is the primacy of the individual, the rights bearer and claimant. Rights are frequently framed as positive or negative. A positive right entitles the bearer to receive something from the duty-bearer, e.g., and individual, the state or some other entity. A negative right requires freedom from interference, abrogation or infringement of the claim.

Virtue ethics in Western tradition derives from the ideas of ancient Greek philosophers including Plato and his student, Aristotle, who lived c.350–450 BCE, the Stoics (c.200 BCE and later) and others. Their explorations of the origin, nature and reasons for moral conduct have been influential to the present day. Aristotle's *Nichomachean Ethics* is one of the touchstones from those ancient concepts [13]. The original impetus for that and other related works of the period was to understand what was meant by "a good life" and how to live one. From those considerations came answers to questions about what constituted good character and moral behavior. In brief, Aristotle held that being virtuous was essential to achieving "happiness" or eudaimonia, translated as flourishing or well-being. Being virtuous meant cultivating and possessing certain qualities of character, among them patience, modesty, justice, courage, righteousness, friendliness, wittiness, generosity, temperance.[16] The virtuous person must also be motivated to want to be virtuous, not merely to possess the traits. The individual who possesses and exercises the traits according to the proper motivation would then be of good character and, in consequence, make good and right decisions to guide proper actions. It should be noted that the concepts of virtue ethics are not unique to Western societies. For example, the virtue-based ethics of Confucius, who lived in the fifth to sixth century BCE, were derived from the cultural values expected of the leadership class of an earlier Asian tribal group, the Zhou (1045–256 BCE) [14].

Arising out of virtue ethics, **care ethics** theory developed in the second half of the twentieth century, taking its philosophical base from concepts of caring that are inherent in the nature of medicine, nursing and related health fields and inform the actions of those professionals. Such caring is considered to be a virtue which incorporates characteristics of sympathy, compassion, trustworthiness, fidelity and more. It has been argued by Gilligan and others that care ethics represents a manifestation of gender differences in attitudes toward moral thinking in which women tend to respond by considering needs and taking care of others, whereas men tend to emphasize rights and justice to a greater extent. Of course, these modes are not unique or specific to each gender, and there is a great deal of overlap. Applying different theoretical models in settings where ethical judgements and decision-making are taking place can aid in resolving ethical conflicts [15].

Communitarianism is another framework for ethical decision-making that places community interests above those of individuals. This approach is seen in cultures which value the welfare of the community above any single individual's welfare and considerations of individual justice. Private and public spheres have no sharp demarcation.

[16]Each virtue is considered to be a "mean" of behavior in Aristotle's formulation, and he established vices of deficiency and excess for each virtue. For example, the virtue of courage (the mean) is contrasted with the vice of cowardice (deficiency) and the vice of foolhardiness (excess).

There are other frameworks for ethical analysis and decision-making—casuistry, feminist ethics and more—which provide useful approaches to ethical decision-making, but they will not be discussed further here. An excellent review of the many approaches to medical ethics is found in the text edited by Sugarman and Sulmasy [16].

29.4 Physician Oaths

Having reviewed some of the commonly used frameworks for examining ethics, let us now turn to oaths and codes of ethics. As noted previously, standards of behavior for physicians which have come down to us were first promulgated in ancient Greece with the Hippocratic Oath required of students at the school of Hippocrates. That oath is divided into two sections. The first section describes ways in which the student will honor his teacher and the profession—by treating the teacher as he would treat his parents, share sustenance, teach the art to the teacher's children and teach the art only to those "bound by stipulation and oath to the law of medicine …" The second portion defines responsibilities toward patients and personal integrity, committing to the benefit and avoidance of harm to patients, abjuring actions beyond the physician's skill set and promising to keep in confidence those matters learned in the course of care "that should not be spoken of abroad."[17]

The Oath fell into obscurity and was largely unknown for centuries until it was encountered by German scholars in the sixteenth century. Consistent with the religious influences of the times, its references to Greek gods were replaced with Christian terminology, and modified versions were slowly adopted by some European medical universities for their graduates. Usage and spread of various versions of the Oath waxed and waned over a few more centuries until it gained traction after World War Two when the World Medical Association, reacting to the horrors perpetrated by Nazi physicians, promoted the use of a revised version of the Hippocratic Oath to medical students as a reminder of the traditional values physicians were expected to take on. While the language of the ancient Hippocratic Oath is no longer the preferred formulation of commitment to the practice of medicine, a survey of US and Canadian medical schools published in 2018 found that of the 111 US schools responding, 99% administered an oath at commencement or other ceremony at the start of a medical career [17]. All of the oaths drew on at least some of the precepts and sentiments of the original.

29.5 Codes of Ethics

A code of ethics is a statement of ideals and rules, drafted by an authoritative individual or body, intended to guide the values and behavior of a profession or group. The specified guidance may be affirmative, prohibitive or both. One of the earliest known codes of ethics for physicians originated in what is now China in the middle of the first millennium CE The first recorded code of ethics in European tradition is thought to be one created for its members by the Royal College of Physicians in 1555. The modern concept of a physician code of ethics is represented by that of Sir Thomas Percival published in 1803. Entitled "*Medical Ethics, or, A Code of Institutes and Precepts Adapted to the Professional Conduct of Physicians and Surgeons*," Percival's Code stated moral duties which were intended to apply to anyone who held himself (virtually always male) out to be a physician or surgeon. It specified duties to patients, medical colleagues and the general public; it was applicable to hospitals, physician practices and apothecaries. In addition to ethics, it also addressed some legal matters.[18]

Percival's medical ethics code soon crossed the Atlantic Ocean to be adopted in part by physician organizations in New England where it was used for governance of the profession and to

[17] Cf. reference [5].

[18] Referenced in Baker, Robert. "Medical codes and oaths." *Bioethics*, edited by Bruce Jennings, 4th ed., vol. 4, Macmillan Reference USA, 2014, pp. 1935–1946. Gale eBooks, https://www.gale.com/apps/doc/CX3727400387/GVRL?u=balt85423&sid=GVRL&xid=b97dad72.

resolve disputes among physician members. Over a few ensuing decades, sections describing moral obligations to the sick were adopted by the Medical Society of the State of New York, the Medical-Chirurgical Society of the City of Baltimore and, in 1847 at its organizational meeting, by the American Medical Association (AMA). Over the next 150 years, that AMA Code and principles based on it underwent numerous revisions and changes to arrive at its current format of nine principles, last revised in 2001.[19]

Since the mid twentieth century, numerous health care-related professional societies and associations as well as international non-governmental bodies, recognizing the need for commitment to practice their professional activities ethically, have promulgated codes of ethics or guides to ethical practice. Besides the AMA code of 1847, selected organizations' codes and their dates of origination of interest to us here include the Nuremburg Code of Research Ethics (1947), World Medical Society (1949), the American Nurses Association (1950), Association for Computing Machinery (1966), American Hospital Association (1974), American College of Healthcare Executives (1995), International Medical Informatics Association (IMIA, 2003), American Medical Informatics Association (AMIA, 2007), Health Information Management Systems Society Code of Conduct (2020).

Many of the themes in these health care codes of ethics and/or conduct reflect ideas and obligations stated in the Hippocratic Oath, specifically, acting with beneficence toward patients, avoiding or preventing harm, maintaining privacy and protecting the confidentiality of information obtained in the provision of medical services.

Ethical standards in informatics are important because of the centrality of the electronic health record (EHR) and the privacy, confidentiality and welfare interests of the often-vulnerable patients or subjects whose information makes up the content of those records. The codes of ethics in health care informatics are grounded in ethical principles, as distinct from legal principles, and recognizing that ethics may require higher standards of conduct based on human rights and moral duties than mere legal requirements.

The IMIA and AMIA are two important professional organizations which have promulgated codes of ethics for health informatics professionals (HIPs). The codes specify the ethical duties and expectations that apply to their work.[20, 21, 22] While the codes apply specifically to the members of the respective organizations, they also serve as standards of conduct for HIPs in general.

The purposes of the Codes are: (1) to provide ethical guidance; (2) to describe principles against which to measure professional conduct; and (3) to inform the public of the ethical considerations that should guide conduct of health informatics professionals. The codes must be clear, unambiguous, easily applied to the many ethical challenges arising in the course of the work and flexible in order to adapt to the rapidly changing landscape of informatics. Another purpose is to facilitate relationships between the various parties involved in the provision of health and health care services, including patients, individual and institutional providers of care, administrators, insurers, government agencies, researchers, educators and others.

Following the structure of many codes of ethics, the codes of interest to HIPs open with a general statement that describes the purpose of the code and rationale behind its creation, followed by statements regarding foundational principles which in turn form the basis for the obligations and expected actions and conduct.

[19] American Medical Association. *Code of Ethics* 2001 et seq. https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview. Accessed 3 Feb 2021.

[20] International Medical Informatics Association. *Code of Ethics for Health Information Professionals*. 2016. https://imia-medinfo.org/wp/imia-code-of-ethics/. Accessed 15 Feb 2021.

[21] International Medical Informatics Association. *Ethics for Health Informatics Professionals-The IMIA Code, its Meaning and Implications*. 2016. https://imia-medinfo.org/wp/wp-content/uploads/2019/08/Handbook-for-revised-Code-of-Ethics.pdf. Accessed 21 Jan 2021.

[22] American Medical Informatics Association. *AMIA's code of professional and ethical conduct 2018*. https://academic.oup.com/jamia/article/25/11/1579/5134082. Accessed 11 Jan 2021.

The IMIA code specifically references and incorporates the four fundamental principles of Beauchamp and Childress cited above—autonomy, beneficence, "non-malfeasance",[23] and justice—to which it adds two more principles considered fundamental—those of impossibility and integrity. The principle of impossibility requires adherence to the four fundamental principles so long as it is possible to do so under the conditions that exist; the principle of integrity requires that one who has an obligation must fulfill that obligation to the best of their ability.

The IMIA code derives general principles from the fundamental principles and defines them as follows:

1. The **Principle of Information Privacy and Disposition** specifies the individual patient's or subject's right to privacy and to control all aspects of handling of [their] personal health information to include its "collection, storage, access, use, communication, manipulation and disposition."
2. The **Principle of Openness** asserts the individual's right to know how [their] information will be handled with respect to all of those activities cited in 1.
3. The **Principle of Security** requires that the individual's information be protected by all "reasonable and appropriate means" from loss, mishandling, unauthorized access, use, alteration and transmission.
4. The **Principle of Access** grants a right of unencumbered access and a right to correct the record with respect to its accuracy, completeness and relevance.
5. The **Principle of Legitimate Infringement** establishes an exception to the individual's absolute control over [their] record specified in Principle 1, in cases of legitimate, appropriate and relevant needs of others or society.
6. The **Principle of Least Intrusiveness** requires that any infringement on the privacy right specified in Principle 1 may only occur in the least intrusive fashion and with a minimum of interference with the rights of the affected individual or subject.
7. The **Principle of Accountability** mandates timely and appropriate justification to the individual or subject for any infringement of [their] of control granted by Principle 5.

These principles generate rules of ethical conduct for HIPs to fulfill their duties to the various stakeholder groups who may have legitimate interests in the records and other areas of HIPs' responsibilities. A brief summary of the rules follows. Details are available in the respective codes of ethics and accompanying explanatory documents cited above [5, 16, 17].

Specific rules derived from these principles define ethical conduct in several categories of stakeholder groups, namely to patients or subjects (such terms also include their authorized representatives), to colleagues and other health care workers, to institutions and businesses related to provision of health and health care, to society, and finally, to oneself as an informatics professional.

For the **patient/subject-oriented obligations**, there are several key elements which HIPs are duty-bound to honor:

1. Patients have a right to know that
   (a) systems and processes exist for the purpose of collecting, handling and communicating their personal health information (PHI),
   (b) such collection, handling and communication may only be done with their voluntary and informed consent;
      - there may be exceptions to this provision required by law or other circumstance in which case the need will be evaluated on independent grounds to determine if and how the exception will be allowed. The patient will be advised of such of such action and outcome.

[23] The IMIA code specifically uses the term "non-malfeasance" which it defines as a duty to prevent harm to another. This is identical with the definition of "non-maleficence," as used by Beauchamp and Childress.

(c) in the course of their health care, a record will be established and maintained and know
   - who has established the record and where and how it will be maintained;
   - what is to be held in the record and how it will be obtained;
   - the purpose(s) to which the information will be put;
   - who will have access and to whom it will be communicated;
   - the length of time it will be maintained;
   - the ultimate nature of its disposition.

(d) they have the authority to create, manage and maintain their own personal health records using a platform of their choice.

(e) they will not be misled about the handling and uses to which the information may be put

(f) they have a right to access, review and correct the information they provided or was generated on their behalf, no matter the source.

(g) safety, reliability, security and confidentiality of the information is of paramount importance as is compliance with applicable laws, regulations, policies and standards.

(h) inappropriate use and disclosure of PHI is a serious matter with potential for significant harm.

(i) If breaches of security, privacy or confidentiality have occurred.

2. HIPs must ensure that PHI, personally identifiable information (PII) and other biomedical information will be collected and handled in a safe, reliable, secure and confidential manner consistent with applicable laws, policies and standards.
3. HIPs must never knowingly disclose PHI, PII or other biomedical data in violation of the applicable laws or accepted practices or in ways inconsistent with what the patient was told about disclosure.

With respect to **obligations to colleagues, team members and other health care professionals** (HCPs) whose needs are served by HIPs, duties include:

1. Assist and support such HCPs in accomplishing their work in patient care, research and education, as appropriate;
2. ensure timely and secure access to the EHR;
3. identify and advise colleagues of problems with systems, processes and other factors which could impair fulfillment of any of the prior specified obligations related to handling of data, PHI or other information;
4. anticipate such problems and have corrective action plans in place to be implemented in a timely response;
5. institute timely and effective solutions to such problems when they arise.

HIP leaders have special obligations to those they supervise in order to assure their own ability to lead effectively and ethically and to facilitate that conduct in others. They must model and communicate ethical values to those they supervise.

Regarding **obligations to institutions, employers, business partners and clients**, HIPs must understand and fulfill their duties and obligations to those entities as well as be cognizant of the obligations those entities have to various constituencies, first and foremost to patients but also to the public, regulatory and government agencies, shareholders, vendors and others. These duties include:

1. to act with competence, diligence, integrity and loyalty;
2. to facilitate an ethically sensitive security culture;
3. to implement and maintain the highest possible quality standards for all informatics-related activities;
4. to anticipate and recognize potential or actual conflicts requiring measured responses to find optimal resolution;
5. to advise when policies or practices might violate ethical or legal obligations, contracts or agreements with patients.
6. to appreciate potential and actual consequences of change and innovation in high-

complexity environments in order to avoid or minimize adverse intended or unintended outcomes.
7. to monitor such changes in order to promptly respond to conditions requiring intervention;
8. to be responsible for informatics education services for HIPs, HCPS and others as needed;
9. to strive to be objective and act in unbiased ways when carrying out professional duties.

Societal obligations include those related to facilitating the institution's role in the community as well as those related to research and the protection of human subjects in compliance with accords and principles such as the Universal Declaration of Human Rights, the Declaration of Helsinki, the Belmont Report as well as relevant laws and policies.[24] HIPs must:

1. facilitate ethical and appropriate collection and handling of data used in planning and provision of health care services to the community and larger society;
2. in research settings, exercise a duty of care to colleagues and subjects even if not specifically included in documents governing research such as Institutional Review Board (IRB), vendor and other materials.
3. balance the good for society and the individual when planning, carrying out, analyzing and reporting conclusion of research.
4. contribute to the timely dissemination of new knowledge.
5. always act with honesty and integrity.
6. ensure appropriate safeguards for individual health information are in place using tools such as anonymizing and otherwise protecting patient identities.

Finally, **self-regarding** duties as a HIP require:

1. acting ethically and with professionalism;
2. maintaining competence and a commitment to life-long learning;
3. using evidence-based methodologies to improve health and health care;
4. avoiding conflicts of interest
5. refraining from impugning the reputations of colleagues
6. conducting oneself to reflect favorably on the profession.

It can be seen that the obligations specified in these codes reflect high standards of behavior on the part of informatics professionals. It is worth noting though that many of the obligations imposed on HIPs are, in fact, carried out by clerical and other frontline staff far from the loci of HIP work. The clerks who obtain general consent for treatment often are not aware of the detailed information in the forms which they ask patients to sign, let alone take the time to explain details and nuances involved in describing the systems, programs, devices, collection and handling of patient records mandated in the codes. If these obligations are taken seriously, and they must be, substantial effort must be exerted by HIPs to "ensure" that those who actually engage with patients or surrogates at their time of vulnerability and anxiety can and do carry out their responsibilities as required. These staff are, in effect, agents of the HIP and as such are obligated to perform to the same ethical standards in these particular responsibilities of their jobs.

Another point to be made is that there will be occasions when conflicts arise out of duality of obligation on the part of HIPs when trying to act in the best interests of parties with different or competing values and objectives. In those situations, consideration of the various ethical platforms described above may offer fruitful approaches to resolving ethics conflicts.

[24] United Nations. *Universal Declaration of Human Rights*. (1948). https://www.jus.uio.no/lm/un.universal.declaration.of.human.rights.1948/portrait.a4.pdf. World Medical Association. *Declaration of Helsinki – ethical principles for medical research involving human subjects*. (2013), https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/. US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. (1979). https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html. Accessed 1 Feb 2021.

These few examples illustrate there are great opportunities and challenges in ethics and informatics facing us today and in the future. Let's consider a few more.

29.6 Looking Ahead

With our understanding of the ethical obligations required of HIPs, let's consider some of the opportunities and challenges presented by the spectrum of activities in the realms of eHealth. Recall the six domains of health care quality from the NAM studies referenced above, i.e., health care should be **safe, effective, patient-centered, timely, efficient and equitable**.[25] These continue to represent the goals we have yet to fully achieve.

Individual performance factors are certainly important contributors to harm from medical errors, but the NAM reports cited above concluded that system factors played a much greater role in sub-par performance, errors and poor quality and safety than individual performance factors. Their conclusion was that "mistakes can best be prevented by designing the health system at all levels to make it safer—to make it harder for people to do something wrong and easier for them to do it right."[26] Certainly, the EHR is a pervasive and critical system factor, with tremendous potential to impact the quality of care; therefore, it should be a major focus for improvement.

Autonomy of decision-making is important to the exercise of an individual's self-determination, but in the realm of health informatics, the fundamental principles of beneficence, non-maleficence and justice will likely have a greater impact on improving the quality and safety of health care as well as realizing fair and equitable treatment in the provision of benefits and burdens which must be among our highest priorities. The challenge is to determine how to apply the resources of HIT to bring these about. Certainly, one of the driving forces behind mandates to achieve wide use of electronic health records via federal laws such as the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 was the belief that such technology would improve the health of patients by facilitating the collection, handling and use of health care-related data. It was also anticipated that access to large amounts of data would enable identification of problems and guide efforts at improving the design and function of systems of care, not to mention the power of aggregate data from patients and populations to reveal patterns of disease and related matters.

The Office of the National Coordinator for Health Care Technology (ONC) lists the following advantages of EHRs:[27]

- Providing **accurate, up-to-date, and complete information about patients** at the point of care
- Enabling quick access to patient records for more **coordinated, efficient care**
- Securely **sharing electronic information** with patients and other clinicians
- Helping providers more effectively **diagnose patients, reduce medical errors, and provide safer care**
- Improving patient and provider interaction and communication, as well as **health care convenience**
- Enabling safer, **more reliable prescribing**
- Helping promote **legible, complete documentation** and accurate, streamlined coding and billing
- Enhancing **privacy and security** of patient data
- Helping providers **improve productivity** and **work-life balance**
- Enabling providers to **improve efficiency and meet their business goals**
- **Reducing costs** through decreased paperwork, improved safety, reduced duplication of testing, and improved health.

[25] Cf references [3] and [4].

[26] Cf reference [3].

[27] Office of the National Coordinator. *What Are the Benefits of Electronic Health Records*. (2019) https://www.healthit.gov/faq/what-are-advantages-electronic-health-records. Accessed 26 Feb 2021.

For each of these putative advantages, the situation in practice is one of, at best, partial accomplishment. This has been particularly frustrating to physicians. Consider the matter of "accurate, up-to-date and complete information" in the EHR. Numerous studies have shown that information of many types in EHRs are inaccurate—medications lists [18], diagnoses [19], cut-and-paste documentation[28] and many others [20]. With regard to errors, reports examining technology-related factors in malpractice claims found EHRs to be frequently associated with significant numbers of medical errors [21, 22].

EHRs are now in use in nearly 90% of US health care settings. Those that are prone to incompleteness or poor usability or contribute to errors simply must be fixed, but the incentives have not favored the end users or patients. The complexity of EHRs and their proprietary nature has meant that vendors have had a great deal of control over their intellectual property, often to the detriment of clients and patients. Contracts have imposed stringent limits on what users can modify, and the costs of changing vendors is usually too great to consider such an action. These issues have led to legislative remedies, one of the most recent being the twenty-first Century Cures Act of 2016, to encourage medical research and improve care across the entire spectrum of activities related to health in order to achieve ease of access, exchange and use of electronic health information (EHI).

A key attribute of the Act is its focus on the patient's perspective and experience. Final Rules, specifying the regulations that will govern implementation of the Act, became effective in April of 2021. Hospitals are feverishly working to comply with the law and implement the user-/patient-friendly components. These will likely have a very significant impact on software vendors by limiting anti-competitive practices and requiring vendors to improve standardization and interoperability. It also mandates incorporation of features in the EHRs which will give patients access to all of their EHI, structured and/or unstructured, at no cost, such access to be readily available through smartphone apps and other patient-facing tools to encourage their participation in the mobile economy. With some exceptions, there are specific prohibitions against blocking the exchange of data between and among health IT systems, patients and providers.

These features will ease the fulfillment of HIPs' ethical obligations to promote patient access to their health information. While patient portals were a starting point for such access, patients' experiences have not met the original promise as they have proven to be cumbersome to use, limited in the information available to patients and lacking timeliness [23]. The twenty-first Century Cares Act aims to fix those deficiencies.

Considering the characteristics of EHRs listed above and others which contribute to their sub-optimal performance as judged by patients, clinicians, administrators and HIPs, it is incumbent on the designers, vendors and all of us users to advocate for their improvement on many of the ethical grounds articulated in the codes of ethics as well as on practical grounds. Business values and business ethics cannot be relied on to achieve the kinds of changes needed to make certain the EHRs function to allow HIPs to fulfill their ethical obligations. Those values of HIPs must drive involvement in decisions regarding EHRs at every level from design to purchase to functionality, security and privacy. Evaluation of EHR performance compared to the expected goals must be frequently performed and problems communicated to the decision-makers and vendors to assure they make the needed improvements.

Another area of ethical obligation and concern is related to the security of information systems, whether or not related to privacy and confidentiality of patient health records. In 1996, the Health Insurance Portability and Accountability Act was enacted to improve the efficiency and effectiveness of health care systems. Privacy protections were incorporated into the law to gain greater security for PHI and PII. HIPAA was an important though challenging advance in managing

[28] National Institute of Standards and Technology. *Examining the 'Copy and Paste' Function in the Use of Electronic Health Records*. 2017 https://nvlpubs.nist.gov/nistpubs/ir/2017/NIST.IR.8166.pdf.

health information, but in recent years, new threats to the security of health information have arisen in the form of outsiders penetrating hospital information systems. The nefarious intent often appears to be disruption of hospital activities in exchange for ransom paid to allow systems to resume working, but the potential for outside access to and misuse of medical records remains a concern. Constant vigilance and innovation dedicated to improving security our information systems for the benefit of the patients will be required to fulfill our ethical obligations.

Related to data ethics, consider this. Most health care institutions are facing the need to address how they manage the IT and informatics questions that arise in the course of operations and planning. The handling of data—financial, managerial, quality, etc.—throughout the organization must conform to policies and procedures which address the same issues of security, privacy, integrity, usability and availability as arise with the EHR. Some examples are (1) how to respond to requests by an outside organization with which the health care organization wants to cultivate a business relationship, when access to anonymized patient data is requested for analysis or even commercial purposes; (2) how to manage and use information in a health information exchange or other external repository to compare patient outcomes within and among institutions; (3) how to answer questions from an institutional review board (IRB) related to proper management of data acquired in a research project; (4) considering whether it is possible to completely anonymize or de-identify patient or other critical data, and if so, how? And more critically, if not, how to proceed. All of these have ethical implications and organizations must develop policies and procedures to address these kinds of issues. The HIPs must know their limits and when to recruit and convene additional expertise or establish internal resources like data integrity committees to assist in developing policies for these kinds of concerns.

In the realm of new technologies with foreign policy and national security implications, a question was recently posed as to how to protect PHI acquired by foreign-owned commercial laboratory interests under a contract for laboratory services with a company owned by a foreign government. As reported on "60 min", shortly after the first cases of COVID-19 were identified in the US, a large Chinese biotech company with ties to the Chinese government and Communist Party made aggressive efforts to contract with the State of Washington to perform COVID testing for the state.[29] The possibility of access by a foreign government to such a potentially large pool of Americans' biodata raised alarm within the US defense and intelligence establishments, speculating that biodata had significant national security implications. While the offer was rejected, the episode continues to fuel concerns over the privacy and security of health information on a scale not contemplated in the past.

The COVID-19 pandemic has opened up many approaches to expanding access to care that had been ignored or exploited only to a limited extent. An explosion in the use of telemedicine has occurred which has created opportunities and challenges for HIT professionals to assist in adapting and improving the usability, security and effectiveness of the technology. A recent comprehensive review of ethical issues in telehealth provides guidance in this area [24].

There is much more to be said about the ethical challenges posed by new technologies, new diseases, innovations and just plain human behavior[30] which will confront health care institutions in the future—artificial intelligence, telehealth, genomics, proteomics, microbiomics, robotics, predictive analytics and especially improving efficiency and efficacy while assuring high quality of care. It is to be hoped that, as we

[29] CBS 60 Minutes. *China's push to control Americans' health care future*. https://www.cbsnews.com/news/biodata-dna-china-collection-60-minutes-2021-01-31/.

[30] Surgical residents taking pictures posing with removed organs and with inappropriate comments and posted them on Instagram. Hospital investigating. Gamble, M. *Instagram photos in OR prompt investigation at Spectrum Health*. Becker's Hospital Review. Posted 03-15-2021. https://www.beckershospitalreview.com/hospital-physician-relationships/instagram-photos-in-or-prompt--investigation-at-spectrum-health.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=8242A8835812D8S.

gain experience with them, the ethical and informatics implications will become clearer as will our understanding of how to address them. Our touchstone must always remain that which is in the patients' best interests.

Finally, the 2020–2025 Federal Information Technology Strategic Plan[31] describes priorities and goals for the foreseeable future. Citing patient-centered care as the guiding principle, the plan's focus is on empowering patients to "take greater control of their health, improve health behaviors, manage chronic conditions, engage in shared decision-making and use bi-directional exchange of data to communicate with healthcare providers." It will serve as the federal government's road map for HIT and HIPs for the next 5 years and a prelude to the years beyond.

29.7 Conclusion

Informatics and information technology are central to reaching the goals articulated in the NAM reports of 20 years ago—that health care must be safe, effective, patient-centered, timely, efficient, and equitable. This cannot be overstated, and it should be clear that HIPs will have important roles in reaching them with resultant benefits to patients and society. Many advances and innovations now gaining traction in twenty-first century health care will raise new ethical questions or require us to look at old ones in new and different ways. While we have an obligation to incorporate useful new tools and ideas into our armamentarium, the benefits will undoubtedly come with risks. Ethics will be our guide to making the best choices to meet the needs of our evolving health system and our patients.

[31] Office of the National Coordinator for Health Information Technology. *2020-2025 Federal Health IT Strategic Plan*. https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf.

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Nurse Informaticists and the Coming Transformation of the U.S. Healthcare System

Mark Hagland

Abstract

From the building of the Golden Gate Bridge to the many health care challenges; all of which are faced with vision, planning, funding, and hard work. With the pandemic presenting challenges not yet foreseen, healthcare is utilizing clinical transformation to try to stay 'one step ahead'. Care must be delivered differently or the results will merely be the same; with the same inefficiencies and cost parameters. Nurses, and the specialized nurse informaticians, will play a vital role as they are the bridge between the patient and family and the entire interdisciplinary healthcare delivery system.

Keywords

Nursing informatics · Clinical transformation
Transformation · Efficiency

Learning Objective

- Analyze how informatics aids clinical transformation.
- Explain the role of a nurse informatician.

Human beings have always aspired to conquer challenges. Look at the history of San Francisco's Golden Gate Bridge, which, after decades of vision, discussion, planning, funding, and hard work, finally became a reality in May 1937.

As History.com explains it [1], "Following the Gold Rush boom that began in 1849, speculators realized the land north of San Francisco Bay would increase in value in direct proportion to its accessibility to the city. Soon, a plan was hatched to build a bridge that would span the Golden Gate, a narrow, 400-foot-deep strait that serves as the mouth of the San Francisco Bay, connecting the San Francisco Peninsula with the southern end of Marin County. Although the idea went back as far as 1869, the proposal took root in 1916. A former engineering student, James Wilkins, working as a journalist with the San Francisco Bulletin, called for a suspension bridge with a center span of 3000 feet, nearly twice the length of any in existence. Wilkins' idea was estimated to cost an astounding $100 million. So, San Francisco's city engineer, Michael M. O'Shaughnessy (he's also credited with coming up with the name Golden Gate Bridge), began asking bridge engineers whether they could do it for less".

As History.com notes, "Eventually, O'Shaughnessy and [engineer Joseph] Strauss concluded they could build a pure suspension bridge within a practical range of $25–30 million with a main span at least 4,000 feet. The

M. Hagland (✉)
Healthcare Innovation, Chicago, IL, USA
e-mail: mhagland@hcinnovationgroup.com

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construction plan still faced opposition, including litigation, from many sources. By the time most of the obstacles were cleared, the Great Depression of 1929 had begun; but, [I]n the end, it cost $35 million to build the bridge ($514 million in contemporary dollars), and it took four years and four months to build it, with thousands of construction workers involved (and 11 deaths from falls)." But the Bridge's completion created great excitement, and beyond its 20 million southbound crossings every day, the Bridge has also become a beloved worldwide symbol of San Francisco. But it's clear that simply imagining the Bridge was not enough; it took tremendous vision, planning, money, and hard work to make it a reality.

I wrote about the building of the Golden Gate Bridge in my editorial in the May/June 2020 issue [2] of *Healthcare Innovation;* and its application to the current moment in the U.S. healthcare system remains as applicable now as it was then. If anything, the impact of the COVID-19 pandemic on the healthcare system has intensified issues around the shift from volume to value in healthcare, as hospitals, medical groups and health systems have had to cope with severe financial stresses at a time when the purchasers and payers of healthcare are becoming increasingly impatient with the providers of healthcare.

Indeed, the Chicago-based Kaufman Hall consulting firm noted in a report published in August 2020—its "National Hospital Flash Report," based on July data from over 800 hospitals—that, during the first seven months of 2020, hospital operating margins plunged 96% in the first seven months of the year, compared to the same seven months of 2019. Nor did the situation look bright on November 30, when Kaufman Hall reported that, "Eight months into the pandemic, the Kaufman Hall median hospital Operating Margin Index was –1.6 percent for January through October, not including federal funding from the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). With the funding, the median margin was 2.4 percent year-to-date. Operating Margin fell 69.4 percent year-to-date (6.0 percentage points) compared to the same period last year, and 9.2 percent year-over-year (1.4 percentage points) without CARES Act funding. With the federal aid, Operating Margin fell 18.7 percent year-to-date (1.7 percentage points) and 8.5 percent (1.2 percentage points) below October 2019 levels."

The pandemic in fact hit U.S. hospitals at what was already a very difficult time, as they struggled to maintain financial stability, even as the purchasers and payers of healthcare were demanding that they move forward into payment for value. Payers and purchasers are increasingly insisting that providers deliver higher-quality, more reliable care, at lower costs, even as our society faces a double problem of aging and continuous increase in chronic illness. As the Medicare actuaries have noted, total U.S. healthcare expenditures are expected to increase from the current $3.3 trillion to nearly $6 trillion per year—a full 61%—in the next seven years. And all of that was before the extraordinary clinical, care delivery, operational, and financial challenges that have come with the COVID-19 crisis.

30.1 Clinical Transformation and the Critical Role of Nurse Informaticists

One thing that has become absolutely clear over the past several years, is this reality: for healthcare providers to provide more of the value that purchasers and payers are demanding, is requiring intensive and profound clinical transformation, meaning, an overhaul of the processes of care delivery, to make them more efficient and cost-effective and to improve patient outcomes. In researching my first book, the 2008 *Paradox and Imperatives in Health Care* (co-authored with healthcare economist and author Jeffrey C. Bauer, Ph.D.), I toured the Toyota auto plant in Georgetown, Kentucky, just outside Lexington. What was absolutely clear to me was how thoroughly the plant's managers and staff had analyzed every single process in that plant, from the broadest processes to the most specific ones. Nothing was left unexamined.

In contrast, most processes in hospitals and medical clinics in the U.S. even today still have

not yet been thoroughly analyzed for their efficacy and optimal operation; and yet it is in the core patient care delivery processes that the most potential for transformative change exists in U.S. healthcare.

What also has become very obvious in all this in the past several years is that clinical informaticists—nurses, physicians, and pharmacists with training and interest in informatics—will be absolute nexus figures in clinical transformation. Working alongside clinician executives and bedside clinicians, it is clinical informaticists who are helping their colleagues in patient care organizations to make the deep changes needed to achieve transformation.

30.2 Clinical Transformation Happening in Patient Care Organizations Nationwide

When data and analytics are leveraged to support clinical transformation, the results can be spectacular. There are countless examples emerging all across the U.S. healthcare delivery system. In 2016, *Healthcare Informatics* (now *Healthcare Innovation*) named Scottsdale Health Partners (SHP), a medical group based in the Phoenix suburb of Scottsdale, as a Second-Place Winner in its annual Innovator Awards Program, for SHP's use of data to support its care management work. As Associate Editor Heather Landi wrote in October 2016 [3], "Scottsdale Health Partners (SHP), a physician-led clinical integration network, was formed in 2012 and has quickly grown to 700 physicians serving 35,000 patients throughout the greater Scottsdale, Arizona community. SHP consists of 115 primary care physicians and the balance are specialists from a wide variety of specialties. SHP also participates in the Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) program. As an organization with a strong focus on transforming healthcare delivery in the Scottsdale area, bridging the gap between patients admitted to local hospitals and their primary care physicians is a critical component of SHP's Care Management Program."

Landi noted that, "As a result of a data-driven, multidisciplinary initiative, SHP has streamlined its care coordination program using health IT solutions, so that care coordinators monitor patients in real-time and see more patients per day, ensuring proper transition care. And, more impressively, SHP has made some remarkable enterprise-wide achievements with reducing hospital readmission rates among its patients—SHP's all-payer readmission rate is now below 9%, compared to the Arizona state average of 15%. For its innovative approach to avoid unnecessary patient hospital admissions, the editors of Healthcare Informatics have named the team at Scottsdale Health Partners the No. 2 winning team in the HCI 2016 Innovator Awards program." *Healthcare Informatics* was renamed *Healthcare Innovation* in January 2019.

"A lot of the success we've had around reducing readmission rates is because we're able to notify the primary care physician in real time and tell them what's going on with their patients in the hospital. As a result, patients get in to see their primary care physician within the right timeframes and the right follow-up is planned, which helps keep them out of the hospital," Tiffany Nelson, M.D., chief strategy officer at SHP, told Landi. "And while care coordination is primarily a clinical function, SHP leadership found that the system was only as good as the data supporting it," Landi wrote. "Currently four SHP-employed transition care managers are responsible for patients in three Scottsdale hospitals in the Honor Health system as well as a post-acute facility, and SHP also has an additional 15 care coordinators working with the primary care physicians. As SHP initially began building and developing its care management program, leadership recognized that there were a lack of appropriate tools available in the health IT market designed specifically for ambulatory care management professionals." "The biggest complaint that our primary care providers had was that they didn't even know that patients were in the hospital. There was a lot of difficulty getting their chart summaries and any information from the hospital. Typically, if physicians got a discharge summary, it was faxed and delayed. It's a problem

that's pretty common and we realized we needed to provide physicians real-time information," Dr. Nelson told Landi. "In addition, reliance on hospital legacy systems led to cumbersome paper documentation and other manual processes, frustrating care managers and impacting efficiency. In order to obtain appropriate information about patients, care management staff were using three or four different health information technology systems, 'taking anywhere from 30 to 45 minutes to get information about any one patient,'" Nelson testified. The work that the SHP leaders did in building their own patient census using their health information exchange (HIE) solution, led to the group's subsequent filtering of the data coming in to ensure the census was accurate. It is precisely that kind of work that is taking place in patent care organizations nationwide, that is moving the needle in the U.S. healthcare delivery system.

30.3 Nurse Informaticists' Unique Role

In all this, "The nursing informaticists have such a unique role and their ability to blend clinical practice and how best to leverage technology is what really makes it a powerful role," Sue Atkinson, R.N., associate principal with The Chartis Group (Chicago), told *Healthcare Informatics* Associate Editor Heather Landi in 2016 [4]. Atkinson, who is based in Aspen, Colorado, is a leader at The Chartis Group's clinical performance excellence practice. "Those are important skills to have—the clinical expertise and the IT knowledge and the ability to bring the two together to make the most of technology to ultimately focus on improving patient care."

According to a recent survey of nursing informatics executives and their peers released by Chicago-based consulting firm Witt/Kieffer, 51% of respondents said their organizations have a CNIO in place, an 82% increase from a similar survey Witt/Kieffer conducted in 2011. In that survey from five years ago, 28% of respondents said they had a CNIO in place. Additionally, one-fourth of respondents (24%) in this year's survey indicated the role was on the corporate radar.

"I think a good surprise from the survey results is that the role is becoming more mainstream and we're seeing more organizations either have hired CNIOs or are thinking about hiring them, more so than five years ago," says Chris Wierz, R.N., an Oak Brook, Ill.-based principal with Witt/Kieffer, and co-lead of the firm's IT practice. Wierz notes that her initial nursing title in healthcare IT was the computer nurse, "so we've come a long way," she says.

30.4 Number, Scope of CNIOs Continue to Grow and Expand

Nurse informaticists continue to grow in number and in responsibility across the U.S. healthcare system, with nurse informaticists being named Chief Nursing Informatics Officers (CNIOs), as well as being named to senior informatics positions in patient care organizations nationwide. Indeed, the HIMSS 2020 Nursing Informatics Workforce Survey [5] found that:

"The role of Chief Nursing Informatics Officer/Senior Nursing Informatics Officer continues to be on the rise with 41 percent of respondents reporting that their organization had the formal role. In 2020, 10 percent of respondents reported holding the title of manager of clinical informatics as compared with just 1 percent in 2017. The percent of director-level respondents increased as well to 11 percent as compared with 7 percent in 2017. Still, the majority of respondents (24 percent) stated their title was nursing informatics specialist, a small increase over 2017's 20 percent. This year also showed a significant change in reporting structure, with more nurse informaticists reporting to Nursing (40 percent), Quality (12 percent) and Operations (9 percent) over the historical trend of reporting to IT (48 percent)."

Some other findings from the HIMSS 2020 Nursing Informatics Workforce Survey:

- Training & Education: Training and education continues to be a priority for nurse informaticists, and 2020 saw a significant rise in formal education. The percentage of respondents who have a master's degree or Ph.D. in nursing informatics is 37% as compared with 31% in 2017. Those who have received a certificate in nursing informatics rose from 20% in 2017 to 25% in 2020. And 15% of respondents reported having completed a vendor/supplier certification, a new category in the 2020 survey. On-the-job training continued its downward trend with 54% of respondents reporting they engaged in it as compared with 56% in 2017 and 58% in 2014.
- Certification: The number of respondents with any certification took a significant jump from 49% in 2017 to 58% in 2020. In a new question for 2020, survey respondents selected enhanced credibility and marketability (49%) and personal satisfaction (45%) as top reasons to pursue certification. These answers also topped the list when asked about perceived value of certification, although personal satisfaction (81%) edged out over enhanced credibility and marketability (78%). Certification was again found to have a fairly high impact on respondents' career paths. The average rating for the impact certification has on career was 5.14 out of seven as compared with 4.96 in 2017.
- Informatics Career: Nearly a third (31%) of respondents reported having more than 10 years of experience in nursing informatics, the same as in 2017. However, the percent with less than a year of experience increased from 8% in 2017 to 14% in 2020. The number of respondents who have been in their current role for more than 5 years also increased a substantial amount from 31% in 2017 to 38%.

Examining some of these broad trends, "Eight nurse executives fulfilling the functional role of chief nursing informatics officers (CNIOs) at major health systems and Scottsdale Institute member organizations met in Scottsdale to discuss 'Managing Change and Optimizing Clinical Innovation' on April 27–28, 2018," Duncan Moore reported in *Healthcare Informatics* in July 2018 [6]. "They talked about such topics as mentorship, encouraging more women to take on IT leadership roles, good hospital citizenship, tamping down the proliferation of one-off apps, dealing with financial pressures and growing this group. This report captures their discussion and shared insights."

Among those whom Moore quoted in his report was Judy Blauwet, R.N., Chief Clinical Information Officer at the Sioux Falls, South Dakota-based Avera Health. Blauwet noted, speaking of her institution, that "We do great on quality. But everything is about bending the cost curve. We have great variability in nursing documentation in terms of efficiency." Moore note that "The EHR system in use at her hospitals has a tool that tracks nurses in the background as they document. They have been concentrating on quality of documentation and efficiency. She plans to use nationally published benchmark data for the pre-survey starting point," he wrote quoting her as saying, "I hadn't thought of including nursing satisfaction, but why not?"

Meanwhile, at the Brewer-based Eastern Maine Health Systems, System Vice-President and Chief Nursing Informatics Officer April Giard noted that her organization "collects all the data and tells her in a monthly dashboard what the biggest opportunities for improvement are. For example, last year Eastern Maine implemented changes in documentation for nurses." "We identified that our NICU nurses are spending much more time documenting in the EMR than national averages…After a re-education effort, we are seeing improvements. As the system CNIO, it's important to understand this is more than implementation—implementation is the easier part. It's how we use it. How do we make sure we're on top of improvement and changes, and how well it's being used? That's where the CNIO can really add value," Giard said.

Further, Moore wrote in his report, "Among their other duties, CNIOs function as change agents within their organizations. Leading change

in complex organizations requires a panoply of soft skills that are unique to the role. Some hospitals may have 'hot spots' where leaders are resistant to change." And he quoted Rosemary Ventura, R.N., Chief Nursing Informatics Officer at New York-Presbyterian Hospital in New York City, as stating that, in order to address those issues, "We have to be strategic; we have to teach them messaging. I have to target particular people, coach them on the message. So they don't say, 'Oh, because the hospital says we have to do it this way.' That's not what you want out there."

The potential going into the future is huge: Tammy Kwiatkowski, Director of Clinical Informatics at HIMSS, put it this way in a podcast [7] posted online on November 12, 2020. She was speaking with Doctor Nurse Dan Weberg, who describes himself as "an author, provocateur, and the Head of Clinical Innovation at Trusted Health go deep with guests you won't hear anywhere else."

Asked by Dan Weberg why she thinks that the professional specialization in nursing informatics is growing these days, Kwiatkowski said, "If you talk history and some of the work that you've done in the past, and we look at the high tech act in 2009, which really drove the adoption of interoperable EHRs throughout the health care delivery system." Further, she told him, "More organizations are becoming very wired," and as the leveraging of informatics expands and intensifies, she said that "the need for informatics will just continue to grow and evolve," with tremendous potential for nurses interested in growing their careers and contributing to the leveraging of informatics healthcare system-wide.

In the end, the pioneers in the U.S. healthcare delivery system agree broadly on the need to move forward to transform the delivery system; and underlying that, there is widespread agreement that clinical transformation will be an essential element in delivery system reform. And underlying that? An intensive and extensive need for leadership shown by clinical informaticists, including nurse informaticists, to help work collaboratively with their clinician and administrative colleagues in order to "get under the hood" of clinical processes and operations and transform care delivery from the inside out. The results might not be as visually spectacular as that of the creation of the Golden Gate Bridge in San Francisco, but they will be no less important for that. The future of our healthcare system depends on it—and the system will be immensely better for their work. Think of it as a shining bridge to the future of U.S. healthcare.

Mark Hagland is Editor-in-Chief of *Healthcare Innovation* (formerly *Healthcare Informatics*). He has been a professional healthcare journalist since 1989, and is the author of two books—*Paradox and Imperatives in Health Care* (2008, co-authored with Jeffrey C. Bauer, Ph.D.), and *Transformative Quality: The Emerging Revolution in Health Care Performance* (2009), both published by Productivity Press (Taylor & Francis Group), and of over 10,000 articles on healthcare policy, operations, quality, process improvement, and strategic information technology issues. He has won numerous national journalism awards, including, in 1997, the National Institute for Health Care Management's Fourth Annual Health Care Journalism Award, for his reporting on the IPA (independent practice association) phenomenon in California, for *California Medicine*. He has also won a number of national awards from the American Society of Healthcare Publication Editors, including a 2009 Gold Award for Best Feature Article, for the healthcare industry's first comprehensive profile (in 2008) of Epic Systems Corporation. He lives and works in Chicago.

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The Future of Health Systems: Health Intelligence

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John S. Silva, Marion J. Ball, Mark Polyak, and Gabriela Mustata Wilson

Insanity, doing the same thing and expecting different results.

Albert Einstein

Abstract

This Chapter discusses fundamental approaches that will drive the shift from today's systems to those that will be successful in the "new normal.". It highlights the changes and emerging technologies that are already affecting health systems. The authors suggest that the evolving post-COVID-19 ecosystem will need **Health Intelligence** tools to provide timely and useful insights. These insights will be drawn from many diverse and rapidly expanding data sources, including social media, anonymized financial, mobility, and IoT data. The authors suggest that 'new normal' systems should be built on a Complex Adaptive System (CAS) framework, much like the Internet, to address the flexibility and extensibility required in the twenty-first Century. It also describes some of the challenges facing the Health Informatics community. It also presents how **Health Intelligence** tools can support the evolution from today's health ecosystem into the set of successful systems for the "next normal." The Chapter concludes with exemplar cases for **Health Intelligence** that support public health and individuals. Users will have always-on access points with them and have more timely, actionable insights.

Keywords

Health intelligence · Complex adaptive system · Health ecosystem · Public health intelligence · COVID-19 · Health informatics Social determinants of health · Smart hybrid layers · Real-time insights

J. S. Silva (✉)
Silva Consulting Services, Phoenix, MD, USA
e-mail: jc-silva-md@att.net

M. J. Ball · G. M. Wilson
Multi-Interprofessional Center for Health Informatics (MICHI), The University of Texas at Arlington, Arlington, TX, USA
e-mail: marion.ball@uta.edu; gabriela.wilson@uta.edu

M. Polyak
Ipsos, Washington, DC, USA
e-mail: mark.polyak@ipsos.com

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Learning Objectives
On completing this chapter, the reader should be able to:

- Characterize a described vision of healthcare as a complex adaptive system.
- Describe components of Health Intelligence.

31.1 Introduction

In the fourth edition of HIMS published in 2015, we described a complex adaptive systems (CAS)[1] architectural framework for twenty-first Century health information systems and why this model is critical for success in the twenty-first Century [1]. For example, the Internet is a Complex Adaptive System that has transformed nearly every sector of the global economy and introduced "social power" to industry and politics. The Web's adaptive behavior manifests in very rapid development and adoption of cloud computing. As an adaptive platform, the Web has spawned fairly robust versions of free software products that are readily available, such as Google Analytics, Web conferencing systems, Teams, Zoom, Go to Meeting, Skype, etc. As a result, today's users expect to access whatever information they need, wherever, whenever, and however they need it and conduct useful transactions with **no learning curve** (high value/high usability), i.e., on Internet Time. Today's users expect these experiences when they 'connect.' The health ecosystem must learn to play by these rules. So far, this is NOT the case!

The Fifth edition of *HIMS* details many of the components of electronic health record (EHR) systems as they exist today. It addresses how an EHR and its components might evolve in the near future and how systems external to an EHR will support healthcare delivery outside traditional settings. Importantly, this Chapter describes **Health Intelligence** as a critical component of the new, multiprofessional health ecosystem**. Health Intelligence** delivers holistic insights into critical situations and issues. It supports data driven decision making similar to what other industries do for competitive advantages [2]. These timely insights assist decision-makers as they plan and respond. It also provides timely feedback to them on the impacts of their decisions.

As Bloomberg has stated, "economic shocks like the coronavirus pandemic of 2020 only arrive once every few generations, and they bring about permanent and far-reaching change" [3]. For the year 2020, Health systems lost up to 34.5% of their pre-COVID-19 outpatient and 19.5% of their inpatient volumes [4]. The total financial loss, as estimated by the American Hospital Association, was $323 billion. As a result, the COVID-19 pandemic has accelerated the transition of care from hospitals and clinic locations towards persons in communities and homes. These changes have stimulated new health delivery models that have embraced a multiprofessional team approach beyond the hospital. In-person interactions have transitioned to telehealth visits to reduce exposure risk to clinicians and other persons. These telehealth visits were enthusiastically received. They are significantly more convenient for the person who does not have to drive, take public transportation or wait for the clinician to see them [5]. Both urban and rural areas saw significant increases in telehealth utilization, with claim rates increasing from 0.2% of medical claims in October 2019 to 6% in October 2020. This increase translates into an impressive 2937% increase at the national level [6]. For those patients in acute care, telemedicine platforms enabled patient families to speak with family members and loved ones [5].

The authors suggest that soon, individuals will maintain their holistic record of crucial information, including their Social Determinants of Health (SDOH) data, that is separate from but interoperates with EHRs and other health data stores. From a person's perspective, they need **Health Intelligence** anytime, anywhere they

[1]Complex Adaptive Systems are characterized by a high degree of adaptive capacity, giving them the ability to **succeed and flourish in the face of change**. They are adaptive, communicative, cooperative, specialized, spatially and temporally organized, and reproduce, often with new parts that are more resilient and effective than earlier ones (Wikipedia, complex adaptive system, accessed 12/28/2020).

make decisions about their social, personal, financial, wellness, health, or prevention activities [7]. A person's access point is not limited to visits to a clinic or interactions with a health worker. Instead, their point of access is always with them, always on – wherever they are, whatever they are doing – to support their decisions and behaviors [8]. They are active on many social network channels where they can conduct useful transactions with no learning curve. Interactions with health systems are exceptions to their daily life. Health and wellness systems must rethink the most effective way to support their clients with **Health Intelligence** to understand their choices clearly. This proactive intelligence approach will have a dramatic positive impact on compliance with health and wellness plans, as the person will be actively involved in creating their plan.

The COVID-19 pandemic has exposed how COVID-19 has significantly impacted disadvantaged and minority communities across the board: higher case and death rates, economic, food, and housing insecurities, unemployment, and social isolation [9]. Lack of SDOH data was evident at all levels. As a result, numerous health systems are rapidly incorporating SDOH data and relevant data from social media channels into their EHR systems [10]. The COVID-19 pandemic demonstrated that integrating these various data streams is essential to developing and implementing equitable strategies appropriate for individual and population-level needs. Individuals already use many sources of information, including home, personal, and community medical or health sensors, rapid diagnostic devices, numerous social media conduits, and streaming data from the myriad of wearable/fixed devices via the Internet of Things (IoT, [11]). Over 25% of adults will be wearing accessories or sensors by 2022 [12]. In addition to the rapidly expanding set of diverse data streams, the sheer volumes of data challenge the health ecosystem. It is estimated that the Web held 4 Zettabytes of data (4×10^{21}) in 2013, while in 2020, it has about 40 Zettabytes of data (40×10^{21}) and continues to double every 2 years. By comparison, the healthcare ecosystem generated an estimated 150 Exabytes (1.5×10^{18}) in 2011 and 2.3 Zettabytes (2.3×10^{21}) in 2020 [13].

One key challenge is how to bring all of these disparate and rapidly expanding data sources together, many of which are external to EHR systems. We believe that an Internet-like approach, i.e., a complex adaptive system architecture, will be required that evolves concurrently with the health ecosystem. As Martin described it, "Complex adaptive systems (CAS) are systems composed of many individual parts or agents in which patterns can emerge as a result of agents deploying "simple rules" from the "bottom-up" without external control—CAS are "self-organizing" systems. "Simple rules" in health care would include seeking to optimize patient well-being and the functioning of professionals. If elements of a CAS system are altered, the system adapts or reacts. The behavior of a complex adaptive system can be inherently unpredictable and non-linear as elements of the system, the internal (e.g., professionals and managers) and external agents (e.g., patients, families, and society), have multiple perturbations, changes, and interdependencies" [14]. Stevens has described her team's experience this way, "Covid-19 has been a painful reminder that health care in the U.S. is a complex adaptive system, complete with rare and nondeterministic events" ([15] *vide infra,* below).

This approach will enable health systems, data streams, and tools to provide timely **Health Intelligence** to all health ecosystem participants. This approach needs to be inclusive: individuals, health workers, and persons who manage health systems, communities, states, and our country. In short, these technologies are ushering in a new age of always-on care support that moves from sick care to self-wellness and self-care at home or their workplace.

31.2 Health Informatics

The traditional healthcare system is based on a sick care model, meaning a person becomes a patient when they fall ill and seek care. As the healthcare ecosystem evolves through in-depth

digitalization, this model transitions towards a person-centric wellness/preventative model [16]. The increased complexity and volume of data and lack of access in new care locations exacerbates the ability of EHRs to provide relevant and usable information to health workers and individuals. The move toward the home as a focus will further complicate EHR use in these locations 'remote' from the hospital. Recent publications from CMS [17] have indicated that 'medical care at home' is an important new mode of treating patients, albeit using traditional clinician-lead practices in the home. The 'Medical Care at Home Comes of Age' report from California Health Care Foundation [18] January 2021 reviewed the literature and developed a set of four models for care in the home. Of particular interest to the Health Informatics community, the authors described that most at-home models were staffed with health workers in multidisciplinary teams. These included M.D.s, PAs, N.P.s, care coordinators, R.N.s, social workers, skilled therapists, community health workers, aids, and behavioral health therapists. Only one of those models had remote patient monitoring and telemedicine as an integral element of their model; the other three relied on telephone calls. In addition to the CMS efforts, several efforts use IoT devices and sensors [19] in the home to monitor the health and activities of its residents [20]. Thus, we leave it to Health Informatics communities to address constructively the 'new normal': where the care setting is moving away from traditional settings; multidisciplinary health practitioners are supporting persons; and the evolving technology base that supports these new practices. The move to teams with multiple professionals has created a demand for interprofessional practice and education (IPE) to help teams operate effectively and efficiently [21]. The challenge is how health information systems can provide timely information to the individual (aka patient) and all team members? **Health Intelligence** is an approach and suite of tools that should become a "keystone" for the Health Informatics technical infrastructure; it is described below.

31.3 Health Intelligence

The COVID-19 pandemic has demonstrated the need for better tools and better collaboration at the community, national and global levels. Traditional health service systems have been overwhelmed with an incredible number of patients and sustained significant revenue losses despite the rapid expansion of telehealth services. Surviving in this environment requires flexibility in developing and integrating multiple data sources and applying relevant analytics to generate the information decision-makers and individuals need. **Health Intelligence** is needed to provide accurate and timely insights into understanding the critical issues that both must address. These same **Health Intelligence** systems must also monitor responses to ensure that the responses are effective for their respective populations.

Health Intelligence is the generic approach to gathering diverse data streams, analyzing them, and constructing relevant and timely products that decision-makers can use to generate more effective and efficient plans and responses for their particular problems. The result is a data driven decision making approach for decision makers to respond and monitor their situations. It should also provide intelligence so that individuals can make informed data driven decisions about their health and wellness. While **Health Intelligence** is a relatively new term, militaries have used "intelligence" to determine what adversaries might do and how they could do it, then provide the relevant information for the most effective and efficient responses. Although there is no 'official' definition of **Health Intelligence**, most explanations include multiple, relevant data sources/streams, several analytic tools, and a knowledge-based synthesis of results that enable decision-makers to make data driven decisions on their specific question or issue.

The CDC defines public **Health Intelligence** as "the process of moving from data through knowledge synthesis to action with the specific aim of early detection for an effective response [22]. Traditional public health surveillance meth-

ods have relied on post hoc observations of events that have occurred; i.e., people have to get sick before most surveillance techniques identify them. The need to respond quickly during a pandemic or a natural disaster and function in a 'plug and play' mode requires merging traditional surveillance data with multidimensional data from search queries, social media, deidentified human movements, social intelligence, and crowdsourcing. Social Media Monitoring, Artificial Intelligence, and Deep Learning (AI/DL) are innovative and transformative tools that may help identify potential or early disease outbreaks when combined with multiple data streams and appropriate analytics [23].

The following examples show how **Health Intelligence** can provide early warning of increased COVID-19 cases to county public health departments.

1. **Mobility Data Analysis:** Analysis of anonymized cell phone data provided a county-level assessment of adherence to social distancing [24]. Counties with a with decreased social distancing had estimated reduced quarantine compliance. There were many more counties with decreased quarantine compliance in December 2020 compared to November 2020, meaning that their population moved around more and did not adhere to social distancing. Recent papers have shown a strong correlation between lack of social distancing and increased rate of COVID-19 cases that follow about a week after decreased social distancing [25]. This intelligence is essential for public health departments to see when their county social distancing gets worse, i.e., more people moving around and not staying at home. Those counties can expect an increase in cases and thus, plan for a surge in contact tracing, increased hospitalizations, resource demands, and, subsequently, increased deaths.
2. **Social Media Monitoring**: Social media monitoring, also known as social media listening or social media measurement, is a powerful tool that can help identify topics and mentions that can provide useful insights and help understand people's attitudes towards a specific topic. It can provide a more in-depth analysis of social media sentiments and insights into what topics people mentioned the most. This data was collected in the state of Texas from December 2020 through January 2021 [26]. In the Government Response topic category, the most frequently mentioned topic was vaccine development. The assessment of positive or negative emotions on topics within the Government Response demonstrated that vaccine development had 89% positive comments while shutdown of schools had the most negative comments (80%). These data are critical for decision-makers to understand what topics are trending on social media and the perceptions of their citizens as being positive or negative.
3. The Multi-Interprofessional Center for Health Informatics at the University of Texas at Arlington, in partnership with industry, developed the Health-Intelligence Atlas (HI-Intel Atlas). It is a **Health Intelligence** core tool that merges traditional surveillance data with multidimensional data to inform public health decision-makers and supported their efforts in vaccine preparedness and distribution. Details on how HIntel-Atlas was implemented and relevant use cases are presented elsewhere [27]. The HIntel-Atlas was initially designed for a large county. It was scaled-up to other locations within Texas and other areas in the U.S. All data sources were used from publicly available sites and included: CDC Social Vulnerability Index (SVI), Medically Underserved Areas and Populations, Poverty Levels, Health Literacy Data, Transportation Data, and COVID-19 case counts. The HIntel-Atlas was rapidly extended to the entire state of Texas by producing dashboards with a smart hybrid layer that combined high SVI (vulnerability index >0.8) and low health literacy (health literacy levels, 0–235, National Quartile). These smart hybrid layers were generated for the entire state (Fig. 31.1) and large population areas in southeast Texas

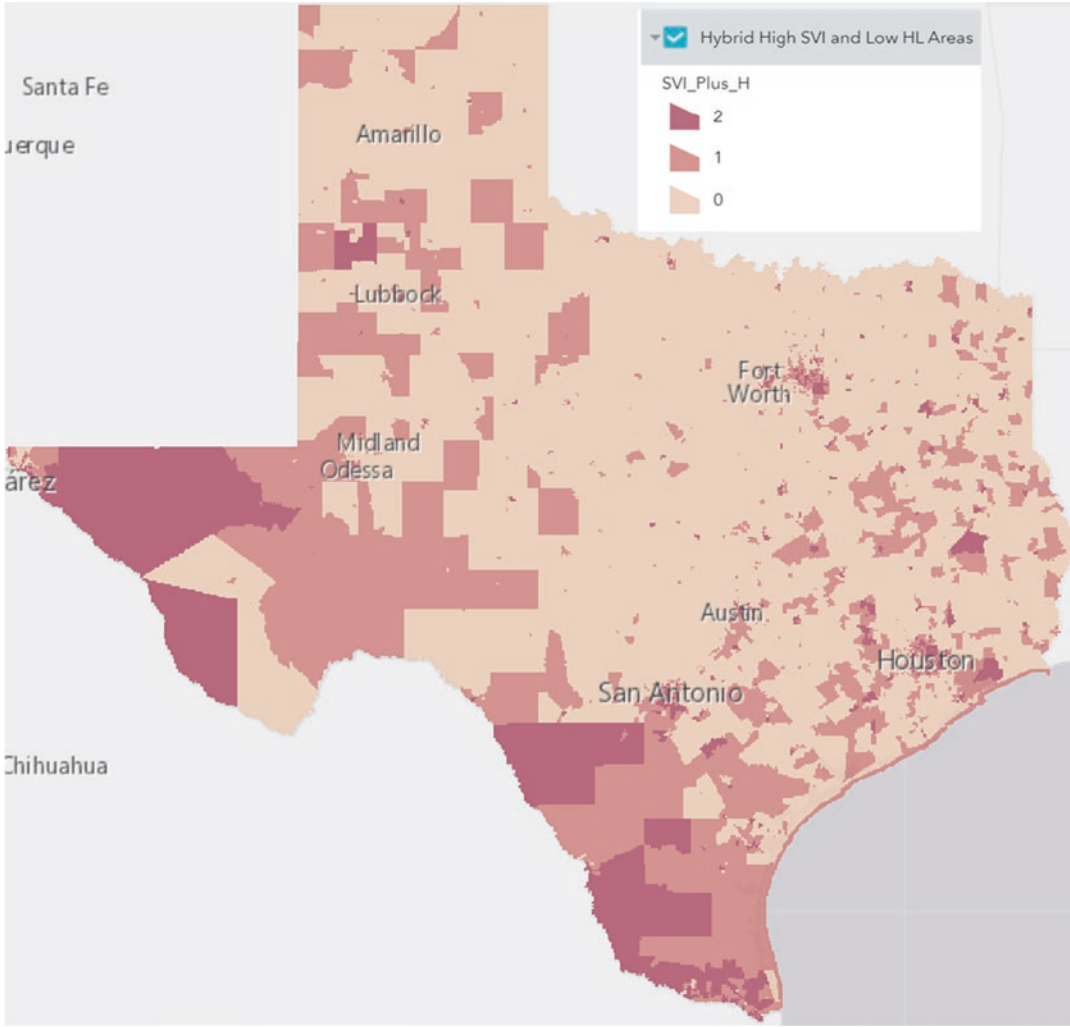

Fig. 31.1 State of Texas. Dark Red - Both SVI >0.8 and H.L. 0-234 were met, Pink – either SVI or H.L. criteria were met. Tan – neither criteria met

(Fig. 31.2). Through the HIntel Atlas, users could zoom in to show the same layers for the county, zip code, and census tract levels of interest, enabling decision makers to see the big picture and the local situation within the same map. Dark red areas indicated where both SVI and health literacy co-occurred and represented the highest risk areas. The lighter red shaded areas indicated where only one criterion was met and tan areas with no vulnerabilities. This type of visualization decluttered the display and helped decision makers focus on the areas of interest.

These exemplars were built for the COVID-19 pandemic. With data sources appropriate for the outbreak, the HI-Intel Atlas can provide similar **Health Intelligence** for other disease outbreaks, epidemics, or pandemics.

31.4 Conclusion and Future Directions

The COVID-19 pandemic demonstrated the need for hybrid surveillance systems to merge traditional surveillance data with multidimensional

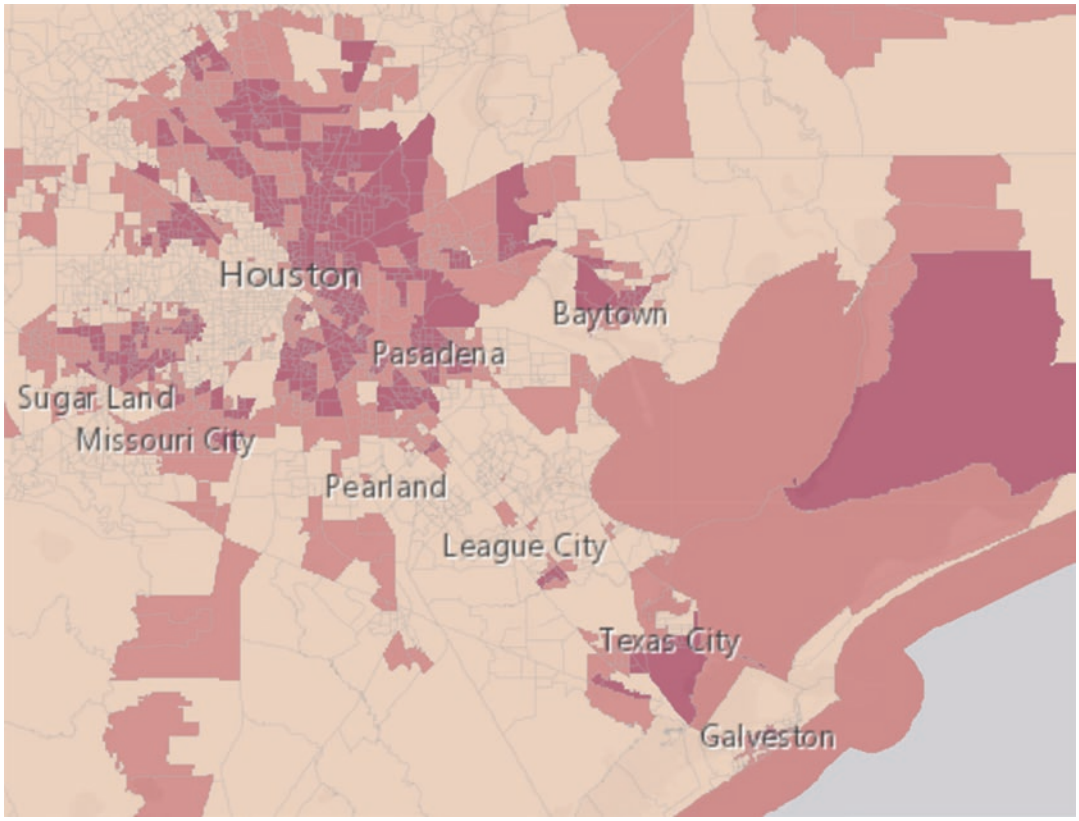

Fig. 31.2 Southeast TX. Dark Red - Both SVI >0.8 and H.L. 0-234 were met, Pink – either SVI or H.L. criteria were met. Tan – neither criteria met

data from search queries. It used smart hybrid **Health Intelligence** layers that fused what decision makers needed to know to plan and monitor COVID-19 activities at the local, state, and national levels. Counties, schools, and states have created multiple dashboards to report or identify 'hotspot' locations. These *post hoc* dashboards displayed what had happened. The community needed to move to real-time insights derived from streaming data sources that provided timely, holistic insights for decision-makers. As the **Health Intelligence** approach takes hold, we can envision generating automated insights based on each user's needs. Associated with those insights would be a list of appropriate, data driven recommendations for response and recovery along with models that project expected outcomes. The HIntel Atlas could then monitor the current situation against projected outcomes to alert uses that the response is not performing as expected. Its users will have always-on access points with them and have more timely, actionable insights.

The approach described in this Chapter recommends using complex adaptive system models to help drive health systems' evolution. The Health Informatics communities should promote standardizing publicly available relevant data sources, like the CDC's Social Vulnerability Index, and tools and analytics. The entire community will have a common starting point for their **Health Intelligence** efforts. Through collective efforts, public health agencies and the health informatics community could foster consortia to collaborate and share data sources, tools, analytics, response recommendations to mitigate or halt the effects of the next major outbreak or pandemic. We also believe that this same approach could be successful as the entire community addresses the terrible social inequities that surfaced during the COVID-19 pandemic.

Moving forward, it will be essential for the Health Informatics community and its subdisciplines to use the complex adaptive system model to help shape the 'new normal' health ecosystem from the bottom up with enabling and adaptive leadership [14]. Stevens and colleagues used complexity science to understand the pandemic as a nondeterministic event and what data tools to support their response to COVID-19 [15]. Finally, the community must be aggressive in developing standardized data sources and an interoperable suite of tools and response actions. In this manner, all decision makers would have access to timely Health Intelligence insights to support their response. Similarly, entities that serve individuals in any new care models should establish standards for data from EHR and non-EHR sources, including streaming data. Individuals would have access to relevant **Health Intelligence** while they are making health or wellness decisions.

Question/Answer

1. What is the objective of Health Intelligence?
   (a) **Health Intelligence** is a critical component of a networked multi-professional health ecosystem**.** Its objective is to deliver holistic insights into critical situations and issues and to support data driven decision making, by providing timely insights to assist decision-makers as they plan and respond, as well as provide timely feedback on the impacts of decisions and actions. [From the Introduction]

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Health IT for the Future – It Isn't (Just) About the Technology

32

Stephanie L. Reel and Steven F. Mandell

Abstract

[Editors' note] As an envoi to the fifth edition of Healthcare Information Management Systems, we asked two colleagues, leaders in the health IT expansion at the Johns Hopkins Health Institutions during these critical decades, to provide thoughts on the future directions of health IT. Their reflections, in part the product of informal discussions with colleagues and peers at similar institutions, reveal that as technology gains power and scope, the future must return to basic considerations and questions about how best to use it.

Keywords

Healthcare information technology · US healthcare · Evolution

32.1 Introduction

Since 1991, five editions of this book have described how information technology (IT) can be used to improve US healthcare processes. In that time, there has been exponential growth in the presence and roles of IT, not only in healthcare, but in everyday life. The last decade has seen widespread adoption of networked certified electronic health record technologies (CEHRT) and their connection to all aspects of healthcare: patient care, population health, clinical and business analytics, billing, and research. This "new" ubiquity of HIT, EHRs and personal health data is creating a new floor and new possibilities for improving and expanding healthcare processes on scales previously not feasible or even explored. And natural questions arise as to where healthcare and health IT can/will go from here.

S. L. Reel (✉)
Johns Hopkins Medicine, Johns Hopkins Health System, Johns Hopkins University, Baltimore, MD, USA

Division of General Internal Medicine, Biomedical Informatics and Data Science, The Johns Hopkins University, Baltimore, MD, USA
e-mail: sreel@jhu.edu

S. F. Mandell
Division of General Internal Medicine, Biomedical Informatics and Data Science, The Johns Hopkins University, Baltimore, MD, USA

Healthcare Information Systems, Johns Hopkins Hospital, Baltimore, MD, USA
e-mail: smandel@jhmi.edu

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Some basic assumptions/assertions about US healthcare are:

1. The purpose of any healthcare information technology must be to:
    - Support the mission of medicine and the culture of healthcare science, discovery and research
    - Assure the privacy, safety, and interests of patients and other stakeholders
    - Assure the highest quality of healthcare data and transactions - correct, current, complete, relevant
    - Assure appropriate, timely and efficient access to information by patients and other stakeholders via CEHRT mandated patient portals
    - Empower efficient, effective, and equitable collaboration among stakeholders across domains
    - Provide flexibility and usability for data sharing, use and innovation
    - Provide stakeholders with timely and relevant data and awareness for optimum decision and response
    - Integrate and make systems interoperable with other healthcare technologies
2. Healthcare stakeholders will be progressively diverse:
    - Patients will have multidimensional differences and needs with respect to health information and technology: language/literacy, health literacy, medical knowledge, care/health information access and technology readiness and dependence
    - Healthcare workers, likewise, will have differences in language/literacy, health literacy, cultural competency with respect to health, domain expertise and technology familiarity, that will require different types and levels of training and support for work
    - As healthcare data, its access and use become progressively complex, other stakeholders (allied health workers, healthcare technologists, administrative and business personnel, and others) will need user-specific training with respect to the proper (secure, technical, administrative, ethical and legal) access and handling of patient-specific data
    - Groups, communities, and cultures with common health information needs will need access to tools that empower communication and collaboration among diverse members across domains for multiple purposes
3. New challenges, some of which are emerging now, will arise, including the need for:
    - Designs for malleable, adaptive, and modifiable information technologies, data models and structures that will meet facilitate collaboration for rapid, efficient, and innovative solutions
    - Selection processes that are rapidly adaptive to the changing nature and demands of consumers
    - Implementation processes that are rapid, rigorous and intolerant of errors
    - Technology-based foundations that support data integration and that foster a culture of collaboration and data-driven decision-making in support of precision medicine, population and public health, across the US and around the world
    - Common conventions and user cultures that support and promote the availability and use of data-driven decision-making and data analysis tools at the point and time of need and action
    - Common technology and business infrastructures, ownership models and funding approaches that support subscription services, software/platform as a service (SaaS/PaaS) solutions and other distributed vended systems

From these, we pose problems and questions:

1. How can the digital divide be reduced?

    Broadband access is quickly becoming a basic human need. It has never been equally distributed, the digital divide clearly accentuated by the 2020/2021 pandemic [1]. More than 55 million U.S. students in

124,000 shuttered schools were able to access education only through the Internet [2], but it is estimated that 12 million of them could not do so from home. Even further, broadband access has been cited as a marker of health [3]. Therefore, more equitable broadband access is essential [4].

At the state level: How should healthcare providers and institutions and other entities engage and encourage broadband efforts at the legislative level? Is it possible to align public and private stakeholders to reduce the digital divide to provide overall benefits for communities on educational, economic, and health levels? Widespread low-cost broadband access can promote literacy and academic achievement through online education, employment, and better clinical and social health through telemedicine.

At the federal level (and beyond): How can health care providers, hospitals, insurers, and technology leaders to work together and lobby for federal guidelines, standards, and financial support to reduce the digital divide? Is the political environment too hostile to expect bipartisan support?

2. How should/will healthcare information technology be paid for?

   Medical Information is the currency of the present and future healthcare. Information technology, by improving the efficiency of systems and networks, reduces time and transaction costs – particularly for small provider groups and disenfranchised patients, is the infrastructure by which that information will be leveraged.

   Should (or can) government underwrite the cost of new network technology services to support marginalized stakeholders or should this be borne by a community of stakeholders? Given that the future of medical research and discovery is and will be dependent on investments in technology services and infrastructures (data governance, data curation, interoperability, and advanced analytics), what roles should universities and academic medical centers have in defining and democratizing these discoveries? Should governments ensure equal access for all? When the Federal Communications Commission auctions mid-band cellular spectrum for billions of dollars to support improved 5G services [5], should a portion be set aside to ensure greater access at lower costs? Is access to information an inalienable right (not restricted to health data) [6]?

3. How will innovation be managed?

   As healthcare applications markets continue to expand, how will the "mega-system" capacity to incorporate and disseminate new (clinical and IT) knowledge and capabilities in a timely, widespread, usable, consistent and safe fashion be managed [7]? Does integration stifle innovation, or require it [8]? As medicine and information technology [9] (inclusive of artificial intelligence [10], robotics/Internet of Things [11], nanotechnology [12], quantum computing) evolve, how will research, development and innovation (and the resultant intellectual properties generated), led by medical, academic and industrial stakeholders, be managed on public health and business levels?

4. How will access to healthcare be impacted and improved?

   How will technology-driven transformation of healthcare work in the cause of optimum productivity be achieved without losing sight of core values of patient care and population health [13]? Who will advocate for patient rights on multiple levels to benefit from the best care in the most equitable fashion? These questions cross diverse disciplines (including policy/economics [14], ethics [15], business [16]) all of which need representation.

5. How will healthcare infrastructure and its assets be protected?

   Cybersecurity is a rapidly growing and evolving challenge in all domains, including healthcare [17]. How must federal and private healthcare and operational information standards for information assurance (IA) evolve to match and surpass new threats [18]? These questions are complex and go beyond static standards and operating proce-

dures and involve all stakeholders. What are to be the "new" and "realistic" expectations by the public (as citizens and as patients) with respect to privacy and security and breaches. What alternatives (financial, procedural, policy, insurance, etc.) [19, 20] are required with respect to recovery from data breach and loss (as a fact of life)?

6. Can incentives be aligned (and maintained)?

   Complete financial alignment of investments in technology are difficult if not impossible in an open healthcare market. Is it possible to share costs, risks, losses, and resources among healthcare institutions, providers (and provider groups) and patients? How are value-based payments [21], the alignment of payment to performance, changing incentives in health insurance and practice? How will such new models (continue to) reshape healthcare, health data infrastructure and policy [22] at state, federal and regional levels to facilitate use and dissemination of empowering healthcare technology such as telehealth [23]? The needs of the 2020 pandemic served as an illustration of what can be done [24, 25].

7. How will clinical research/trials be assimilated and promoted?

   The 2020 pandemic saw an increase in medical school applicants due to the "Fauci Effect" [26]. Consumers have taken a greater interest in science, research, and discovery. Will this increase in scientific and medical interest result in more activity by researchers and potential human subjects? How does/will this differ among different populations [27, 28]? In the US, the information and legislative infrastructure for making clinical trials information available to the public has been established [29] at the federal level and by numerous investigator-led clinical trials groups. How will federal/public/academic collaboration with private industry evolve, particularly in research, development, and marketing of therapies and products? Will access to new therapies and clinical trials be equitable to patients? Will the availability of health information increase or reduce transparency and/or fair representation of rapidly evolving data information about recommended treatments to the public as seen during the 2020 pandemic [30]?

8. What are guiding ethical principles in allocating care and resources?

   During the 2020 pandemic, many resources (equipment, medications, vaccines, healthcare personnel) required rationing as demand fluctuated (creating difficult decisions by leadership on many levels – from local to international). What is fair? How can technology, systems, information, and policy be best deployed to assure fairness in rationing care [31–35]?

9. How can burnout be mitigated and workforce resiliency be maintained?

   Change fatigue and clinician burnout can drastically decrease the healthcare workforce through attrition, especially during prolonged global stress, as occurred during the 2020 pandemic [36]. This phenomenon has been described in other high stress/high patient mortality situations [37] and in general healthcare [38, 39]. Can technology provide support to alleviate stress and burdens of care in overwhelmed clinicians and allied health professionals? What other approaches are needed to detect and address the problem adequately [40]? What is there to be learned from other high-stress industries [41] with respect to managing burnout and resiliency? What do commercial healthcare vendors with thousands of employees around the globe need to do to safely train their staff and prevent burnout and clinical errors?

10. How do we define success in healthcare technology?

    What are dimensions of quality in healthcare technology [42]? Some attributes that come to mind include transparency, invisibility, performance, assurance (of confidentiality, integrity, availability of data and functionality), usability and cost that support the work, partnership and a culture of common innovation, discovery, and mutual respect for stakeholders [43]. But these go beyond the technology. How are these

dimensions related to healthcare quality (safety [44], effectiveness, patient-centeredness, timeliness, efficiency and equity) [45] as useful metrics by which systems, and CIO's [46] and CMIO's [47] and CNIO's [48] can be evaluated?

Looking forward, looking back (a personal perspective):

It's an amazing time in our industry. Thinking back to those very early days when health IT professionals were "order-takers". We were learning how to use computers to process data, collect charges, understand our costs, and meet the most rudimentary needs of our users. We were hoping to find a way to be invited to "the table" for meaningful dialogue and to promote a sense of belonging! We longed to be invited, included, involved, and respected. Such a simple time….

But things changed. The promise of technology, and the "democratization of data" have been empowering, enlightening, and energizing. And expectations have evolved. Our "users" have become our collaborators. Our vendors have become our partners. And our solutions are pervasive, ubiquitous, and embedded. The science of safety caused us to think differently; the commitment to service compelled us to work differently. No longer "order takers", we are innovators. We extended our reach in meaningful ways, seeing the world through the lens of a sick child, or a frightened father, an overwhelmed basic scientist, or a weary worried clinician. We have learned to consider the burden of chronic disease, and not just the balance sheet; we have learned to focus not only on the financial statement, but on the family. We have evolved into visible and valued members of the care team. We have emerged as data scientists, solution architects, and trusted collaborators. These changes have provided purpose.

But there is so much more to do. We must strive to achieve value from the use of securely and broadly shared information to inform and improve care, and to provide better outcomes. From population health to precision medicine, we must continue to insist on the integration of multiple data streams to ensure we can render more informed decisions, and to enable the application of more meaningful and more timely interventions. We are making real progress, and we must do more. We have indeed "earned the right" to be at the table – to be at every table. Such an incredibly exciting place to be!

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