

HEALTH INFORMATICS

Practical Guide for Healthcare and
Information Technology Professionals

SIXTH EDITION



Robert E Hoyt Editor

Ann Yoshihashi Associate Editor



Endorsed by



Health Informatics

**Practical Guide for Healthcare and
Information Technology Professionals**

Sixth Edition

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Health Informatics

Practical Guide for Healthcare and Information Technology Professional
Sixth Edition

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Preface to the Sixth Edition

Health Informatics is an information science that is concerned with the management of healthcare data and information using a variety of technologies. As a result of exploding technologies and expansive healthcare data, in addition to support from US Federal Government programs, there is tremendous interest in this relatively new field.

In order to keep up with the rapid pace of developments in Health Informatics, this is our sixth edition since publishing the original textbook in 2007.

The sixth edition has been endorsed by the AMIA for continuing education of informaticists. Many of our textbook authors are AMIA members and major contributors to the field of Health Informatics.

In this edition we have re-written all chapters to reflect the rapid changes in the field. We have focused heavily on Meaningful Use, the yard stick for electronic health record implementation in the United States.

We added a new chapter on Healthcare Data Analytics, given the interest in managing healthcare data, to include “big data.” We consolidated the chapter on electronic prescribing and practice management systems into the chapter on electronic health records. The PACS chapter was changed to Medical Imaging Informatics and we added an academic radiologist as co-author.

Readers can expect similar organization to each chapter. All chapters start with learning objectives and an introduction and end with recommended reading, key points, future trends and a conclusion. In addition, most chapters include case studies to highlight interesting national and international initiatives. We have made every

attempt to provide the most up-to-date information about health informatics recent information and the most interesting concepts. We are dedicated to presenting the issues fairly and objectively and have avoided the hype some times associated with new technologies. This textbook should give readers, especially those new to healthcare or technology, a better understanding of this burgeoning field. It is also a resource/reference for people in the field, reviewing for clinical informatics board and for both graduate and undergraduate courses. Approximately 1900 medical literature references and web links are included in this book that help direct readers to additional information.

While we are vendor agnostic we are not opposed to presenting interesting hardware and software, including open source, we think will be of interest to our readers. One of the goals of this book is to promote and disseminate innovations that might help healthcare workers as well as technology developers. The fact that we mention specific hardware or software or web-based applications does not mean we endorse the vendor; instead, it is our attempt to highlight an interesting concept or innovation that might lead others in a new direction.

A Resource Center was created for each book chapter that contains articles, web links and videos for students and instructors located at www.informaticseducation.org.

We appreciate feedback regarding how to make this book as user friendly, accurate, up-to-date and educational as possible. Please note that book proceeds will be donated to support the advancement of health informatics education.

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Table of Contents

CONTRIBUTORS	II
PREFACE TO SIXTH EDITION.....	V
CHAPTER 1 OVERVIEW OF HEALTH INFORMATICS.....	1
LEARNING OBJECTIVES.....	1
INTRODUCTION.....	1
INFORMATICS DEFINITIONS.....	4
BACKGROUND.....	5
HISTORICAL HIGHLIGHTS.....	9
KEY PLAYERS IN HEALTH INFORMATION TECHNOLOGY.....	11
ORGANIZATIONS INVOLVED WITH HIT.....	13
BARRIERS TO HIT ADOPTION.....	21
HEALTH INFORMATICS PROGRAMS, ORGANIZATIONS AND CAREERS.....	24
HEALTH INFORMATICS RESOURCES.....	28
FUTURE TRENDS	31
CONCLUSION	32
REFERENCES.....	32
CHAPTER 2 HEALTHCARE DATA, INFORMATION AND KNOWLEDGE.....	39
LEARNING OBJECTIVES.....	39
INTRODUCTION.....	39
DEFINITIONS AND CONCEPTS	42
CONVERTING DATA TO INFORMATION TO KNOWLEDGE.....	44
CLINICAL DATA WAREHOUSES (CDWS).....	46
WHAT MAKES INFORMATICS DIFFICULT?.....	51
WHY HEALTH IT FAILS SOMETIMES	54
FUTURE TRENDS.....	56
CONCLUSION.....	58
REFERENCES.....	58
CHAPTER 3 HEALTHCARE DATA ANALYTICS	62
LEARNING OBJECTIVES.....	62
INTRODUCTION.....	62
TERMINOLOGY OF ANALYTICS.....	62
CHALLENGES TO DATA ANALYTICS.....	64
RESEARCH AND APPLICATION OF ANALYTICS.....	65
ROLE OF INFORMATICIANS IN ANALYTICS.....	67
RECOMMENDED READING.....	68
FUTURE TRENDS.....	68
CONCLUSION.....	69
REFERENCES.....	70
CHAPTER 4 ELECTRONIC HEALTH RECORDS.....	76
LEARNING OBJECTIVES	76
INTRODUCTION.....	76
NEED FOR ELECTRONIC HEALTH RECORDS	77
INSTITUTE OF MEDICINE'S VISION FOR EHR'S	82
ELECTRONIC HEALTH RECORD KEY COMPONENTS.....	83
COMPUTERIZED PHYSICIAN ORDER ENTRY (CPOE)	84
CLINICAL DECISION SUPPORT SYSTEMS (CDSS)	86

ELECTRONIC PRESCRIBING.....	89
PRACTICE MANAGEMENT INTEGRATION.....	91
ELECTRONIC HEALTH RECORD ADOPTION.....	95
ELECTRONIC HEALTH RECORD AND MEANINGFUL USE CHALLENGES	97
THE HITECH ACT AND EHR REIMBURSEMENT	102
ELECTRONIC HEALTH RECORD EXAMPLES.....	106
LOGICAL STEPS TO SELECTING AND IMPLEMENTING AN EHR.....	109
RECOMMENDED READING.....	116
FUTURE TRENDS	117
CONCLUSION	118
APPENDIX 4.1 STAGE 1 AND 2 MEANINGFUL USE CORE OBJECTIVES AND MEASURES ...	119
APPENDIX 4.2 PROPOSED STAGE 3 MEANINGFUL USE GOALS	122
REFERENCES.....	123
CHAPTER 5 HEALTH INFORMATION EXCHANGE	134
LEARNING OBJECTIVES.....	134
INTRODUCTION.....	134
HISTORY OF THE NATIONWIDE HEALTH INFORMATION NETWORK.....	136
HITECH ACT IMPACT	143
HEALTH INFORMATION ORGANIZATIONS	145
HEALTH INFORMATION ORGANIZATION EXAMPLES.....	150
STATEWIDE HIE COOPERATIVE AGREEMENT PROGRAM.....	153
CURRENT STATUS OF US HEALTH INFORMATION EXCHANGE.....	154
HEALTH INFORMATION EXCHANGE CONCERNS	155
HEALTH INFORMATION ORGANIZATION RESOURCES	155
RECOMMENDED READING	157
FUTURE TRENDS.....	157
CONCLUSION	158
REFERENCES.....	159
CHAPTER 6 DATA STANDARDS AND MEDICAL CODING	163
LEARNING OBJECTIVES.....	163
INTRODUCTION.....	163
CONTENT STANDARDS.....	163
TERMINOLOGY STANDARDS.....	167
TRANSPORT STANDARDS.....	170
MEDICAL CODING AND REIMBURSEMENT.....	171
FUTURE TRENDS	176
CONCLUSION	176
REFERENCES.....	176
CHAPTER 7 ARCHITECTURES OF INFORMATION SYSTEMS.....	179
LEARNING OBJECTIVES.....	179
INTRODUCTION.....	179
THE INTERNET AND WORLD WIDE WEB	179
WEB SERVICES.....	181
NETWORKS.....	184
FUTURE TRENDS	190
CONCLUSION	191
REFERENCES.....	191
CHAPTER 8 HEALTH INFORMATION PRIVACY AND SECURITY.....	193
LEARNING OBJECTIVES.....	193
INTRODUCTION.....	193
HIPAA REVIEW.....	194
BASIC SECURITY PRINCIPLES	197
HIPAA, MEANINGFUL USE, AND THE HITECH ACT	199

AUTHENTICATION AND IDENTITY MANAGEMENT.....	200
DATA SECURITY IN THE CLOUD AND CLIENT/SERVER SOLUTIONS.....	203
STANDARDS, COMPLIANCE AND LAW	205
SECURITY BREACHES AND ATTACKS.....	205
MEDICAL PRIVACY AND SECURITY STORIES IN THE NEWS	208
RECOMMENDED READING.....	209
FUTURE TRENDS	210
CONCLUSION.....	211
REFERENCES.....	212
CHAPTER 9 HEALTH INFORMATICS ETHICS	217
LEARNING OBJECTIVES	217
INTRODUCTION.....	217
THE ROAD FROM NUREMBERG.....	217
INFORMATICS ETHICS.....	219
INTERNATIONAL CONSIDERATIONS: ETHICS, LAWS AND CULTURE.....	221
CODES OF INDIVIDUAL COUNTRIES.....	223
PERTINENT ETHICAL PRINCIPLES.....	224
DIFFICULTIES APPLYING MEDICAL ETHICS IN THE DIGITAL WORLD.....	225
TRANSFERRING ETHICAL RESPONSIBILITY	227
ELECTRONIC COMMUNICATION WITH PATENTS AND CAREGIVERS	228
PRACTICAL STEPS.....	229
HEALTH INFORMATICS ETHICS AND MEDICAL STUDENTS.....	232
FUTURE TRENDS	234
CONCLUSION.....	235
REFERENCES.....	236
CHAPTER 10 CONSUMER HEALTH INFORMATICS.....	242
LEARNING OBJECTIVES	242
INTRODUCTION.....	242
THE ORIGINS OF CONSUMER HEALTH INFORMATICS.....	243
CLASSIFICATION OF HEALTH INFORMATICS APPLICATIONS.....	245
HEALTH EDUCATION & INFORMATION APPLICATIONS	247
HOME TELEMEDICINE DEVICES	249
PATIENT WEB PORTALS	250
PERSONAL HEALTH RECORDS (PHRS)	252
ELECTRONIC PATIENT TO PHYSICIAN COMMUNICATION	253
SOCIAL MEDIA.....	256
RECOMMENDED READING.....	257
BARRIERS TO CHI ADOPTION.....	258
FUTURE TRENDS	259
CONCLUSION.....	260
REFERENCES.....	261
CHAPTER 11 MOBILE TECHNOLOGY.....	265
LEARNING OBJECTIVES	265
INTRODUCTION.....	265
HISTORY OF MOBILE TECHNOLOGY	266
MOBILE HEALTH (MHEALTH).....	268
MOBILE TECHNOLOGY AND PATIENTS	269
MOBILE TECHNOLOGY AND CLINICIANS.....	272
MOBILE TECHNOLOGY TO TRACK HEALTH HABITS.....	276
MOBILE TELEMEDICINE PROJECTS	277
RECOMMENDED READING.....	277
MOBILE TECHNOLOGY RESOURCES.....	279
MOBILE TECHNOLOGY CHALLENGES	279
FUTURE TRENDS	280

CONCLUSION	281
REFERENCES.....	281
CHAPTER 12 ONLINE MEDICAL RESOURCES.....	285
LEARNING OBJECTIVES.....	285
INTRODUCTION.....	285
SPONSORED MEDICAL WEB SITES.....	293
SPONSORED AND NON-SPONSORED RESOURCES.....	294
GOVERNMENT MEDICAL WEB SITES.....	294
FREE MEDICAL WEB SITES.....	295
FREE PATIENT EDUCATION SITES.....	296
SUBSCRIPTION (FEE-BASED) RESOURCES.....	296
EVIDENCE BASED SUBSCRIPTION PRODUCTS.....	298
RECOMMENDED READING.....	299
FUTURE TRENDS.....	299
CONCLUSION.....	300
REFERENCES.....	300
CHAPTER 13 MEDICAL INFORMATION RETRIEVAL	304
LEARNING OBJECTIVES.....	304
INTRODUCTION.....	304
GOOGLE.....	305
PUBMED SEARCH ENGINE.....	306
RECOMMENDED READING.....	320
FUTURE TRENDS.....	320
CONCLUSION.....	320
REFERENCES.....	321
CHAPTER 14 EVIDENCE BASED MEDICINE & CLINICAL PRACTICE GUIDELINES	323
LEARNING OBJECTIVES.....	323
INTRODUCTION.....	323
IMPORTANCE OF EBM.....	325
THE EVIDENCE PYRAMID.....	326
RISK MEASURES AND TERMINOLOGY.....	328
LIMITATIONS OF THE MEDICAL LITERATURE AND EBM.....	331
EVIDENCE BASED HEALTH INFORMATICS.....	333
EBM RESOURCES.....	335
CLINICAL PRACTICE GUIDELINES.....	336
DEVELOPING CLINICAL PRACTICE GUIDELINES.....	337
BARRIERS TO CLINICAL PRACTICE GUIDELINES.....	338
INITIATING CLINICAL PRACTICE GUIDELINES.....	339
CLINICAL PRACTICE GUIDELINE EXAMPLE.....	340
ELECTRONIC CLINICAL PRACTICE GUIDELINES.....	340
CLINICAL PRACTICE GUIDELINE RESOURCES.....	342
RECOMMENDED READING.....	343
FUTURE TRENDS.....	344
CONCLUSION.....	345
REFERENCES.....	345
CHAPTER 15 DISEASE MANAGEMENT AND DISEASE REGISTRIES	351
LEARNING OBJECTIVES.....	351
INTRODUCTION.....	351
DISEASE MANAGEMENT PROGRAMS (DMPS).....	352
DISEASE MANAGEMENT AND THE US FEDERAL GOVERNMENT.....	356
RECOMMENDED READING.....	359
DISEASE REGISTRIES.....	362
FUTURE TRENDS.....	364

x | Table of Contents

CONCLUSION.....	365
REFERENCES.....	366
CHAPTER 16 QUALITY IMPROVEMENT STRATEGIES	369
LEARNING OBJECTIVES	369
INTRODUCTION.....	369
QUALITY IMPROVEMENT STRATEGIES.....	371
QUALITY IMPROVEMENT PROJECTS.....	377
QUALITY IMPROVEMENT DASHBOARDS	378
RECOMMENDED READING	380
QUALITY IMPROVEMENT CONCERNS AND LIMITATIONS.....	381
FUTURE TRENDS	381
CONCLUSION.....	382
REFERENCES.....	383
CHAPTER 17 PATIENT SAFETY AND HEALTH INFORMATION TECHNOLOGY.....	388
LEARNING OBJECTIVES	388
INTRODUCTION.....	388
PATIENT SAFETY REPORTS.....	391
ORGANIZATIONS AND PROGRAMS SUPPORTING PATIENT SAFETY.....	393
HEALTH INFORMATION TECHNOLOGY AND PATIENT SAFETY.....	398
TECHNOLOGIES WITH POTENTIAL TO DECREASE MEDICATION ERRORS.....	399
RECOMMENDED READING	405
BARRIERS TO IMPROVING PATIENT SAFETY THROUGH TECHNOLOGY.....	405
FUTURE TRENDS	407
CONCLUSION.....	409
REFERENCES.....	409
CHAPTER 18 TELEMEDICINE	416
LEARNING OBJECTIVES	416
INTRODUCTION.....	416
TELECONSULTATIONS	418
TELEMONITORING.....	422
TELEMEDICINE INITIATIVES.....	426
INTERNATIONAL TELEMEDICINE.....	428
RECOMMENDED READING.....	429
BARRIERS TO TELEMEDICINE	431
TELEMEDICINE ORGANIZATIONS AND RESOURCES.....	433
FUTURE TRENDS	434
CONCLUSION.....	434
REFERENCES.....	434
CHAPTER 19 MEDICAL IMAGING INFORMATICS	440
LEARNING OBJECTIVES	440
INTRODUCTION.....	440
TYPICAL PACS WORKFLOW.....	444
WEB BASED IMAGE DISTRIBUTION	445
PACS AND MOBILE TECHNOLOGY	448
PACS FOR A HOSPITAL DESKTOP COMPUTER	450
PACS ADVANTAGES AND DISADVANTAGES	451
RECOMMENDED READING.....	451
FUTURE TRENDS	452
CONCLUSION.....	453
REFERENCES.....	453
CHAPTER 20 BIOINFORMATICS	455
LEARNING OBJECTIVES	455

INTRODUCTION.....	455
GENOMIC PRIMER	456
IMPORTANCE OF BIOINFORMATICS.....	457
BIOINFORMATICS PROJECTS AND CENTERS.....	458
PERSONAL GENOMICS	463
GENOMIC INFORMATION INTEGRATED WITH EHRS	465
RECOMMENDED READING	467
FUTURE TRENDS.....	468
CONCLUSION	469
REFERENCES.....	469
CHAPTER 21 PUBLIC HEALTH INFORMATICS.....	473
LEARNING OBJECTIVES.....	473
INTRODUCTION.....	473
DEFINITIONS.....	474
PUBLIC HEALTH SURVEILLANCE.....	474
THE PUBLIC HEALTH INFORMATION NETWORK.....	479
GEOGRAPHIC INFORMATION SYSTEMS (GIS).....	481
PUBLIC HEALTH DATA TOOLS AND STATISTICS.....	483
PUBLIC HEALTH INFORMATICS WORKFORCE	484
GLOBAL PUBLIC HEALTH INFORMATICS.....	485
RECOMMENDED READING	490
FUTURE TRENDS	490
CONCLUSION	492
APPENDIX 21.1.INTERNATIONAL SURVEILLANCE SYSTEMS AND PLATFORMS.....	493
REFERENCES.....	496
CHAPTER 22 E-RESEARCH	500
LEARNING OBJECTIVES.....	500
INTRODUCTION.....	500
PREPARATORY TO RESEARCH	501
STUDY INITIATION.....	502
STUDY MANAGEMENT AND DATA MANAGEMENT	504
DATA MANAGEMENT SYSTEMS FOR FDA REGULATED STUDIES	506
INTERFACES AND QUERY TOOLS	506
DATA ANALYSIS	507
RECOMMENDED READING	508
FUTURE TRENDS	508
CONCLUSION	509
REFERENCES.....	509
INDEX	513

Chapter 1

Overview of Health Informatics

ROBERT E. HOYT

ELMER V. BERNSTAM

Learning Objectives

After reading this chapter the reader should be able to:

- State the definition and origin of health informatics
- Identify the forces behind health informatics
- Describe the key players involved in health informatics
- State the potential impact of the HITECH Act on health informatics in the United States
- List the barriers to health information technology (HIT) adoption
- Describe educational and career opportunities in health informatics

“During the past few decades the volume of medical knowledge has increased so rapidly that we are witnessing an unprecedented growth in the number of medical specialties and subspecialties. Bringing this new knowledge to the aid of our patients in an economical and equitable fashion has stressed our system of medical care to the point where it is now declared to be in a crisis. All these difficulties arise from the present, nearly unmanageable volume of medical knowledge and the limitations under which humans can process information.”

- Marsden S. Blois, *Information and Medicine: The Nature of Medical Descriptions*, 1984

Introduction

Health informatics began as a new field of study in the 1950s-1960s time frame but only recently gained recognition as an important component of many aspects of healthcare. Its emergence is partly due to the multiple challenges facing the practice of medicine today. As the 1984 quote above indicates, the growth in the volume of medical knowledge and patient information that has occurred due to better

understanding of human health has resulted in more treatments and interventions that produce more information. Likewise, the increase in specialization has also created the need to share and coordinate patient information. Furthermore, clinicians need to be able to access medical information expeditiously, regardless of location or time of day. Technology has the potential to help with each of those areas.

With the advent of the internet, high speed computers, voice recognition, wireless and

2 | Chapter 1 Overview of Health Informatics

mobile technology healthcare professionals today have many more tools available at their disposal. However, in general, technology is advancing faster than healthcare professionals can assimilate it into their practice of medicine. One could also argue that there is a critical limitation of current information technology that manages data and not information. Thus, there is a mismatch between what clinicians need (i.e. something to help us manage meaningful data = information) and what they have (ineffective ways to manage information). Additionally, given the volume of data and rapidly changing technologies, there is a great need for ongoing informatics education of all healthcare workers.

In this chapter an overview of health informatics is presented with emphasis on the factors that helped create and sustain this new field and the key players involved.

Data, Information, Knowledge, Wisdom Hierarchy

Informatics is the science of information and the blending of people, biomedicine and technology. Individuals who practice informatics are known as informaticians or informaticists, such as, a nurse informaticist. There is an information hierarchy that is important in the information sciences, as depicted in the pyramid in Figure 1.1. Notice that there is much more data than information, knowledge or wisdom. As data are consumed and analyzed the amount of knowledge and wisdom produced is much smaller. The following are definitions to better understand the hierarchy:

- Data are symbols or observations reflecting differences in the world. Data are the plural of datum (singular). Thus, a datum is the lowest level of abstraction, such as a number in a database (e.g. 5), or packets sent across a network (e.g. 10010100). Note that there is no meaning associated with data; the 5 could represent five fingers, five minutes or have no real meaning at all. Modern computers process data accurately and rapidly.

- Information is meaningful data or facts from which conclusions can be drawn by humans or computers. For example, *five fingers* has meaning in that it is the number of fingers on a normal human hand. Modern computers do not process information, they process data. This is a fundamental problem and challenge in informatics.
- Knowledge is information that is justifiably considered to be true. For example, a rising prostate specific antigen (PSA) level suggests an increased likelihood of prostate cancer.
- Wisdom is the critical use of knowledge to make intelligent decisions and to work through situations of signal versus noise. For example, a rising PSA could mean prostate infection and not cancer.

Figure 1.1: Information hierarchy



Health information technology provides the tools to generate information from data that humans (clinicians and researchers) can turn into knowledge and wisdom.¹⁻² Thus, enabling and improving human decision making with usable information is a central concern of informaticians. This concept is discussed in much more detail in the chapter on healthcare data, information and knowledge.

Another important concept to understand about data is that there are different levels of data (Figure 1.2). Paper forms would be considered level 1 with serious limitations, in regards to sharing, storing and analyzing. Level 2 data could be scanned-in documents. Level 3 data are entered into a computer and are data that

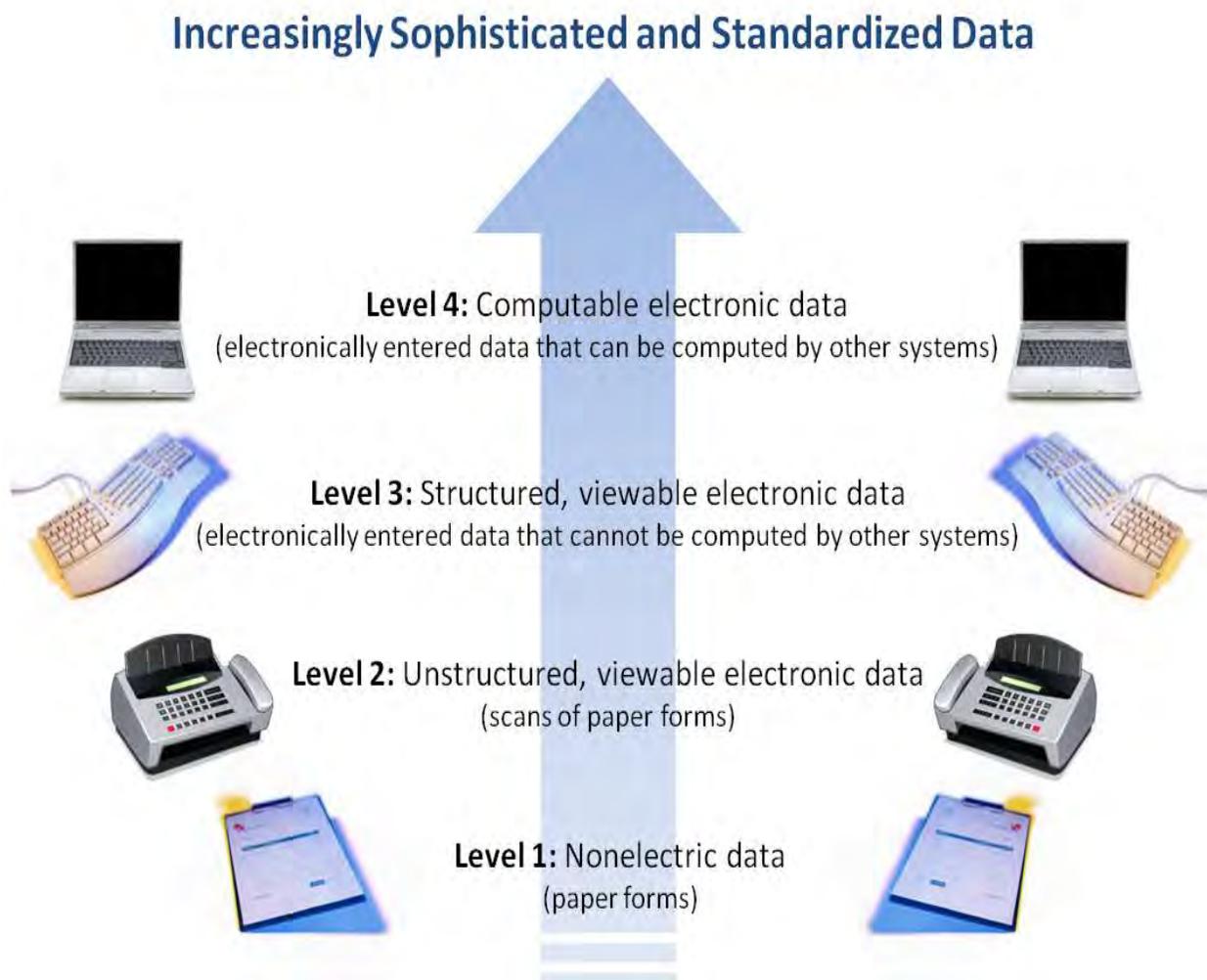
are structured and retrievable, but not computable between different computers. Level 4 data are computable data. That means the data are electronic, capable of being stored in data fields and computable because it is in a format that disparate computers can share (interoperable) and interpret (analyzable).

Therefore, the information sciences tend to promote data in formats that can be rapidly transmitted, shared and analyzed. Paper records and reports do not allow this, without a great deal of manual labor. The advent of electronic health records, health information exchange (HIE) and multiple hospital electronic information systems provided the ability and the

need to collate and analyze large amounts of data to improve health and financial decisions. Figure 1.3 displays some of the common sources of health data.

With ever increasing amounts of health-related data we have seen the growth of new hardware and software and specialities to handle “Big Data.” Enterprise systems have been developed that: integrate disparate information (clinical, financial and administrative); archive data; provide the ability to data mine using business intelligence and analytic tools. This is discussed in more detail in the chapter on data mining and analytics. Figure 1.4 demonstrates a typical enterprise data system.

Figure 1.2: Levels of data (Courtesy Government Accounting Office)



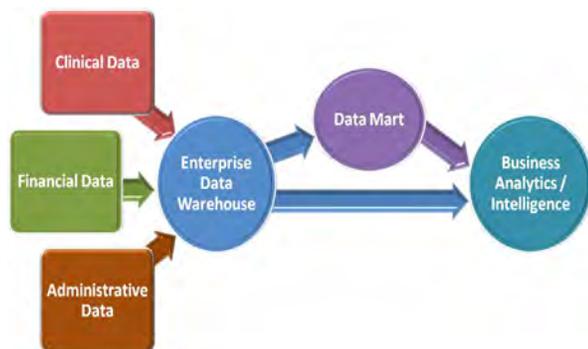
Informatics Definitions

Health informatics is the field of information science concerned with management of healthcare data and information through the application of computers and other technologies. In reality, it is more about applying information in the healthcare field than it is about technology per se. That is one of the many reasons it is different than a pure information technology (IT) position in a healthcare organization. Technology merely facilitates the collection, storage, transmission and analysis of data. This field also includes data standards (such as HL7) and controlled medical vocabularies (such as SNOMED) that will be covered in the chapter on data standards.

Figure 1.3: Health Data Sources (EHR=electronic health records, PHR=personal health record, HIE=health information exchange)



Figure 1.4: Enterprise data warehouse and data mining



The definition of health informatics is dynamic because the field is relatively new and rapidly changing. The following are several definitions frequently cited:

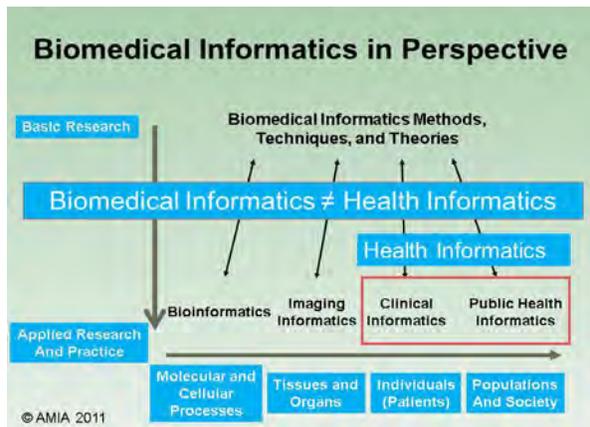
- “science of information, where information is defined as data with meaning. Biomedical informatics is the science of information applied to, or studied in the context of biomedicine. Some, but not all of this information is also knowledge”³
- “scientific field that deals with resources, devices and formalized methods for optimizing the storage, retrieval and management of biomedical information for problem solving and decision making”⁴
- “application of computers, communications and information technology and systems to all fields of medicine - medical care, medical education and medical research”⁵

Health informatics is also known as *clinical informatics* or *medical informatics* and *biomedical informatics* in some circles. If the information science deals primarily with actual applications and programs and not theory, it can be referred to as applied informatics.

Biomedical Informatics. Some prefer the broader term *biomedical informatics* because it encompasses bioinformatics as well as medical, dental, nursing, public health, pharmacy, medical imaging and veterinary informatics. The American Medical Informatics Association (AMIA) and the American Health Information Management Association (AHIMA) proposed the following definition of biomedical informatics “the interdisciplinary field that studies and pursues the effective uses of biomedical information and knowledge for scientific inquiry, problem solving and decision making, motivated by efforts to improve human health.”⁶ As the field moves closer to integrating human genetics into the day-to-day practice of medicine this more global definition may gain traction. Health informatics will be used throughout the book for consistency. The AMIA uses the term “medical informatics” solely to refer to the branch of clinical informatics that deals with disease diagnosis and management, with an emphasis on physicians (and therefore a

parallel to "nursing informatics" or "dental informatics").⁶ Their conceptualization of biomedical informatics is displayed in Figure 1.5. The AMIA web site posts a Board White Paper on the definition of biomedical informatics and the core competencies required for graduate education.

Figure 1.5: Biomedical Informatics Schema (Courtesy AMIA)



Bioinformatics is sub-field of biomedical informatics that is concerned with biological data, particularly DNA and genomic information, as opposed to clinical, public health or other data.

Health information technology (HIT or healthIT) is defined as the application of computers and technology in healthcare settings.

Health information management (HIM) traditionally focused on the paper medical record and coding. With the advent of the electronic health record HIM specialists now have to deal with a new set of issues, such as privacy and multiple new concepts such as voice recognition.

For a discussion of the definition, concepts and implications (e.g. distinguishing from other related fields) of this field, we refer readers to a 2010 article by Bernstam, Smith and Johnson and a 2009 article by Hersh^{3,7}

Background

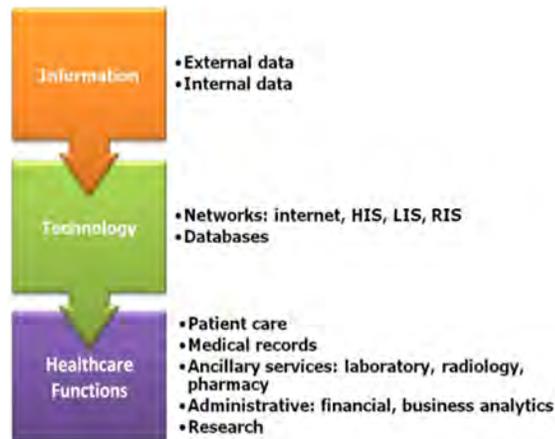
Given the fact that most businesses incorporate technology into their enterprise fabric, one could argue that it was just a matter of time before the tectonic forces of medicine and technology collided. As more medical information was published and more healthcare data became available as a result of computerization, the need to automate, collect, archive and analyze data escalated. Also, as new technologies such as electronic health records appeared, ancillary technologies such as disease registries, voice recognition and picture archiving and communication systems arose to augment functionality. In turn, these new technologies prompted the need for expertise in health information technology that spawned new specialties and careers.

Health informatics emphasizes *information brokerage*; the sharing of a variety of information back and forth between people and healthcare entities. Examples of medical information that needs to be shared include: lab results, x-ray results, vaccination status, medication allergy status, consultant's notes and hospital discharge summaries. Medical informaticians harness the power of information technology to expedite the transfer and analysis of data, leading to improved efficiencies and knowledge. The field also interfaces with other fields such as the health sciences, computer sciences, biomedical engineering, biology, library sciences and public health, to mention a few. Informatics training, therefore, must be expansive and in addition to the topics covered in the chapters of this book must include IT knowledge about networks and systems, usability, process re-engineering, workflow analysis and redesign quality improvement, project management, leadership, teamwork, implementation and training.

Health information technology (HIT) facilitates the processing, transmission and analysis of information and HIT interacts with many important functions in healthcare organizations and serves as a common thread (Figure 1.6). This is one of the reasons the Joint Commission

created the management of information standard for hospital certification.⁸

Figure 1.6: Information, information technology and healthcare functions



Many aspects of health informatics noted in Figure 1.6 are interconnected. To accomplish data collection and analysis there are hospital information systems (HISs) that collect financial, administrative and clinical information and subsystems such as the laboratory (LISs) and radiology information systems (RISs). As an example, a healthcare organization might be concerned that too many of its diabetic patients are not well controlled and believes it would benefit by offering a disease management web portal. With a portal, patients can upload blood sugars and blood pressures to a central web site so diabetic educators and/or clinicians can analyze the results and make recommendations. They also have the option to upload physiologic parameters via their smart phone. The following technologies and issues are involved with just this one initiative and these will be covered in other chapters:

- The web-based portal involves consumer (patient) informatics and telemedicine.
- Use of a smart phone is an important type of mobile technology.
- Management of diabetes requires online medical resources, evidence based medicine,

clinical practice guidelines, disease management and an electronic health record with a disease registry.

- If the use of the diabetic web portal improves diabetic control, clinicians may be eligible for improved reimbursement, known as pay-for-performance, a quality improvement strategy.

There are multiple forces driving the adoption of health information technology, but the major ones are the need to:

- Increase the efficiency of healthcare (improve physician, nurse and overall healthcare productivity)
- Improve the quality (patient outcomes) of healthcare, resulting in improved patient safety
- Reduce healthcare costs
- Improve healthcare access with technologies such as telemedicine
- Improve communication, coordination and continuity of care
- Improve medical education for clinicians and patients
- Standardize of medical care

Over the past 40 years, there has been increasing recognition that wide variation in practice cannot be justified. For example, patients in some areas of the United States are undergoing more invasive procedures than similar patients in other areas. Thus, there has been a movement to standardize the care of common and expensive conditions, such as coronary artery disease, congestive heart failure and diabetes. Computerized clinical practice guidelines are one way to provide advice at the point of care and this will be discussed in more detail in the chapter on evidence based medicine.

In this book there will be a discussion of the driving forces motivating informatics and their inter-relationships. In addition to the motivation to deliver more efficient, safer and less costly healthcare, there is the natural diffusion of technology which also exerts an influence. In other words, as technologies such as wireless and voice recognition become more

common place, easier to use and less expensive, they will have an inevitable impact or pressure on the practice of medicine. Technological innovations appear at a startling pace as stated by Moore's Law:

*"Moore's Law, states that the number of transistors on a chip will double approximately every two years."⁹
Gordon Moore, co-founder Intel Corporation 1965*

Moore's Law describes the exponential growth of transistors in computers. Technology will continue to evolve at a rapid rate but it is important to realize that it often advances in an asynchronous manner. For example, laptop computers have advanced greatly with excellent processor speed and memory but their utility is limited by a battery life of roughly 4-6 hours. This is a significant limitation given the fact that most nurses now work eight to twelve hour shifts, so short battery life is one factor that currently limits the utility of laptop computers in healthcare. This may be overcome with tablet computers or a new battery design.

The healthcare field is also subject to "disruptive innovations (technologies)" which are innovations that just appear and soon take over mainstream technologies. A good example of that would be mobile technology that was quickly adopted by a huge percentage of the population, during a recession and is strongly competing with landlines and desktop PCs. Digital imaging and voice recognition could also be considered disruptive innovations. There will be more disruptive innovations in the future, and it can only be hoped they are associated with a lower, not higher price tag than existing technologies.¹⁰

The electronic health record (EHR), covered in another chapter could be considered the centerpiece of health informatics with its potential to improve patient safety, medical quality, productivity and data retrieval. EHRs will likely become the focal point of all patient encounters in the future. Multiple resources that are currently standalone programs are being incorporated/ integrated into the EHR,

e.g. electronic prescribing, physician/patient education, genetic profiles, disease registries and artificial intelligence, to mention a few. It is anticipated that EHR use will eventually be shown to improve patient outcomes like morbidity and mortality as a result of decision support tools that decrease medication errors and standardize care with embedded clinical guidelines. However, at present, because EHRs do not adequately support clinicians' information needs and workflow, they do little to improve patient care and in some cases have been shown to reduce the quality of care.¹¹ Informaticians will play a major role in helping to reverse this trend. It will not be enough to simply store electronic data; it must be shared among disparate partners. Health information exchange (information sharing) will be addressed in a separate chapter.

The Importance of Data

It is also important to realize that one of the outcomes of EHRs will be voluminous healthcare data. As pointed out by Steve Ballmer, the CEO of Microsoft, there will be an "explosion of data" as a result of automating and digitizing multiple medical processes.¹² Adding new technologies such as electronic prescribing and health information exchanges will produce data that heretofore has not been available. This explains, in part, why technology giants such as Microsoft, Intel and IBM have entered the healthcare arena. As healthcare data mining begins from entire regions or organizations organizations will be able to make much better evidence based decisions. We will point out in other chapters, large organizations such as Kaiser Permanente have the necessary information technology tools, financial resources, leadership and large patient population to be able to make evidence based decisions in almost all facets of medicine. Pooling data is essential because most practices in the United States are small and do not provide enough information on their own to show the kind of statistical significance we need to alter the practice of medicine.¹³

The federal government understands the importance of data and information to make

evidence based medical decisions. In 2009 a Presidential Open Government Directive was issued for the heads of the government agencies to promote the publication of government information online, improve the quality of data and to promote transparency.¹⁴ Consistent with that policy Data.gov was created to share data of interest to multiple communities. HealthData.gov is part of this initiative and serves to make datasets from the federal agencies available to a multitude of interested parties, such as healthcare organizations, developers, researchers, etc. Datasets are available through categories: raw data, special tools and a geodata catalog. Users can filter based on data type, subject, agency, date updated, coverage period, collection frequency, geographic area, release date and output format. As a result of this initiative, a variety of applications, mashups and visualizations have been developed. The following are examples of some of the applications/programs producing health-related data:

- Community Health Status Indicators
- Child Growth Charts
- Health Data Interactive
- Behavioral Risk Factor Surveillance System (CDC)
- Births (CDC)
- Mortality (CDC)

- Fourth National Survey of Older Americans
- Health Indicators Warehouse (see info box)
- Population (census) (CDC)
- Cancer Profiles
- Archimedes data modeling and analytics tool¹⁵

The federal government continues to add new sources of health-related data available to the public, healthcare professionals and researchers. We have added several of the new health data resources to other chapters of this textbook. Health Datapalooza is an annual event launched as a result of the Health Data Initiative (HDI), sponsored by HHS and the Institute of Medicine (IOM) and now called the Health Data Consortium. This public-private partnership brings together disparate users of healthcare data, in an effort to improve healthcare quality and safety.¹⁶⁻¹⁷

Similarly, the Department of Health and Human Services created a Health Indicators Warehouse (HIW) in 2010 that included hundreds of health indicators that will help measure progress towards the Healthy People 2020 program (see info box below). New indicators continue to be added and updated. Importantly, this initiative will be working with technology companies, researchers and others to develop applications and initiatives to improve healthcare.^{15,18-19}

Health Indicators Warehouse

Users can search by:

Topics: chronic disease and conditions, demographics, disabilities, geography, health behaviors, health care, health care resources, health outcomes, health risk factors, hospital referral region, infectious disease initiative, injury and violence, maternal and infant health, mental health and substance abuse, occupational health and safety, oral health, physical environment, population, prevention through healthcare, public health infrastructure, social determinants of health and women's health

Geography: state or county

Initiative: County Health Rankings, 2008 Community Health Status Indicators, Healthy People 2020, CMS Community Indicators

Data is available to developers via an open application programming interface (API).



Healthdata.gov



Users can search/filter by:

Subject: Medicare, population statistics, administrative, safety, health care providers, other, health care cost, biomedical research, epidemiology, children's health, Medicaid, quality measurement, treatments

Agency: Department of Health and Human Services, National Institutes of Health

Sub-agency: Centers for Medicare & Medicaid Services, Department of Health & Human Services, Centers for Disease Control and Prevention, national Library of Medicine, Administration for Children and Families, U.S. Food and Drug Administration, Agency for Healthcare Research and Quality, National Institutes of Health, Administration for Community Living, National Cancer Institute, National Institute on Drug Abuse, New York State Department of Health

Date coverage period start: 1984-2013

Collection frequency: annually, semi-annually, quarterly, monthly, weekly, daily

Geography: ZIP code, country, state, county, city, street address, MSA, sub-national region, Latitude/Longitude Coordinate

Media format: CSV, query tool, API, XLS, Widget, Text, XML, Feed, RDF, query tool ¹⁵

The most recent and significant event to affect the information sciences in the United States was the multiple programs associated with the HITECH Act of 2009, discussed later in the chapter. The programs include substantial financial support for electronic health records, health information exchange and a skilled HIT workforce. In other chapters we will refer to accountable care organizations (ACOs) and their technology requirements that are part of the Affordable Care Act of 2010.

The introduction of information technology into the practice of medicine has been tumultuous for many reasons. Not only are new technologies expensive, they affect workflow and require advanced training. Unfortunately, this type of training rarely occurs during medical or nursing school or after graduation. More healthcare professionals who are *bilingual* in technology and medicine will be needed to realize the potential of new technologies. Vendors, insurance companies and governmental

organizations will also be looking for the same expertise.

Historical Highlights

Information technology has been pervasive in the field of Medicine for only about three decades but its roots began in the 1950s.²⁰ Since the earlier days we have experienced astronomical advances in technology, to include, personal computers, high resolution imaging, the internet, mobile technology and wireless, to mention only a few. In the beginning there was no strategy or vision as to how to advance healthcare using information technology. Now, we have the involvement of multiple federal and private agencies that are plotting future healthcare reform, supported by health information technology. The following are some of the more noteworthy developments related to health information technology:

- Computers. The first general purpose computer (ENIAC) was released in 1946 and required 1,000 sq. ft. of floor space.

Primitive computers such as the Commodore and Atari appeared in the early 1980s along with IBM's first personal computer, with a total of 16K of memory.²¹ Ironically, not everyone saw the future popularity of personal computers. Ken Olson, the president and chairman of Digital Equipment Corporation said in 1977 "There is no reason anyone would want a computer in their home."²² By 2015 it is predicted that there will be 2 billion personal computers in use.²³

- German scientist Gustav Wagner developed the first professional organization for informatics in 1949.²⁴ Computers were first theorized to be useful for medical diagnosis and treatment by Ledley and Lusted in the 1950's.²⁵ They reasoned that computers could archive and process information more rapidly than humans. The programming language known as Massachusetts General Hospital Multi-Programming System (MUMPS) was developed in Octo Barnett's lab at Massachusetts General Hospital in the 1970s. MUMPS exists today in the popular electronic health record known as Vista, used by the Veterans Affairs medical system and Epic Systems Corporation.²⁶
- It is thought that the origin of the term medical informatics dates back to the 1960's in France ("Informatique Medicale").²⁴
- MEDLINE. In the mid-1960s MEDLINE and MEDLARS were created to organize the world's medical literature. For older clinicians who can recall trying to research a topic using the multi-volume text Index Medicus, this represented a quantum leap forward.²⁷
- Artificial Intelligence. Artificial intelligence (AI) medical projects such as MYCIN (Stanford University) and INTERNIST-1 (University of Pittsburg) appeared in the 1970s and 1980s.²⁸ Since 1966 AI has had many periods where research flourished and where it floundered, known as AI winters.¹¹ Natural language processing (NLP) is gaining traction in medicine as it has the potential to intelligently interpret free text.
- Internet. The development of the internet began in 1969 with the creation of the government project ARPANET.²⁹ The World Wide Web (WWW or web) was conceived by Tim Berners-Lee in 1990 and the first web browser Mosaic appeared in 1993.³⁰⁻³¹ The internet is the backbone for digital medical libraries, health information exchanges and web-based medical applications, to include electronic health records. Although the terms *web* and *internet* are often used interchangeably, the internet is the *network-of-networks* consisting of hardware and software that connects computers to each other. The web is a set of protocols (particularly related to HyperText Transfer Protocol or HTTP) that are supported by the internet. Thus, there are many internet applications (e.g. email) that are not part of the web. This is discussed further in the chapter on architectures of information systems.
- Electronic Health Record (EHR). The electronic health record has been discussed since the 1970's and recommended by the Institute of Medicine in 1991.³² EHRs will be discussed in much more detail in the EHR chapter.
- Mobile technology. The PalmPilot PDA appeared in 1996 as the first truly popular handheld computing device.³³ Personal Digital Assistants (PDAs) loaded with medical software became standard equipment for residents in training. They have been quickly supplanted by smartphones like the iPhone. Smartphones and tablets will be discussed in more detail in the chapter on mobile technology. The popularity of mobile technology is evidenced by the fact that in 2011 smartphone sales exceeded the sale of personal computers.³⁴ Gartner, the world's largest information technology research analyst reports that 8.2 million smartphones were purchased worldwide in 2012, accounting for 70% of total device sales. It is predicted that in

2013 sales intensify to 1.2 billion worldwide.³⁵

- Human Genome Project. In 2003 the Human Genome Project (HGP) was completed after thirteen years of international collaborative research. Mapping all human genes was one of the greatest accomplishments in scientific history. Finalizing a draft of the genome is the first step. What remains is making sense of the data. In other words, we need to understand the difference between data (the code), information (what the code means) and knowledge (what we do with the information).³⁶ Data from mega-databases will likely change the way we practice medicine in the future. The HGP will be discussed in the chapter on bioinformatics.
- Nationwide Health Information Network (NwHIN). The concept was developed in 2004 as the National Health Information Infrastructure and renamed the Nationwide Health Information Network (NwHIN). It was again renamed the eHealth Exchange in late 2012 when a new public-private organization (HealtheWay) was created for governance. The goal of this initiative is to connect all electronic health records, health information organizations and government agencies in one decade.³⁷⁻³⁸ Achieving interoperability among all healthcare systems and workers in the United States will be a monumental challenge. This will be discussed in more detail in several other chapters.

Health information technology (HIT) is important to multiple players in the field of medicine. In the next section we list the key players and how they need and utilize HIT. (Adapted from *Crossing the Quality Chasm*).³⁹

Key Players in Health Information Technology

Patients

- Online searches for health information and research choice of physician, hospital or insurance plan
- Smartphone technology for text message reminders, health and fitness apps, internet access, etc.
- Web portals for storing personal medical information, making appointments, checking lab results, e-visits, drug refills, etc.
- Online patient surveys
- Online chat, blogs, podcasts, vodcasts and support groups and Web 2.0 social networking
- Personal health records
- Limited access to electronic health records and health information exchanges (HIEs)
- Telemedicine and home telemonitoring

Physicians and Nurses

- Online searches with PubMed, Google and other search engines
- Online resources and digital libraries
- Patient web portals, secure e-mail and e-visits, telehomecare
- Physician web portals
- Clinical decision support, e.g. reminders and alerts
- Electronic medication administration record (eMAR) and bar coding medications
- Electronic health records (EHRs)
- Smartphones loaded with medical software and remote access to EHRs
- Telemedicine and telehomecare
- Voice recognition software
- Online continuing medical education (CME)
- Electronic prescribing
- Disease registries

- Picture archiving and communication systems (PACS)
- Pay-for-performance (P4P)
- Health information organizations (HIOs)
- E-research
- Electronic billing and coding

Support Staff

- Patient enrollment
- Electronic appointments
- Electronic coding and billing
- EHRs
- Web-based credentialing
- Web-based claims clearinghouses
- Telehomecare monitoring
- Practice management software
- Secure patient-office e-mail communication
- Online educational resources and CME
- Disease registries

Public Health

- Incident reports
- Syndromic surveillance as part of bio-terrorism program and Meaningful Use program criteria
- Establish link to all public health departments
- Geographic information systems to link disease outbreaks with geography
- Telemedicine
- Disease registries as part of EHRs or health information exchanges
- Remote reporting using mobile technology

Federal and State Governments

- Nationwide Health Information Network (HealtheWay)

- Financial support for EHR adoption and health information exchange
- Development of standards, services and policies for HIT
- Information technology pilot projects and grants
- Disease management
- Pay-for-performance
- Electronic health records and personal health records
- Electronic prescribing
- Telemedicine
- Broadband adoption
- Health information organizations (HIOs)
- Regional extension centers
- Health IT workforce development

Medical Educators

- Online medical resources for clinicians, patients and staff
- Online CME
- PubMed searches
- Telehealth via video conferencing, podcasts, etc.

Insurance Companies (Payers)

- Electronic claims transmission
- Trend analysis through data analytics
- Physician profiling
- Information systems for quality improvement initiatives
- Monitor adherence to clinical guidelines
- Monitor adherence to preferred formularies
- Promote claims-based personal health records and information exchanges
- Reduce litigation by improved patient safety through fewer medication errors

- Alerts to reduce test duplication
- Member of HIOs

Hospitals

- Electronic health records
- Electronic coding and billing
- Information systems to monitor outcomes, length of stay, disease management, etc.
- eMARs
- Bar coding and radio frequency identification (RFID) to track patients, medications, assets, etc.
- Wireless technology
- E-intensive care units (eICUs)
- Patient and physician portals
- E-prescribing
- Member of health information organizations (HIOs)
- Telemedicine
- Picture archiving and communication systems (PACS)

Medical Researchers

- Database creation to study populations, genetics and disease states
- Online collaborative research web sites
- Electronic case report forms (eCRFs)
- Software for statistical analysis of data e.g. SPSS
- Literature searches with multiple search engines
- Randomization using software programs
- Improved subject recruitment using EHRs and e-mail
- Smartphones to monitor research
- Online submission of grants

Technology Vendors

- Applying new technology innovations in the field of medicine: hardware, software, genomics, etc.
- Data mining
- Interoperability
- Certification

Organizations Involved with HIT

Academic Organizations

Institute of Medicine (IOM). One of the leading organizations in the United States to promote health information technology is the Institute of Medicine. It was established in 1970 by the National Academy of Sciences with the task of evaluating policy relevant to healthcare and providing feedback to the Federal Government and the public. In their two pioneering books *To Err is Human* (1999) and *Crossing the Quality Chasm* (2001), they reported approximately 98,000 deaths occur yearly due to medical errors. It is their contention that an information technology infrastructure will help the six aims set forth by the IOM: safe, effective, patient centered, timely, efficient and equitable medical care. The infrastructure would support “efforts to re-engineer care processes, manage the burgeoning clinical knowledge base, coordinate patient care across clinicians and settings over time, support multidisciplinary team functioning, and facilitate performance and outcome measurements for improvement and accountability.” They also stress “the importance of building such an infrastructure to support evidence based practice, including the provision of more organized and reliable information sources on the internet for both consumers and clinicians and the development and application of decision support tools.” Clearly, the IOM had an impact with the creation and direction of the HITECH Act.

Two of the IOM’s twelve executive recommendations regarding improved

healthcare directly relate to information technology:

- “improve access to clinical information and support clinical decision making”
- “Congress, the executive branch, leaders of health care organizations, public and private purchasers and health informatics associations and vendors should make a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education. This commitment should lead to the elimination of most handwritten clinical data by the end of the decade.”

The IOM cited twelve information technology applications that might narrow the quality chasm. Many of these will be discussed in other chapters:

- Web-based personal health records
- Patient’s access to hospital information systems to access their lab and x-ray reports
- Access to general health information via the internet
- Electronic medical records with clinical decision support
- Pre-visit online histories
- Inter-hospital data sharing (health information exchange), e.g. lab results
- Information to manage populations using patient registries and reminders
- Patient - physician electronic messaging
- Online data entry by patients for monitoring, e.g. glucose results
- Online scheduling
- Computer assisted telephone triage and assistance (nurse call centers)
- Online access to clinician or hospital performance data.⁴⁰⁻⁴¹

The Association of American Medical Colleges (AAMC). For more than twenty years the AAMC has been an advocate of incorporating informatics into medical school curricula and promoting health informatics in general. In their *Better Health 2010 Report* they made the following recommendations:

- Optimize the health and healthcare of individuals and populations through best practice information management
- Enable continuous and life-long performance-based learning
- Create tools and resources to support discovery, innovation and dissemination of research results
- Build and operate a robust information environment that simultaneously enables healthcare, fosters learning and advances science.⁴²

Public-Private Organizations

Bridges to Excellence. This is a program that rewards practitioners who provide superior patient care, with special emphasis on caring for patients with chronic conditions. This organization consists of employers, physicians, health plans and patients. They currently have multiple care recognition programs incentivized by bonuses: diabetes, cardiac care, congestive heart failure, coronary artery disease, cardiology, spine care, COPD, asthma, depression, hypertension, physician’s office technology, inflammatory bowel disease and medical home.⁴³

eHealth Initiative. This is a non-profit organization promoting the use of information technology to improve quality and patient safety. Its membership includes virtually all stakeholders involved in the delivery of healthcare. This organization deals with multiple topics related to HIT and has a reports section that provides multiple articles on a variety of HIT topics. They also provide an annual survey of HIOs, starting in 2005. The 2013 survey results are available for download

and discussed further in the chapter on health information exchange.⁴⁴

Leapfrog. Leapfrog is a consortium of over one hundred and seventy major employers seeking to purchase the highest quality and safest healthcare. Voluntary reporting by hospitals has made hospital comparisons possible and the results are reported on their website. They also have a hospital rewards program to provide incentives to hospitals that show they deliver quality care. One of their patient safety measures is the use of inpatient computerized physician order entry (CPOE) that will be covered in several other chapters.⁴⁵

Markle Connecting For Health. This organization is a public-private collaboration operated by the Markle Foundation and funded partially by the Robert Wood Johnson Foundation. With over 100 stakeholders, its primary mission is to promote interoperable HIT. They published *Common Framework: Resources for Implementing Private and Secure Health Information Exchange* that helps organizations exchange information in a secure and private manner, with shared policies and technical standards. The Common Framework with nine policy guides and seven technical guides is available free for download on their web site.⁴⁶

National eHealth Collaborative (NeHC). This government-civilian-consumer collaborative took over in early 2009 when the American Health Information Community (AHIC) was dissolved. They are charged with prioritization of HIT standards to promote interoperability. They create *value cases* and refer those for harmonization of standards and once accepted they will be adopted by the certification organizations such as the Certification Commission for Health Information Technology (CCHIT). NeHC is a cooperative agreement partner of the Office of the National Coordinator for Health IT (ONC) and the US Department of Health and Human Services (HHS). NeHC University is an online education program to inform stakeholders about multiple HIT issues, created in 2011.⁴⁷

Healthcare Information Technology Standards Panel (HITSP). This panel was a public-private partnership established in 2005 by the Department of Health and Human Services (DHHS). HITSP was charged by the ONC to harmonize standards-based on *use cases* derived from AHIC requirements. Each interoperability specification is a suite of documents that provides a roadmap of how standards and specifications will answer the requirements of the use case. For instance, specifics of the standard for using the Continuity of Care Document (CCD) were released as C32 in March 2008 with a detailed explanation of the technical aspects. The CCD is discussed further in the chapter on data standards. Their contract with the government was terminated in April 2010 and their function was largely replaced by the HIT Standards Sub-Committee discussed in a following section.⁴⁸

The Certification Commission for Healthcare Information Technology (CCHIT) was created by HIMSS and multiple other healthcare professional organizations. Its goals are to: reduce the risk of health information technology (HIT) investment by physicians; ensure interoperability of HIT; enhance the availability of HIT incentives and accelerate the adoption of interoperable HIT. Their initial step was to certify ambulatory electronic health records. By mid-2011 they certified the following categories of HIT: ambulatory EHRs, inpatient EHRs, Health Information Exchanges, Emergency EHRs, Cardiovascular Medicine EHRs, Child Health EHRs, Behavioral Health EHRs, Dermatology, Long Term/Post-Acute Care EHRs, Home Health EHRs and E-prescribing. EHRs that have received certification are listed on the web site. The Commission consists of 20 commissioners from a variety of backgrounds and numerous volunteers in their work groups. CCHIT decided they would offer different levels of EHR certification so more EHRs would qualify for Medicare or Medicaid reimbursement under ARRA: (1) CCHIT certified® 2011 and 2014, a comprehensive certification that would actually exceed federal standards and includes a usability score, (2) ONC-ATCB Certification will

test EHRs against Meaningful Use regulations, hosted by the National Institute of Standards and Technology (NIST), (3) EHR vendors can elect to be certified by both CCHIT and ONC-ATCB criteria, and (4) EHR Alternative Certification for Healthcare Providers (EACH) that certifies homegrown technology created by healthcare organizations and not vendors.

As of mid-2013 seventy one ambulatory EHRs were CCHIT certified using 2011 criteria, to include usability ratings. Multiple EHR-related resources are also available. Certification is quite expensive as noted by one reference.⁴⁹⁻⁵⁰

National Committee on Vital and Health Statistics (NCVHS) is a public advisory body to the Secretary of Health and Human Services. It is composed of 18 members from the private sector who are subject matter experts in the fields of health statistics, electronic health information exchange, privacy/security, data standards and epidemiology. They have been very involved in advising the Secretary in matters related to eHealth Exchange (Nationwide Health Information Network).⁵¹

US Federal Government

The federal government has maintained that information technology is essential to improving the quality of medical care and containing costs; two important aspects of healthcare reform. It is a major financier of health care with the following programs: Medicare/Medicaid, Veterans Health Administration, Military Health System, Indian Health Service and the Federal Employees Health Benefits Program. It is therefore no surprise that they are heavily involved in health information technology and stand to benefit greatly from an interoperable Nationwide Health Information Network. Agencies such as Medicare/Medicaid and the Agency for Healthcare Research and Quality conduct HIT pilot projects that potentially could improve the quality of medical care and/or decrease medical costs. The federal government has recognized the importance of technology in multiple areas and as a result has a new federal

chief technology officer and chief technology officer for HHS.

Before specific government agencies are discussed we will outline the new programs included in the American Recovery and Reinvestment Act of 2009 that impact the information sciences.

American Recovery and Reinvestment Act (ARRA). Without a doubt, the most significant recent governmental initiative that affected the field of Informatics was the ARRA. This legislation impacts HIT adoption, particularly EHRs, as well as training and research. ARRA had five broad goals: (a) improve medical quality, patient safety, healthcare efficiency and reduce health disparities; (b) engage patients and families; (c) improve care coordination; (d) ensure adequate privacy and security of personal health information; (e) improve population and public health. Title IV and XIII of ARRA, known as the Health Information Technology for Economic and Clinical Health (HITECH) Act was devoted to funding of HIT programs. Table 1.1 summarizes the major pertinent programs that have monies dedicated for these initiatives. The HealthIT website under the DHHS outlines the details of many of the programs listed in the table. In addition to the programs listed in Table 1.1, the following are also important initiatives that were part of the ARRA:

- Privacy and HIPAA changes; to be discussed in chapter on privacy
- The National Telecommunications and Information Administration's Broadband Technology Opportunities Program. This will fund the National Broadband plan discussed in the chapter on telemedicine
- USDA's Distance Learning, Telemedicine and Broadband Program
- Indian Health Services HIT programs
- Social Security Administration HIT programs
- Veterans Affairs (VA) HIT programs ⁵²

Table 1.1: ARRA and HITECH programs that impact information sciences and HIT

Program	Programmatic Details
ONC	Discretionary money to develop the support for multiple programs. Establish Privacy Officer, HIT Standards and HIT Policy Committees
States	Support for statewide health information exchanges. As of mid-2011, fifty six states, territories and other entities have been funded. Details discussed in the chapter on health information exchange
NIST	Develop HIT standards
HRSA	Upgrade community health centers to include HIT initiatives, such as EHRs
AHRQ, NIH	Develop comparative effective research (CER) programs
Medicare / Medicaid	Medicare and state administered Medicaid will reimburse physicians for Meaningful Use of certified electronic health records (EHRs). Details outlined in the chapter on EHRs
Regional Extension Centers	Create 62 Regional Extension Centers to promote HIT, particularly EHRs for primary care physicians in rural areas. Goal is to support 100,000 clinicians in two years. More than 100,000 primary care physicians have signed on as of August 2013
HIT Research Center	Collect feedback from the regional extension centers, in order to generate lessons learned
Beacon Community Program	Beacon Program will support 17 communities that serve as role models for the early adoption of HIT
Community College Consortia to Educate HIT Professionals	82 participating community colleges throughout all 50 states receive funding to rapidly create or expand HIT training programs that can be completed in six months or less; emphasis is on training the following roles: practice workflow and information management redesign specialists, clinician/practitioner consultants, implementation support specialists, implementation managers, technical/software support, and trainers
Health IT Curriculum Project	ONC Health IT Curriculum Project designated 12 healthcare workforce roles, six of to be educated through 6-month community college programs and six to be educated through one to two year programs at the university level. Five universities were funded as Curriculum Development Centers. The community college curriculum built by the Curriculum Development Centers covers 20 components with 8-12 units within each component and is available to faculty and the public at http://www.onc-ntdc.org/
Competency Exam Program	Support one center to create a competency exam. There will be no charge for the first 10,000 students to take the exam
Program of Assistance for University-based Training	Support for eight institutions to develop programs for HIT professionals requiring university level training. The professional roles targeted by this program are: Clinician/Public Health Leader, Health Information Management and Exchange Specialist, Health Information Privacy and Security Specialist, Research and Development Scientist, Programmers and Software Engineer, and Health IT Sub-specialist
Strategic HIT Advanced Research Projects (SHARP)	Awarded to four centers in 2010. Four focus areas are: HIT security to reduce risk and cultivate technologies of trust, support clinicians to align patient centered care with their practice, improve architectures and applications to exchange information accurately and securely and secondary use of EHR data to improve quality, population health and clinical research

The Patient Protection and Affordable Care Act (PPACA) was enacted into law in March 2010 and is commonly known as the Affordable Care Act. Its primary goals were to increase insurance coverage and improve patient outcomes. The primary focus of the Act is to expand private insurance and Medicaid coverage. Other interesting areas within the act include:

- Patient Centered Outcomes Research Institute that will fund patient-centered and comparative effectiveness research
- The CMS Innovation Center that will evaluate healthcare models such as the Accountable Care Organization (ACOs), discussed in another chapter
- The National Prevention and Health Promotion Strategy
- Independence at Home Demonstration Projects
- Readmission Reduction Program to penalize healthcare systems with excessive readmissions
- Value based reimbursement to hospitals and physicians based on quality measures
- Scholarships and loan repayments for primary care physicians
- Grants for Health Centers to support health information technology ⁵³

US Department of Health & Human Services (HHS) is the department that serves as an umbrella for most of the important government agencies that impact HIT. The Office of the National Coordinator for Health Information Technology reports directly to the Secretary of HHS and is not an agency. The following are some of the operating divisions under HHS:

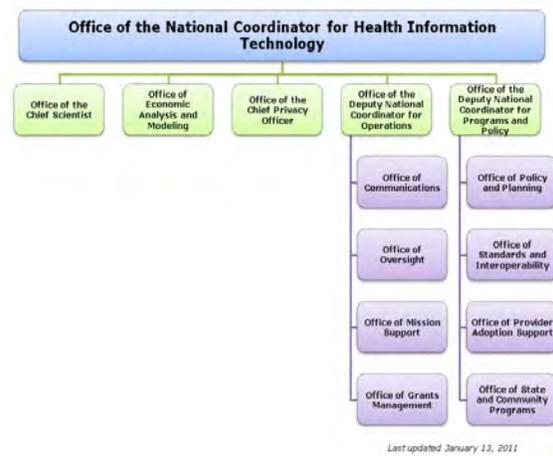
- Agency for Healthcare Research & Quality (AHRQ)
- Centers for Medicare & Medicaid Services (CMS)
- Centers for Disease Control & Prevention (CDC)
- Health Resources & Services Administration (HRSA)
- Indian Health Service (HIS)

- Food and Drug Administration (FDA)
- Administration on Aging (AOA)
- National Institutes of Health (NIH)⁵⁴

Office of the National Coordinator for Health Information Technology (ONC).

The most significant goal of (ONC) is the creation of a universal interoperable electronic health record by the year 2014. To accomplish this goal they are working to harmonize data standards to ensure interoperability and to facilitate health information exchange. ONC reorganized in December 2009, resulting in the following offices: Office of Economic Modeling and Analysis, Office of the Chief Scientist, Office of the Deputy Coordinator for Programs and Policy, Office of the Deputy National Coordinator for Operations and Office of the Chief Privacy Officer. (See figure 1.7)

Figure 1.7: ONC organization chart (Courtesy ONC)



The following are the broad goals of the 2011-2015 Federal Health IT Strategic Plan developed by ONC. The specific objectives and strategies are outlined in detail in the plan:

Goal 1: Achieve adoption and information exchange through meaningful use of health IT

Goal 2: Improve care, improve population health and reduce health care costs through the use of Health IT

Goal 3: Inspire confidence and trust in health IT

Goal 4: Empower individuals with Health IT to improve their health and the healthcare system

Goal 5: Achieve rapid learning and technological advancement⁵⁵

In summary, ONC is responsible for coordinating all aspects of health information technology in the United States. They are involved with the adoption, standards harmonization, inter-operability, privacy/security and certification of electronic health records. In addition they are coordinating the efforts to create the Nationwide Health Information Exchange (NwHIN); now known as the eHealth Exchange. They participate with and support multiple private and public health information technology initiatives. The next two federal advisory committees discussed are part of ONC and were created as part of the ARRA.⁵⁶

Health IT Policy Committee (HITPC). The main goal of this committee is to set priorities regarding what standards are needed for information exchange and establish the policy framework for the development and adoption of national health information exchange. The committee has 20 multi-disciplinary members. In 2013 the working groups were as follows: Accountable Care, Meaningful Use, Consumer Empowerment, Certification/Adoption, HIE, NwHIN, FDASIA, PCAST Report, Strategic Plan, Privacy and Security, Enrollment, the Data Intermediaries, Governance and Quality Measures. The National Coordinator is the chair of the HITPC and their recommendations are posted on their web site.⁵⁶

Health IT Standards Committee (HITSC). This committee has 26 multi-disciplinary members, 1 chair and 1 vice-chair that are tasked to look at standards, implementation specifications and certification criteria for the exchange of health information. They will focus on issues that are prioritized by HITPC. They will use the National Institute of Standards and Technology (NIST) to test standards. Both committees will make recommendations to the National Coordinator. They have established several working groups: Clinical Quality, Clinical Operations, Consumer/Patient Engagement, Consumer Technology, NwHIN,

Implementation, Vocabulary and Privacy/Security.⁵⁶

Agency for Healthcare Research and Quality (AHRQ). The AHRQ is “the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. As one of 12 agencies within the Department of Health and Human Services, AHRQ supports health services research that will improve the quality of health care and promote evidence based decision making.”⁵⁷ This agency sets aside significant grant money to support healthcare information technology (HIT) each year. Since 2004 AHRQ has invested about \$166 million in grants to research HIT. The AHRQ also maintains the National Resource Center for HIT and an extensive patient safety and quality section. They also maintain an extensive HIT Knowledge Library with over 6,000 resources.⁵⁷

Centers for Medicare and Medicaid Services (CMS). CMS is responsible for providing care to 47.5 million Medicare (2010 data) and 61.8 million Medicaid patients (2009 data). In an effort to improve quality and decrease costs, CMS has information technology pilot projects in multiple areas, to include pay-for-performance demonstration projects that link payments to improved patient outcomes. They will reimburse for Meaningful Use of certified EHRs. Several informatics-related projects will be discussed in later chapters.⁵⁸

Centers for Disease Control and Prevention (CDC). Although not a primary information technology agency, the CDC has used HIT to promote population health-related issues. Among their programs of interest:

- Public Health Information Network (PHIN), covered in the chapter on public health informatics
- Human Genome Epidemiology Network (HuGENET™) correlates genetic information with public health
- Family History Public Health Initiative is a web site that records family history information and encourages saving it in a

digital format so it can be shared. Discussed more in chapter on bioinformatics

- Public Health Image Library contains photos, images and videos on medical topics
- Geographic information systems (GIS) are also covered in chapter on public health informatics
- Podcasts, RSS feeds and web widgets on medical topics
- Online Health Library
- Mobile Pilot Project to text message patients about public health issues ⁵⁹

Health Resources and Services Administration (HRSA) is part of HHS with the primary mission of assisting medical care for the underserved and uninsured in the United States, particularly in rural areas. They support federally qualified health centers (FQHCs) and rural health centers (RHCs). As noted in the section on the ARRA, HRSA will support grants for community health centers to include the installation and upgrades of health information technology. They have been a long term grant supporter of telemedicine. On their site they post a variety of health-related data in their HRSA data warehouse. A variety of searchable topics are presented with the ability to present as a table, chart, map or report.⁶⁰

National Institute of Standards and Technology (NIST) is a physical science laboratory that is part of the U.S. Department of Commerce, and serves to promote and verify measurements and standards. This federal agency makes EHR testing recommendations. The following is a list of some of the pertinent publications related to EHRs:

- (NISTIR 7741) NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records
- (NISTIR 7742) Customized Common Industry Format Template for Electronic Health Record Usability Testing

- (NISTIR 7743) Usability in Health IT: Technical Strategy, Research, and Implementation
- (NISTIR 7769) Human Factors Guidance to Prevent Healthcare Disparities with the Adoption of EHRs⁶¹

State Governments and HIT

There are a variety of state-based HIT initiatives, evaluating the adoption of technologies such as electronic health records, HIE and e-prescribing. State Medicaid offices are anxious to conduct pilot projects aimed at reducing costs and/or improving quality of care. The State Alliance for e-Health was created in 2006 in an attempt to navigate the issues of best practices, policies and adoption obstacles. Support for the Alliance is from ONC as well as a private-public advisory committee. They have three task forces: health information protection, health care practice-health information communication and data exchange taskforces. Their highest priorities are e-prescribing and the privacy and security of health information.⁶²

International Governments and HIT

This chapter focuses primarily on US health informatics, but the reality is that this is an important and emerging field worldwide. Other countries have less expensive and less fragmented healthcare systems but they also have to deal with aging populations and rising chronic diseases. Meanwhile, technology continues to evolve unabated and in the case of mobile technology is quite affordable. They are therefore looking for healthcare solutions using cost-effective health information technology. Issues such as IT interoperability among European nations and certification are challenges all countries face. In the case of Europe and the European Union they refer to Health IT as eHealth and IT as information and communication technology (ICT).

The Digital Agenda for Europe (DAE) was created to enhance the economic condition in Europe and modernize all industries, to include healthcare. They have also established ICT-

related cooperative efforts outside the EU. In 2013 they established ties with the US Department of Health and Human Services to further eHealth cooperation. The established Roadmap focuses on two high priority areas: standards development for interoperability and workforce development to increase skilled health IT workers in Europe. The timeline for this cooperative initiative is 18 months.⁶³ Multiple other international eHealth initiatives, collaborations and innovations are discussed in other chapters.

International health informatics is a mature sophisticated movement that is supported by multiple countries and international organizations such as the World Health Organization (WHO). The WHO fully supports eHealth with multiple programs and projects. One of their newest collaborations is the WHO Collaborating Centre in Consumer Health Informatics, established to help patients manage their own health. The most prominent international informatics organization is the International Medical Informatics Association (IMIA) that supports the International Journal of Medical Informatics; both discussed later in this chapter. Several international conferences are held to collaborate and support health informatics research efforts. Other international medical informatics associations are discussed in the health informatics organizations section.

Barriers to Health Information Technology Adoption

According to Anderson in 2006, the United States was at least 12 years behind many industrialized nations, in terms of HIT adoption. Total investment in 2005 per capita was 43 cents, compared to \$21 for Canada, \$4.93 for Australia, \$21 for Germany and \$192 for the United Kingdom.⁶⁴ This situation changed dramatically after HITECH implementation. As

of December 2013 CMS paid \$17 billion out for adoption and meaningful use of EHRs.⁶⁵ Healthcare information technology adoption has multiple barriers listed below and discussed in later chapters:

Inadequate time. This complaint is a common thread that runs throughout most discussions of technology barriers. Busy clinicians complain that they don't have enough time to read, learn new technologies or research vendors. They are also not reimbursed to become technology experts. They usually have to turn to physician champions, local IT support, Regional HIT Extension Centers or others for technology advice.

Inadequate information. As already pointed out earlier in the chapter, clinicians need information, not data. Current HIT systems are data rich but information poor. This is discussed in detail in the Healthcare Data, Information and Knowledge chapter.

Inadequate expertise and workforce. In order for the United States to experience widespread HIT adoption and implementation, it will require education of all healthcare workers. According to Dr. Blumenthal (previous National Coordinator for HIT) the United States will need approximately 51,000 skilled health informaticians over the next five years to create, install and maintain HIT.⁶⁶ Dr. William Hersh of the Oregon Health and Science University, echoes the need for a work force capable of leading implementation of the electronic health record and other technologies.⁶⁷ Educational offerings will need to be expanded at universities, community colleges and medical, nursing and pharmacy schools. There is a substantial difference between healthcare organizations, in terms of HIT sophistication. The first Work Force for Health Information Transformation Strategy Summit, hosted by the American Medical Informatics Association (AMIA) and the American Health Information Management Association (AHIMA) made several strategic recommendations regarding how to improve the work force.⁶⁸ The American Medical Informatics Association has been the leader in attempting to increase the health

information technology workforce with its AMIA 10x10 Program.⁶⁹ Their goal is to train 10,000 skilled workers in the next 10 years. The Community College Consortium graduated a significant number of students but it is too early to know how successful job placement will be. HIT vendors are looking for applicants with both IT and clinical experience, in addition to good people skills and project management experience.⁷⁰ In addition to skilled informaticians; we will need to educate residents in training and faculty at medical schools, given the rapidly changing nature of HIT. The APA Summit on Medical Student Education Task Force on Informatics and Technology recommended that instead of CME, we need “longitudinal, skills-based tutoring by informaticians.”⁷¹ Family Medicine residency programs are generally ahead of other specialty training programs in regards to IT training, promoting a longitudinal approach to IT competencies.⁷²

Inadequate cost and return on investment data. The literature on the economic aspects of HIT adoption and implementation is mixed and based on different assumptions and methods. In a 2013 article by Bassi and Lau they posit that such an evaluation should have six components: having a perspective, options for comparison, time frame, costs, outcomes and comparison of costs and outcomes for each option. Examples of high quality economic reviews are available in their paper.⁷³

High cost to adopt. It is estimated that a Nationwide Health Information Network (eHealth Exchange) will cost \$156 billion dollars over five years and \$48 billion annually in operating expenses.⁷⁴ Technologies such as picture archiving and communications systems (PACS) and electronic health records are also very expensive. The ARRA will help underwrite the initial purchase of some technologies but long term support will be a different challenge. There is still limited evidence that most technologies will actually save money. This is discussed in more detail in the chapter on electronic health records.

Lack of interoperability. Electronic health records and the NwHIN cannot share medical information until data standards are adopted and implemented nationwide. Interoperability and data standards are covered in more detail in other chapters.

Change in workflow. Significant changes in workflow will be required to integrate technology into the inpatient and outpatient setting. As an example, clinicians may be accustomed to ordering lab or x-rays by giving a handwritten request to a nurse who actually places the order. Now they have to learn to use computerized physician order entry (CPOE). As with most new technologies, older users have more difficulty changing their habits, even if it will eventually save time or money. Poor usability is also an important impediment to good workflow and we will address this in the chapter on electronic health records. There is also some evidence that young physicians are spending more time on the computer and less with the patient which is disconcerting.⁷⁵ According to Dr. Carolyn Clancy, the director of AHRQ:

“The main challenges are not technical; it’s more about integrating HIT with workflow, making it work for patients and clinicians who don’t necessarily think like the computer guys do”⁷⁶

Privacy concerns. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 was created initially for the portability, privacy and security of personal health information (PHI) that was largely paper-based. HIPAA regulations were updated in 2009, and again in 2013, to better cover the electronic transmission of PHI or (ePHI). This Act has caused healthcare organizations to re-think healthcare information privacy and security. This will be covered in more detail in the chapter on privacy and security. In the past few years there have been a series of privacy breaches and stolen identities in healthcare organizations, thus adding to the angst.

Legal issues. The Stark and Anti-kickback laws prevent hospital systems from providing or sharing technology such as computers and

software with referring physicians. Exceptions were made to these laws in 2006, as will be pointed out in other chapters. This is particularly important for hospitals in order to share electronic health records and e-prescribing programs with clinician’s offices. Many new legal issues are likely to appear.

Behavioral change. Perhaps the most challenging barrier is behavior. In *The Prince* by Machiavelli, it was stated “there is nothing more difficult to be taken in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things.”⁷⁷ Dr. Frederick Knoll of Stanford University described the five stages of medical technology acceptance: (1) abject horror, (2) swift denunciation, (3) profound skepticism, (4) clinical evaluation, then, finally (5) acceptance as the standard of care.⁷⁸ It is unrealistic to expect all medical personnel to embrace technology. In 1962, Everett Rogers wrote *Diffusion of Innovations* in which he delineated different categories of acceptance of innovation:

- The innovators (2.5%) are so motivated; they may need to be slowed down
- Early adopters (13.5%) accept the new change and teach others
- Early majority adopters (34%) require some

motivation and information from others in order to adopt

- The late majority (34%) require encouragement to get them to eventually accept the innovation
- Laggards (16%) require removal of all barriers and often require a direct order ⁷⁹

It is important to realize, therefore, that at least 50% of medical personnel will be slow to accept any information technology innovations and they will be perceived as dragging their feet or being *Luddites*.⁸⁰ With declining reimbursement and emphasis on increased productivity, clinicians have a natural and sometimes healthy dose of skepticism. They dread widespread implementation of anything new unless they feel certain it will make their lives or the lives of their patients better. In this situation, selecting clinical champions and conducting intensive training are critical to implementation success.

HIT hype versus fact. The Gartner IT Research Group describes five phases of the hype-cycle that detail the progression of technology from the technology trigger to the peak of inflated expectations to the trough of disillusionment to the slope of enlightenment to the plateau of productivity.⁸¹ Figure 1.8 shows the hype curve for a variety of IT technologies for 2013.

Figure 1.8: Gartner Hype Cycle of Emerging Technology 2013
(Courtesy www.Gartner.com)



As already noted, clinicians tend to be leery about new technologies that promise a lot, but deliver little. As a rule, if technology doesn't save time or money physicians are not interested. Importantly, current studies that evaluate HIT often yield mixed results for multiple reasons contributing to skepticism discussed in these articles.⁸²⁻⁸³

Both the RAND Corporation and the Center for Information Technology Leadership reported in 2005 that HIT would save the US about \$80-180 billion annually for widespread EHR and HIE adoption.⁸⁴ The Congressional Budget Office (CBO), on the other hand, refuted this optimistic viewpoint in May 2008. They published a monograph entitled *Evidence on the Costs and Benefits of Health Information Technology* that reviewed the evidence on the adoption and benefits of HIT, the costs of implementing, possible factors to explain the low adoption rate and the role of the federal government in implementing HIT. The bottom line for the CBO was "By itself, the adoption of more health IT is generally not sufficient to produce significant cost savings."⁸⁵

Another article by Rand in 2013 confirmed that HIT adoption has been less than ideal because EHR adoption has not been widespread, EHRs are not interoperable, EHRs are not as usable as desired and many healthcare organizations and professionals failed to modify their processes to maximize the benefits of HIT.⁸⁶

A systematic review by RAND, sponsored by ONC and reported in January 2014 summarized research articles from 2010 to August 2013. Overall, most studies reporting on HIT and quality, safety and efficiency were positive. It was still unclear why some HIT implementations were successful and others not.⁸⁷

Furthermore, there has been several recent articles that called into question the presumption that HIT adoption will generate significant cost saving, along with one positive review.⁸⁸⁻⁹³ Karsh et al. discussed twelve HIT fallacies that added a sober note to the discourse.⁹⁴ Finally, Carol Diamond of the Markle Foundation pointed out that HIT success

can't be measured by the number of hospitals that have adopted EHRs or other HIT, but instead whether patient outcomes improve.⁹⁵

Health Informatics Programs, Organizations and Careers

Health Informatics Academic Programs

One of the best sites to review the various health informatics programs in the United States can be found on the American Medical Informatics Association's web site. Health informatics programs can be degree, certificate, fellowship and short courses. Most programs are part of a university, community college, medical or nursing school and others may be part of a health related organization such as the National Library of Medicine. Courses can be online, taught in a classroom setting or both. Health informatics degree programs are available as follows: associate degree, undergraduate degree, Master's degree, PhD degree or part of another degree program. Master's degrees may be focused on applied training or readying students for a research career. The AMIA program listings will give the reader an idea of how many programs are available in North America and in which category. In addition, it will provide an idea as to the rapid growth of health informatics programs in a relatively short period of time.⁶⁹ Another resource is the Health Informatics Forum that lists international health informatics programs.⁹⁶

As of February 2013, community colleges participating in ONC's Community College Consortia to Educate Health IT Professionals have trained 17,523 individuals.⁵⁶ The majority of health informatics students in the past have come from healthcare fields. With the current economy and the new monies from the ARRA, IT professionals from other industries are enrolling in health informatics training programs. Often these professionals bring

expertise in technology implementation, evaluation and/or user training and programming skills but they often lack clinical experience in healthcare.

Health Informatics Organizations

The following organizations are considered among the most important and influential.

AMIA

- Founded in 1989 by the merger of the American Association for Medical Systems and Informatics, the American College of Medical Informatics and the Symposium on Computer Applications in Medical Care
- In 2006 it became a member of the Council of Medical Specialty Societies
- As of 2013 AMIA has greater than 4000 members from clinical, technical and research sectors
- They support five main domains: translational bioinformatics, clinical research informatics, health informatics, consumer health informatics and public health informatics
- They offer a Clinical Informatics Board Review course and a practice exam
- They also offer 10 x 10 courses
- Members are from 65 countries
- They frequently collaborate with AHIMA, discussed later
- Developed the clinical informatics board certification process with the first exam in late 2013
- Web site includes a career center, academic programs and education, policy positions, news, events, fellowships, grants, and an e-newsletter
- Membership includes subscription to the Journal of the American Medical Informatics Association (JAMIA)
- Opportunity to join a working group (20) to discuss issues and formulate white papers
- Annual national symposium in the fall as well as a spring Congress ⁶⁹

International Medical Informatics Association (IMIA)

- Began in 1967 but became officially an independent endorsed organization in 1989
- Membership consists of national, institutional, affiliate members and honorary fellows
- AMIA is the US representative to the IMIA
- IMIA supports the triennial World Congress on Medical and Health Informatics, known as Medinfo
- IMIA supports multiple working groups and special interest groups
- Official journals: International Journal of Medical Informatics, Methods of Information in Science, and Applied Clinical Informatics ⁹⁷

European Federation for Medical Informatics (EFMI)

- Organization began as a collaboration of 10 countries in 1976
- Members represent the informatics society of their country
- In 2013, thirty countries have joined the Federation⁹⁸

Asia Pacific Association for Medical Informatics (APAMI)

- APAMI is an extension of the IMIA in the Asia Pacific region that began in 1994
- Current members include informatics societies from: Australia, China, Hong Kong, Indonesia, Japan, Korea, Malaysia, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam ⁹⁹

Health Informatics in Africa (HELINA)

- Supports the IMIA vision in Africa
- Current members include informatics societies from: Ethiopia, Cameroon, Malawi, Ivory Coast, Nigeria, Mali, South Africa, Togo and Ghana ¹⁰⁰

Canada's Health Information Association (COACH)

- IMIA representation in Canada since 1975

- As of 2013 they have more than 1500 members
- Comprehensive services to members, such as professional development ¹⁰¹

Healthcare Information and Management Systems Society (HIMSS)

- Founded in 1961
- As of 2013 has about 50,000 individual members and 570 corporate members
- Annual symposium with more than 20,000 attendees
- Professional certification
- Educational publications, books and CD-ROMs
- Web conferences on health informatics topics
- HIMSS Health IT Body of Knowledge resource site
- HIMSS Analytics is a subsidiary that provides data and analytic expertise
- Surveys on multiple topics ⁶⁶

American Health Information Management Association (AHIMA)

- Founded in 1928 for medical records librarians and in 1991 became known as the AHIMA
- As of 2013 has more than 67,000 members
- It began as a medical records association but now includes any healthcare worker involved in information and data management. It offers seven credentials related to four areas: Coding, HIM, privacy and analysis
- “AHIMA supports the common goal of applying modern technology to and advancing best practices in health information management”
- AHIMA web site has an excellent HIT resource section, CME and certification information, and books available from AHIMA Press
- AHIMA Journal and Perspectives in Health Information Management are available on their web site at no cost⁶⁸

Alliance for Nursing Informatics (ANI)

- Combines 25 separate nursing informatics organizations
- As of 2007 has more than 3,000 members
- Sponsored by both the AMIA and HIMSS
- Provides a collaborative group for consensus about nursing informatics ¹⁰²

American Telemedicine Association

- Established in 1993 to promote telecommunications technology
- Has transitioned to telemedicine, telehealth or eHealth
- Mission is to promote remote access to medical care through telemedicine technology
- Web site has a variety of educational resources and telemedicine forms
- Official journal is Telemedicine and e-Health ¹⁰³

Health Informatics Careers

The timing is excellent for a career in health informatics. With the emphasis on increasing adoption of electronic health records and health information exchange, coupled with support from the HITECH Act there has been tremendous interest in health informatics. Healthcare organizations and HIT vendors will be looking for workers who are knowledgeable in both technology and healthcare. They are looking for experienced individuals who can hit the ground running, in order to direct implementation of multiple types of HIT such as EHRs and new standards such as ICD-10. The Department of Labor estimates that there will be 4% growth in the demand for trained health informatics specialists in multiple areas in the private, federal and military sectors. This estimate may be too conservative, given the fact that postings for health IT jobs tripled between 2009 to 2012.¹⁰⁴ Informaticians will be needed to design, implement and govern many new technologies arriving on the medical scene, as well as train users. Informatics training programs will need to continue the process of designing curricula based on actual needs from

the industry. It is anticipated that government reimbursement for EHRs and support for health information exchange will only increase the need for skilled HIT workers. The Health Informatics Forum, HIMSS, American Nurse Informatics, Health IT News, AHIMA and the AMIA web sites list multiple interesting health IT jobs. According to the HIMSS Jobmine site the job titles in highest demand in decreasing order were: IT technical management, analyst, healthcare informatics, systems analyst and project management.¹⁰⁵ Other job categories include: nurse and physician informaticists, information directors, chief information officers (CIOs) and chief medical information officers (CMIOs).^{66,68-69,96,106} Recruiting organizations also maintain multiple listings for health IT jobs.

There are a wide variety of jobs available in the informatics realm. The following are just a few of the known positions in a healthcare organization:

Chief Medical Informatics Officer (CMIO) is usually a physician but could be a nurse who generally reports to the Chief Information Officer (CIO), Chief Executive Officer (CEO) or Chief Medical Officer (CMO). This individual usually works with the CIO to develop a strategic IT plan and to help with the implementation of technologies by clinical staff. CMIOs are less IT oriented and more oriented towards overcoming the barriers to adoption and they provide feedback and education to their staff. They evaluate new technologies that may transform healthcare and along with the CIO they help develop policies that affect privacy and security. They commonly have a Master's degree in one of the information sciences. In 2002 HIMSS developed a Certified Professional in Health Information Management Systems (CPHIMS) certification and exam. This is primarily aimed at professionals who work in healthcare. In 2011 1651 individuals were certified (68% nurses and 18% physicians). They must have a bachelor's degree and 5 years of information management experience (2 years in healthcare) or a graduate degree and 3 years of information management experience (2 years in healthcare).⁶⁶

Nurse Informaticist (NI) is a nurse who can be the CMIO or can be an individual who works in the nursing department, IT department or is dual hatted. There are three million nurses in the United States, compared to about 800,000 physicians so they are a large pool of knowledge workers. Most nurses are trained to think in terms of systems and process improvement. They are therefore extremely valuable for project management, IT systems managers, data analysts, technology adoption, implementation and training. Nurse Informaticians have had a certification exam since 1995 and published their Scope and Standards in 2008. To take the certification exam, candidates must have an RN degree, at least 2 years of clinical practice, 30 hours of continuing education in informatics in the prior year and other qualifications. In 2010 there were 729 certified nurse informaticists.¹⁰²

Clinician Informatician (CI) is a clinician who may have formal training with a variety of degrees or simply may have extensive on the job experience and an aptitude for technology. As a result, they are usually early adopters and clinician champions who help the clinical staff in a healthcare organization understand and accept transformational technologies.¹⁰⁷

AMIA helped establish the medical subspecialty of *clinical informatics*. In September 2011 it was announced that *clinical informatics* was an approved subspecialty, sponsored by the American Board of Preventive Medicine and the American Board of Pathology. The certification will be available to physicians who have a primary specialty designated through the American Board of Medical Specialties (ABMS). There will be a period of 5 years in which physicians can be "grandfathered" in without formal informatics education. In the 2009 March/April issue of JAMIA, the core content for this new specialty is spelled out.¹⁰⁸⁻¹⁰⁹ The plan is to make board certification exams available starting in the Fall of 2013. The following are admission requirements for certification:

- ABMS member board certification in a current specialty

- Attendance at an accredited in the US or Canada or one deemed satisfactory to the Board
- Current license holder
- Completion of one of the following pathways (acceptable through 2017; after that candidates will need to complete 24 months in an accredited clinical informatics program):
 - Three years of practice (in the past 5 years) in the clinical informatics field; at least 25% of a FTE
 - If a candidate has completed less than 24 months in a non-accredited program, candidates must submit evidence of the training program.
 - Similar certification is being discussed for nurses, pharmacists, PhDs and others. Further details are available at this reference.¹¹⁰

In mid-2013 AMIA provided more detail about a proposed Advanced Interprofessional Informatics Certification. The goal would be to provide certification for those individuals who are not eligible for the subspecialty of clinical informatics. A majority of workers in the health informatics field and members of AMIA are not eligible for certification in clinical informatics so this advanced certification should have broad appeal. The certification should have the same requirements as the subspecialty certification and should be at the graduate level.¹¹¹

Although physicians can become chief medical information officers in very large organizations, the reality is that nurses have the greatest potential to be involved with IT implementation and training at the average hospital or large clinic. Larger, more urban clinics may have the luxury of in-house IT staff, unlike smaller and more rural practices.

Table 1.2 lists the salaries of individuals in the information sciences. Many of these figures are averages or medians, actual salary will vary depending on location, education, job demand, job scope and size of the organization.¹¹²⁻¹¹³ The job site Indeed.com provides a search by city, state or zip code with filters for salary estimate,

job title, company, location, job type and employer/recruiter.¹¹⁴

While there are many IT certifications available, there is no state or federal licensing or credentialing for health informatics. However, nursing already has an informatics specialty certification.

Table 1.2: Informatics Positions and Salaries

Informatics Position	Salary
Chief Medical Information Officer	\$125,000-\$300,000 (range)
Health Informatics Consultant	\$88,000 (median)
Health Informatics Director	\$85,000-\$105,000 (range)
Nurse Informatics Specialist	\$88,000 (median)
Health IT Project Manager	\$90,000 (median)
Security Officer	\$83,000 (median)
Privacy Officer	\$65,000 (median)
Data Systems Analyst	\$58,000 (median)
Coding Professional	\$43,000 (median)
EHR Clerk	\$32,000 (median)

Health Informatics Resources

Because of the rapidly changing nature of technology it is difficult to find resources that are current. It is also difficult to find resources that are not overly technical that would be

appropriate for the health informatics neophyte. There are numerous excellent journals, e-journals and e-newsletters that contain articles that discuss important aspects of health information technology. Because health informatics is gaining popularity in the field of medicine many excellent articles can also be found in major medical journals that do not normally focus on technology. As an example, *Health Affairs*, a bimonthly health policy journal features web exclusives, blogs and e-newsletters of interest to informaticians.¹¹³ Furthermore, several informatics-related web sites link to the major national and international health informatics print and online journals.¹¹⁶⁻¹¹⁷

Books

- *Handbook of Biomedical Informatics*. Wikipedia Books. 2009¹¹⁸
- *Guide to Health Informatics*. Enrico Coiera. 2003¹¹⁹
- *Biomedical informatics: Computer Applications in Health Care and Biomedicine*. EH Shortliffe and J Cimino 2006¹²⁰
- *Medical Informatics: Concepts, Methodologies, Tools and Applications*. J Tan. Four Volumes. 2009¹²¹
- *Health Informatics: An Interprofessional Approach*. Nelson R, Staggers N. 2013¹²²

Journals

- *Journal of the American Medical Informatics Association* is the bimonthly journal of the AMIA. It features peer reviewed articles that run the gamut from theoretical models to practical solutions. The journal is included in the AMIA membership and is most appropriate for medical and IT professionals.¹²³
- *International Journal of Medical Informatics* is an international monthly journal that covers information systems, decision support, computerized educational programs and articles aimed at healthcare organizations. In addition to standard articles, they publish short technical articles and reviews.¹²⁴

- *Journal of Biomedical Informatics* was formally known as *Computers and Biomedical Research*. Its editor is Dr. Ted Shortliffe and the emphasis of this bimonthly journal is bioinformatics.¹²⁵
- *Journal of AHIMA* is published 11 months of the year for its members to stay current in health information management-related issues.¹²⁶
- *Computers, Informatics, Nursing (CIN)* is a bimonthly print journal targeting the nursing professional. Also offers PDA downloads, RSS feeds and a newsletter.¹²⁷

E-journals

- *BMC Medical Informatics and Decision Making* is an open-access free online journal publishing peer-reviewed research articles. This journal is part of BioMed Central, an online publisher of 188 online free full text journals. Because it is an open-access model it allows for much more rapid review and publication, a plus for informatics journals.¹²⁸
- *The Open Medical Informatics Journal* is another open-access free online journal that publishes health informatics research articles and reviews. Bentham Science publishes 89 online and print journals as well as 200 online open-access journals. An abstract is available online and the full text pdf copy is downloadable.¹²⁹
- *Journal of Medical Internet Research (JMIR)* is an independent open-access online journal that publishes articles related to medicine and the internet. The articles are free to read in an html format but there is a cost to download articles in a pdf format or to become a member.¹³⁰
- *Electronic Journal of Health Informatics (eJHI)* is an Australian-based international open access electronic journal that offers open access (no fee) to both authors and readers.¹³¹
- *Applied Clinical Informatics* is the fee-based e-journal for the International Medical Informatics Association (IMIA) and the

Association of Medical Directors of Information Systems (AMDIS). Its first issue appeared in early 2010.¹³²

- *Perspectives in Health Information Management* is the open-access research peer-reviewed e-journal for AHIMA, published four times a year.¹³³
- *Online Journal of Public Health Informatics* is an open source general interest peer reviewed e-journal published three times annually.¹³⁴

Informatics-Related E-newsletters

- *iHealthBeat* is a free daily e-mail newsletter on health information technology published as a courtesy by the California Healthcare Foundation. It is also available through RSS feeds, Twitter and they offer frequent podcasts.¹³⁵
- *HealthCareITNews* is available as a daily online, RSS feed or print journal. It is published in partnership with HIMSS and reviews broad topics in HIT. They also publish the online e-journals *NHINWatch*, *MobileHealthWatch* and *Health IT Blog*.¹⁰⁵
- *eHealth SmartBrief* is a free newsletter e-mailed three times weekly. In addition to broad coverage of HIT, they offer RSS feeds, blogs, reader polls and job postings.¹³⁶
- *Health Data Management* offers a free daily e-newsletter, in addition to their comprehensive web site. The web site offers 20 channels or categories of IT information, webinars, whitepapers, podcasts and RSS feeds.¹³⁷

Online Resource Sites

- *InformaticsEducation.org* resource center was created to augment this textbook. The site augments this book with valuable web links organized in a similar manner as the book chapters. It also includes links to excellent informatics newsletters and journals.¹³⁸
- *Agency for Healthcare Research and Quality Knowledge Library* is another

excellent resource with over 6,000 articles and other resources that discuss health information technology related issues.¹³⁹

- *HIMSS Health IT Body of Knowledge* is a new site to introduce readers to more than 25 topic categories. Articles, tools and guidelines are offered by HIMSS and other resources.¹⁴⁰
- *HealthIT.gov* is the official web site for the Office of the National Coordinator for Health Information Technology. The site provides valuable information about HIT initiatives and progress throughout the United States.⁵⁶
- *AHIMA HIM Body of Knowledge™* is a searchable database of HIM-oriented material from AHIMA and governmental sources.⁶⁸
- *Family Medicine Digital Resources Library* was created by Dr. Tom Agresta and supported by the Society of Teachers of Family Medicine to promote Informatics education of Family Medicine physicians. In early 2010 they posted 14 presentations that are available to the public.¹⁴¹
- *OpenClinical* is a not-for-profit organization that supports advanced knowledge management in the following areas: background, research clinical, commercial and public. The site includes resources that are pertinent to many chapters in this textbook.¹⁴²
- *Health Informatics Forum* is an international forum and blog. In addition the site offers the massive open online course (MOOC) on health informatics free of charge. This is the same course administered by many community colleges under the HITECH Act funding.⁹⁶

Informatics Blogs

- *HealthIT Buzz Blog* provides HIT updates from the HHS Office of the National Coordinator for Health Information Technology (ONC).¹⁴³
- *Informatics Professor Blog* and provides the insights of Dr. William Hersh, Professor and Chair of the Department of Medical

Informatics & Clinical Epidemiology, Oregon Health & Science University.¹⁴⁴ Additional health informatics resources are posted on his website.¹⁴⁵

- The *Health Care Blog* is hosted by Matthew Holt and considered to be “a free-wheeling discussion of the latest healthcare developments” to include health information technology.¹⁴⁶
- *E-CareManagement* focuses on chronic disease management, technology, strategy, issues and trends. Content is posted by Vince Kuraitis, a HIT consultant for Better Health Technologies.¹⁴⁷
- *Health Informatics Forum*, administered by Dr. Chris Paton, is an international social network for health informatics professionals and students with extensive web links.⁹⁶
- *Biological Informatics* was created by Marcus Zillman to compile multiple biomedical informatics sites (100+) into one, as well as a blog.¹⁴⁸
- *HealthTectopia* compiles the top 50 health informatics blogs. It is subdivided into General Health Informatics, Anatomy & Physiology, Information Science and Information Technology, Computer Science, Statistics and Radiology and Medical Imaging.¹⁴⁹
- *Biomedexperts* is a free social network for biomedical researchers. They have created groups based on what articles have been published by the scientists involved. The claim to have profiles on 1.8 million biomedical researchers from 190 countries. Profiles were generated from the last 10 years of PubMed. In this manner research networks can be created.¹⁵⁰
- *EMR & HIPAA Blog* hosted by John Lynn covers EHRs, HIPAA and HIT issues.¹⁵¹

Future Trends

Given the relative newness of health informatics it is not easy to predict the future but some

trends seem worth stressing. Many of these points are discussed in more detail in other chapters.

Regardless of the speed of HIT adoption in medicine, the technology itself will continue to evolve rapidly. Many disruptive technologies such as tablets will present outstanding opportunities. This will require uniquely well trained individuals who understand the technology and have the clinical experience to know how it can be applied successfully in the field of medicine.

Meaningful Use requirements will continue to evolve (stages 2 and 3) and the bar will be slowly raised. More research is needed to determine what additions are evidence based, worthwhile and will actually impact clinical outcomes.

New healthcare delivery models such as accountable care organizations will be an experiment well worth watching. If they demonstrate cost savings that are strongly supported by HIT we can expect increased adoption.

We anticipate more patient centric medical care and associated technologies; for example, more medical apps for smartphones and personalized genetic profiles.

Mobile technologies will continue to be an important medical platform for patients and clinicians.

Expect more artificial intelligence in medicine (AIM) to retrospectively and prospectively interpret medical data. As AI improves we can expect real time predictive analytics, alerts and clinical decision support. Of note, healthcare organizations such as WellPoint and Memorial Sloan-Kettering Cancer Center are using IBM's Watson to analyze complex medical datasets. Watson will be in the cloud in 2014 with open APIs so developers can create new data applications for multiple industries.¹⁵²

Key Points

- Health informatics focuses on the science of information, as applied to healthcare and biomedicine
- Health information technology (HIT) holds promise for improving healthcare quality, reducing costs and expediting the exchange of information
- The HITECH Act programs have been a major driver of HIT in the United States
- Barriers to widespread adoption of HIT include: time, cost, privacy, change in workflow, legal, behavioral barriers and lack of high quality studies
- Many new degree and certificate programs are available in health informatics
- A variety of health informatics resources are available for a wide audience
- Interoperability and health information exchange is a major priority of the federal government but is challenged by sustainable issues

Conclusion

Health informatics is a new, exciting and evolving field. New specialties and careers are now possible. In spite of its importance and popularity, significant obstacles remain. Health information technology has the potential to improve medical quality, patient safety, educational resources and patient - physician communication, while decreasing cost. Although technology holds great promise, it is not the solution for every problem facing medicine today. As noted by Dr. Safran of the American Medical Informatics Association “technology is not the destination, it is the transportation.”⁷⁹ We must continue to focus on improved patient care as the single most important goal of this new field.

The effects of the multiple programs supported by the HITECH and Affordable Care Acts will likely be both transformational and challenging for the average practitioner.

Research in health informatics is being published at an increasing rate so hopefully new approaches and tools will be evaluated more often and more objectively. Better studies are needed to demonstrate the effects of health information technology on actual patient outcomes and return on investment, rather than observational studies and studies based solely on surveys and expert opinion.

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Chapter 2

Healthcare Data, Information, and Knowledge

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Learning Objectives

After reading this chapter the reader should be able to:

- Define Data, Information, and Knowledge
- Understand how vocabularies convert data to information
- Describe methods that convert information to knowledge
- Distinguish informatics from other computational disciplines, particularly computer science
- Describe the differences between data-centric and information-centric technology

“...current efforts aimed at the nationwide deployment of health care IT will not be sufficient to achieve the vision of 21st century health care, and may even set back the cause if these efforts continue wholly without change from their present course.”¹

Introduction

In this chapter, a framework for understanding informatics is presented. In chapter 1, the definitions of data, information, and knowledge were presented and now this chapter will build upon these definitions to answer fundamental questions regarding health informatics. What makes informatics different from other computational disciplines? Why is informatics difficult? Why do some health IT projects fail? In chapter 1, the fundamental mismatch between available technology (i.e., traditional computers) and problems faced by

In chapter 1, the fundamental mismatch between available technology (i.e., traditional computers) and problems faced by informaticians was mentioned. In this chapter these ideas were expanded to understand why many health IT (HIT) projects fail. To help organizations appropriately apply HIT, informaticians must understand the limitations of HIT as well as the potential of HIT to improve health.

To illustrate several points, this chapter will begin with a real world example of informational challenges.

Case Study: The Story of E-patient Dave

In January 2007, Dave deBronkart was diagnosed with a kidney cancer that had spread to both lungs, bone and muscles. His prognosis was grim. He was treated at Beth Israel Deaconess Medical Center in Boston with a combination of surgery and enrolled in a clinical trial of High Dosage Interleukin-2 (HDIL-2) therapy. That combination did the trick and by July 2007, it was clear that Dave had beaten the cancer. He is now a blogger and an advocate and activist for patient empowerment.

In March 2009, Dave decided to copy his medical record from the Beth Israel Deaconess EHR to Google Health, a personally-controlled health record or PHR. He was motivated by a desire to contribute to a collection of clinical data that could be used for research. Beth Israel Deaconess had worked with Google to create an interface (or conduit) between their medical record and Google Health. Thus, copying the data was automated. Dave clicked all of the options to copy his complete record and pushed the big red button. The data flowed smoothly between computers and the copy process completed in only few moments.

What happened next vividly illustrated the difference between data and information. Multiple urgent warnings immediately appeared (Figure 2.1). Dave was taking hydrochlorothiazide, a common blood pressure medication, but had not had a low potassium level since he had been hospitalized nearly two years earlier.

Worse, the new record contained a long list of deadly diseases (Figure 2.2). Everything that Dave had ever had was transmitted, but with no dates attached. When the dates were attached, they were wrong. Worse, Dave had never had some of the conditions listed in the new record. He was understandably distressed to learn that he had an aortic aneurysm, a potentially deadly expansion of the aorta, the largest artery in the human body.

Why did this happen? In part, it was because the system transmitted billing codes, rather than doctors' diagnoses. Thus, if a doctor ordered a computed tomography (CT) scan, perhaps to track the size of a tumor, but did not put a reason for the test, a clerk may have added a billing code to ensure proper billing (e.g., rule out aortic aneurysm). This billing code became permanently associated with the record.

After Dave described what happened in his online blog² (<http://epatientdave.com/>), the story was picked up by a number of newspapers including the front page of the Boston Globe.³ It also brought international attention to the problem of meaning. It became very clear that transmitting data from system to system is not enough to ensure a usable result. To be useful, systems must not mangle the meaning as they input, store, manipulate and transmit information. Unfortunately, as this story illustrates, even when standard codes are stored electronically, their meaning may not be clear.

Figure 2.1: Urgent warning in e-patient Dave’s record

 Requires immediate attention
  Discuss with your doctor soon

 **Hydrochlorothiazide and Low Amount of Potassium in the Blood**

Medications given to people who have certain conditions can lead to an increase in side effects and/or worsening of the condition. [Hydrochlorothiazide Oral](#) generally should not be given to people with [Hypokalemia](#). This health profile includes this condition.

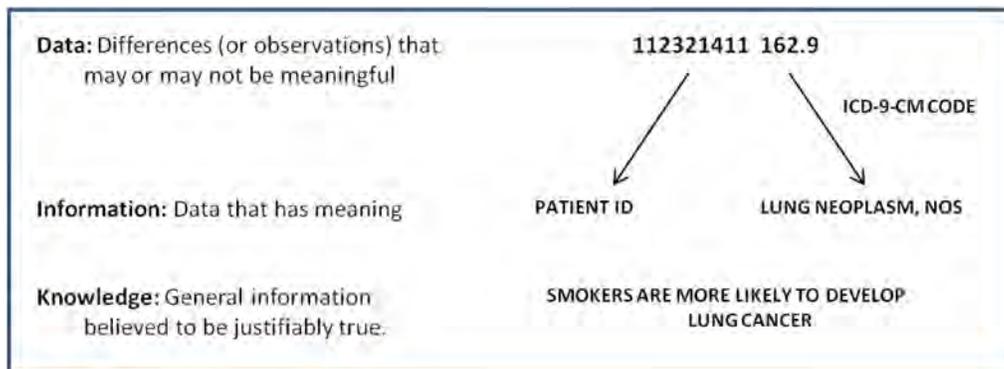
Figure 2.2: e-patient Dave’s conditions as reflected in the newly-created personal health record (PHR)

[Profile summary](#) 

[Conditions](#)

- Acidosis [More info >](#)
- Anxiety Disorder [More info >](#)
- Aortic Aneurysm
- Arthroplasty – Hip, Total Replacement
- Bone Disease
- CANCER
- Cancer Metastasis to Bone
- CHEST MASS
- Chronic Lung Disease
- Depressed Mood [More info >](#)
- DEPRESSION [More info >](#)
- Diarrhea
- Elevated Blood Pressure [More info >](#)
- Hair Follicle Inflammation with Abscess in Sweat Gland Areas
- HEALTH MAINTENANCE
- HYDRADENITIS
- HYPERTENSION [More info >](#)
- Inflammation of the Large Intestine [More info >](#)
- Intestinal Parasitic Infection

Figure 2.3: Data, information and knowledge



Definitions and Concepts

Data, Information and Knowledge

In chapter 1, data, information and knowledge (see Figure 1.1) were defined.^{4,5} Recall that **data** are observations reflecting differences in the world (e.g., “162.9”). Note that “data” is the plural of “datum.” Thus, “data are” is grammatically correct; “data is” is not correct. **Information** is meaningful data or facts from which conclusions can be drawn (e.g., ICD-9-CM code 162.9 = “Lung neoplasm, Not Otherwise Specified”). **Knowledge** is information that is justifiably believed to be true (e.g., “Smokers are more likely to develop lung cancer”). This relationship is shown in Figure 2.3 and readers will be referred to this diagram later in the chapter.

Data

To understand the relationship between data, information and knowledge in health informatics, readers must understand the relationship between what happens in a computer and the real world. Computers do not represent meaning. They input, store, process and output zero (off) and one (on). Each zero or one is known as a **bit**. A series of eight bits is called a **byte**. Note that these bits and bytes have no intrinsic meaning. They can represent anything or nothing at all (e.g., random sequences of zeroes and ones).

Bits within computers are aggregated into a variety of **data types**. Some of the most common data types are listed below.

- *Integers* such as 32767, 15 and -20
- *Floating point numbers* (or floats) such as 3.14159, -12.014, and 14.01; the floating point refers to the decimal point
- *Characters* “a,” and “z”
- (*Character*) *Strings* such as “hello” or “ball”

Note that these data types do not define meaning. It does not matter whether 3.14159 is a random number or the ratio of the circumference to the diameter of a circle (known as Pi or π).

Data can be aggregated into a variety of file formats. These file formats specify the way that data are organized within the file. For example, the file header may contain the colors used in an image file (known as the palette) and the compression method used to minimize storage requirements. Common or standardized file formats allow sharing of files between computers and between applications. For example, as long as your digital camera stores photos as JPG files, you can use any program that can read JPG files to view your photos.

- Image files such as JPG, GIF and PNG.
- Text files
- Sound files such as WAV and MP3

- Video files such as MPG

Again, it is important to recognize that neither data types nor file formats define the meaning of the data, except for the purpose of storing or display on a computer. For example, photographs of balloons and microscopes can be stored in JPG files. Nothing about the file format helps us recognize the subject of the photograph.

Informatics vs. Information Technology and Computer Science

Data are largely the domain of information technology (IT) professionals and computer scientists. As computers become increasingly important in biomedicine, biomedical researchers are starting to collaborate with computer scientists. IT professionals and computer scientists concentrate on technology, including computing systems composed of hardware and software as well as the algorithms implemented in such systems. For example, computer scientists develop algorithms to search or sort data more efficiently. Note that *what* is being sorted or searched is largely irrelevant. In other words, the meaning of the data is of secondary importance. It does not matter whether the strings that are being sorting represent names, email addresses, weights, names of cars or heights of buildings.

Though they may be motivated by specific applications, computer scientists typically develop general-purpose approaches to classes of problems that involve computation. For example, a computer scientist may design a memory architecture that efficiently stores and retrieves large data sets. The computer science contribution is the development of the better memory architecture for large data sets; while

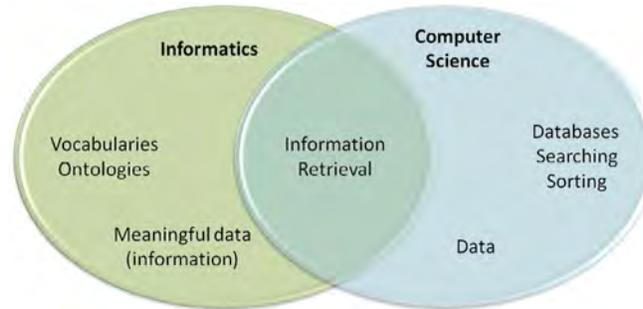
the memory architecture is not a direct improvement of an EHR per se, it is nonetheless critical to its advancement.

Information and knowledge, on the other hand, are addressed by informatics. To an informatician, computers are tools for manipulating information. Indeed, there are many other useful information tools, such as pen, paper and reminder cards. There are significant advantages to manipulating digitized data, including the ability to display the same data in a variety of ways and to communicate with remote collaborators. From an informatics perspective however, one should choose the optimal tool for the information task – often, but not always, the best tool for the task is computer-based.^{4,6}

There are areas that combine computer science and informatics. For example, information retrieval draws on both disciplines. Information retrieval is “finding material (usually documents) of an unstructured nature (usually text) that satisfies an information need by retrieving documents from large collections (usually stored on computers).⁷”

Note that information retrieval is concerned with retrieval of information, not data. For example, finding documents that describe the relationship between aspirin and heart attack (myocardial infarction) is an example of an information retrieval task. The central problem is identifying documents that contain certain meaning. In contrast, retrieval of documents (or records) that contain the string “aspirin” is a database problem (an area of computer science). Importantly, informatics and computer science differ in the problems that they address (see Figure 2.4). It should not be implied that computer science is easier or less intellectually challenging compared to informatics.

Figure 2.4: Relationship between informatics and computer science



Converting Data to Information to Knowledge

We live in the real world that contains physical objects (e.g., aspirin tablet), people (e.g., John Smith), things that can be done (e.g., John Smith took an aspirin tablet) and other concepts. In order to do useful computation, one has to segregate some part of the physical world and create a **conceptual model**. The conceptual model contains only the parts of the physical world that are relevant to the computation. Importantly, everything that is not in the conceptual model is excluded from the computation and assumed to be irrelevant.

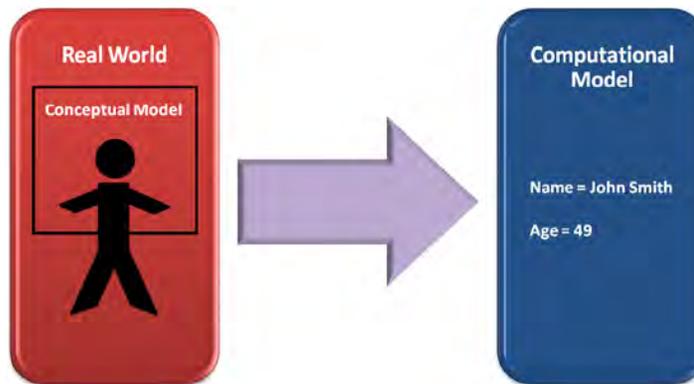
The conceptual model is used to design and implement a **computational model**. In Figure 2.5, the real world contains a person, John Smith. There are many other things in the real world including other people, physical objects, etc. There are many things that we can say about this person, they have a name, height, weight, parents, thoughts, feelings, etc. The conceptual model defines what is relevant; everything that is not in the conceptual model is therefore assumed to be not relevant. In our example (Figure 2.5), name and age are chosen. Thus, the height, weight and all other things about John Smith are assumed to be irrelevant. For example, given our conceptual and computational models, one would not be able to answer questions about height. Next a **representation** must be defined. (Figure 2.5). A simple example is whole numbers. A

representation has three components. The **represented world** is the information that one wants to represent (e.g., whole numbers: 0, 1, 2, 3, ...). The **representing world** contains the data that represent the information (e.g., symbols “0”, “1”, “2”, “3”, ...). There must be a **mapping** between the represented world and the representing world. In our example, the mapping is the correspondence between whole numbers and symbols that are used to represent them. Note that the data are, in and of themselves, meaningless.

To do anything useful, one must also have rules regarding the mapping (i.e., relationship between the symbols and the real world) what can be done with the symbols. In our example, these rules are the rules governing the manipulation of whole numbers systems (e.g., addition, multiplication, division, etc.).

The data part of a representational system may also be called its “form”, in which case meaning is called its’ “content.” The word “form” is significant because of its relationship to **formal methods**, which are methods that manipulate data using systematic rules that depend only on form, not content (meaning). These formal methods, including computer programs, depend only on systematic manipulation of data without regard for meaning. Thus, only a human can ensure that the input and output of a formal method (e.g., computer program) correctly capture and preserve meaning.

Figure 2.5: Computational framework



In spite of the fact that formal methods manipulate only form (or data), not meaning, they can be very useful. As long as the formal method does not violate the rules of the physical world, one can apply the method to solve problems in the real world. For example, a whole number representation can be used to determine how many 8-person boats are needed to transport 256 people across the Nile river (i.e., 256 people divided by 8 people/boat = 32 boats).

However, one must be careful because the formal method (division) can easily violate the rules of the real world. For example, suppose that 250 people are in Cairo and six people are in Khartoum (1,000 miles away) and they must cross at the same time. In this case, 32 boats is the wrong answer since 32 boats are needed in Cairo and another boat is needed at Khartoum. In this example, the real world includes location (Cairo vs. Khartoum), but the conceptual model includes only the number of people; location and distance are ignored. Thus, the computational model (based on the conceptual model) gives an inappropriate answer. It can't be said that the answer is "wrong." Clearly $256/8=32$; the computer did not malfunction. However, in the case where location is important, the numerical answer is not useful.

The distinction between the real (represented) world, the conceptual model (representing world) and the computational model (that which the computer manipulates) is fundamental to informatics.

When the real world, the conceptual model and the computational model match, it is possible to get useful answers from the computer. When they do not match, such as the case when a critical constraint was left out of the conceptual model, the answers obtained from the computer are not useful.

This is what happened in the case of e-patient Dave. Formal methods (computer programs) were developed that linked fields in the Beth Israel Deaconess EHR to fields in Google Health. Data from one were dutifully transferred to the other. However, the meaning (i.e., that the data being transmitted were billing codes, not actual diagnoses) was lost. Further, there was a flaw in the conceptual model, the computational model or both models that prevented dates from being maintained correctly; perhaps because the dates reflected billing dates, rather than the date when a diagnosis was made.

Data to Information

The next step is to convert data into information. Consider the example in Figure 2.1. "162.9" is, in and of itself, meaningless (i.e., it is a data item or datum). However, ICD-9-CM gives us a way to interpret 162.9 as "Lung neoplasm, not otherwise specified." Thus, the vocabulary ICD-9-CM turns the datum into a unit of information.

The computer still stores only data, not information. Thus, only a human can determine whether the meaning is preserved or not. In the

case of e-patient Dave, all of the computer systems functioned as they were designed. There were not errors, but upon human review, the meaning was found have been mangled.

However, associating ICD-9-CM 162.9 with a patient record labels the patient record (and thus the patient) as having “Lung neoplasm, not otherwise specified.” Of course, one could design systems that turn data into information without using vocabularies. For example, patient records could be designed that include a bit for each possible diagnosis. Thus, setting the bit corresponding to lung cancer to 1 would be **semantically equivalent** to associating ICD-9-CM 162.9 with the patient’s record. Semantically equivalent is simply another way of stating that the meanings are the same.

Transmission of information, often referred to as **interoperability**, requires consistency of interpretation. The source system (Beth Israel Deaconess EHR for e-patient Dave) and the receiving system (Google Health for e-patient Dave) must share a common way of transforming data into information. However, this is not sufficient. Note that in the case of e-patient Dave, both systems used ICD codes. However, associated information such as dates and most importantly the context: billing code vs. actual diagnosis, was not shared correctly.

Information to Knowledge

Multiple methods have been developed to extract knowledge from information. Note that it would not make sense to directly convert data (which by definition are not meaningful) to knowledge (justified, true belief). Thus, information is required to produce knowledge. Transformation of information (meaningful data) into knowledge (justified, true belief) is a core goal of science.

In the clinical world, most available knowledge is best described as justified (i.e., evidence exists that it is true), rather than proven fact (i.e., it must be true). This is an important distinction from traditional hard sciences such as physics or mathematics.

In this chapter, there is a focus on informatics techniques that are designed to convert clinical information into knowledge. Thus, clinical data warehouses (CDWs) are described that are often the basis for attempts to turn clinical information into knowledge, as well as methods for transforming information into knowledge.

Clinical research informatics is becoming increasingly recognized as a distinct sub-field within informatics (see separate chapter on e-research for further information). Clinical research informaticians leverage informatics to enable and transform clinical research.^{8,9} By “enable,” what is meant is helping researchers accomplish their goals faster and cheaper than is possible using existing methods. For example, searching electronic clinical data is potentially faster than manually reviewing paper clinical charts. “Transform” means developing methods that allow researchers to do things that they cannot do using existing methods. For example, it is not currently possible to use aggregated clinical data to help people make decisions. One cannot ask, in real-time or near real-time, “what happened to patients like me, at your institution, who chose treatment A vs. treatment B?” Although the information required to answer this question is found in the clinical records, a manual chart review cannot be performed in real time. However, before the benefits of computerized information can be realized, that meaning must be preserved.

Clinical Data Warehouses (CDWs)

The enterprise data warehouse was introduced in chapter 1 (see Figure 1.3). In this chapter, the focus will be on clinical, rather than administrative data, hence the reference to a **clinical data warehouse** or **CDW**.

Increasingly, clinical data are collected via electronic health records (EHRs). Clinical records within EHRs are composed of both **structured data** and **unstructured or (free text)**. Structured data may include billing codes, lab results (e.g., Sodium = 140 mg/dl),

problem lists (e.g., Problem #1 = ICD-9-CM 162.9 = “Lung Neoplasm, Not Otherwise Specified”), medication lists, etc. In contrast, free text is similar to this chapter – simply human language such as English, called **natural language**. Clinical notes are often dictated and are represented in records as free text.

From an informatics perspective, structured data is much easier to manage – it is computationally tractable. Ideally, but not always, these data are encoded using a standard such as ICD-9-CM (see chapter on data standards). Thus, retrieving patients with a particular problem is, theoretically, simply a matter of identifying all records that are tagged with a particular code. As one will see later in this chapter, in practice this does not always work. Further, nuances (e.g., similarity to a previous case) or vague concepts (e.g., light-colored lesion, tall man) may be difficult to convey with a “one size fits all” vocabulary.

Similarly, computerized physician order entry (see chapter on electronic health records) can be difficult to implement. If designers allow only structured data, they must anticipate what will be ordered and make choices that constrain the possible inputs. For example, they may choose to use a particular vocabulary for medication orders, allow specific dosing frequencies, etc. Inevitably, however, physicians will want to write unusual orders that will be difficult to accommodate.

Free text, on the other hand, has the advantage of being able to express anything that can be expressed using natural language. On the other hand, it is difficult for computers to process. Indeed, the field of **natural language**

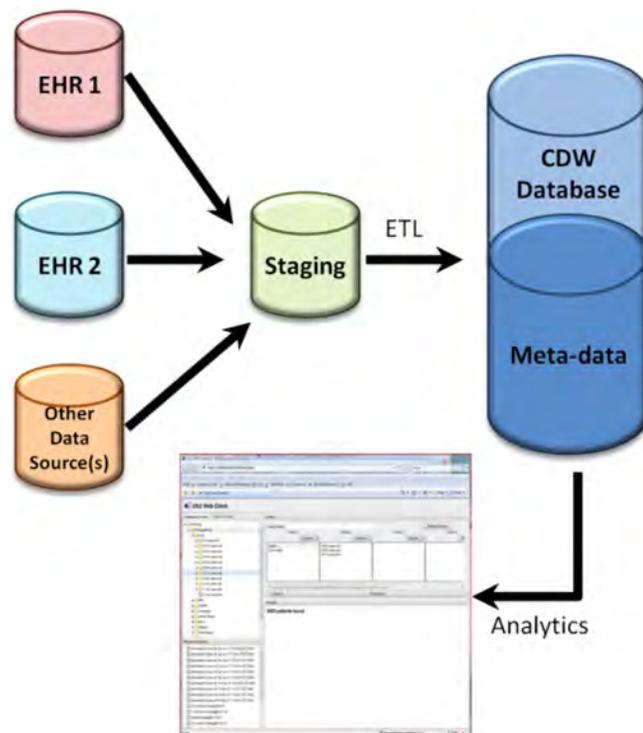
processing (NLP) is an active area of research in both computer science and informatics. Within clinical records, the free text notes are critically important. Indeed, as in the case of e-patient Dave, structured data (such as billing codes) may not be clinically accurate. This is not necessarily anyone’s fault. Billing codes were assigned for billing, not for clinical care. Thus, it should not be surprising that using billing codes for a different purpose does not yield the desired result. Over 20 years ago, van der Lei warned:

...under the assumption that laws of medical informatics exist, I would like to nominate the first law: Data shall be used only for the purpose for which they were collected. This law has a collateral: If no purpose was defined prior to the collection of the data, then the data should not be used.¹⁰

To make sense of clinical records, both structured data and free text must be leveraged. This remains an active area of informatics research.

A clinical data warehouse is a shared database that collects, integrates and stores clinical data from a variety of sources including electronic health records, radiology and other information systems. EHRs are designed to support real-time updating and retrieval of individual data (e.g., Joan Smith’s age). The general process is shown in Figure 2.6. Data from multiple sources including one or more EHRs are copied into a staging database, cleaned and loaded into a common database where they are associated with **meta-data**. Meta-data are data that describe other data. For example, the notation that a particular data item is an ICD-9-CM term represents meta-data.

Figure 2.6: Overview of clinical data warehousing (ETL = Extract, transform and load)



Once loaded into a CDW, a variety of analytics can be applied and the results presented to the user via a user interface. Examples of simple analytics include summary statistics such as counts, means, medians and standard deviations. More sophisticated analytics include associations (e.g., does A co-occur with B) and similarity determinations (e.g., is A similar to B).

In contrast to EHRs, CDWs are designed to support queries about groups (e.g., average age of patients with breast cancer). Although in principle an EHR may contain the same data as a CDW, databases that support EHRs are designed for efficient real-time updating and retrieval of individual data. Thus, a query across patients rather than regarding an individual may take much more time. Further, since EHRs support patient care, queries about groups may be restricted to ensure adequate performance for clinicians. Another important distinction is that CDWs are usually not updated in real-time. Although update schedules differ, daily or

weekly updates of the institutional CDW are typical.

CDWs are rapidly becoming critical resources. They enable organizations to monitor quality by allowing users to query for specific quality measures (see chapter on quality improvement strategies) in specific patient populations (e.g., retrieve all women who are 40 years old or older who have not had a mammogram in the past year). Similarly, clinical and translational researchers use CDWs to identify trends (e.g., did screening mammograms detect breast cancer at an early stage?).¹¹ Comparative effectiveness research (CER) or, more broadly, practice-based research, are increasingly important fields that attempt to link research with clinical practice using CDWs. They complement traditional clinical trials that ask very focused questions. For example, a clinical trial might be designed to compare treatment A vs. treatment B in particular population of patients. In contrast, CER practitioners ask what actually happened in practice. For

example, treatment A has been found to be more effective than treatment B in a clinical trial. What actually happened in practice?

Hospital infection control specialists use CDWs to track pathogens within hospitals. Public health agencies traditionally rely on reporting to conduct surveillance for natural or man-made illnesses (see chapter on public health informatics). However, reporting introduces a delay. Accessing aggregated data at the institutional level can be done much faster.

One of the most popular clinical data warehousing platforms is the product of the Informatics for Integrating Biology and the Bedside (i2b2) project based at Harvard Medical School.¹² The open source and very modular i2b2 platform was designed to enable the reuse of clinical data for research, but can also be very useful for non-research tasks such as quality monitoring. As of December 2011, i2b2 has been implemented at 72 academic institutions (60 in the United States alone).¹³

i2b2 relies on a star schema composed of facts and dimensions (Figure 2.7.). *Facts* are pieces of information that are queried by users (e.g., diagnoses, demographics, laboratory results, etc.) and *dimensions* describe the facts. Note that the data model is organized around facts, rather than individual patients, as would be the case for an EHR. Another benefit of organizing the CDW around observations is that data from

multiple sources (e.g., different hospitals) can be aggregated into a common data model – new observations are simply added to the table of facts. Meta-data, such as the vocabulary that was used for encoding the fact, is an important component. Thus, the i2b2 data model by itself is not sufficient to ensure interoperability.

It provides a very usable interface to an institutional CDW that can be used by non-informaticians (see Figure 2.8). Users click and drag concepts from the ontology window (upper left) into the query panes (upper right) and obtain results, such as the number of patients fulfilling certain criteria, in lower right. In addition to the basic i2b2 package, specialized modules have been developed for NLP and other tasks.

In short, clinical data are collected via EHRs and archived in CDWs. As EHRs are becoming increasingly common, CDWs are becoming increasingly important. However, to realize the potential of CDWs to improve health, we must do more than archive data. One must turn these data into information and knowledge. Users must be able to “make sense” of clinical data; to make clinical data meaningful (data → information) and then learn from aggregated clinical data (information → knowledge). In practice, many of the benefits of EHRs (see chapter 3) actually require a CDW. The transformation of data into information and knowledge is a core concern of informaticians.

Figure 2.7: i2b2 data model 12

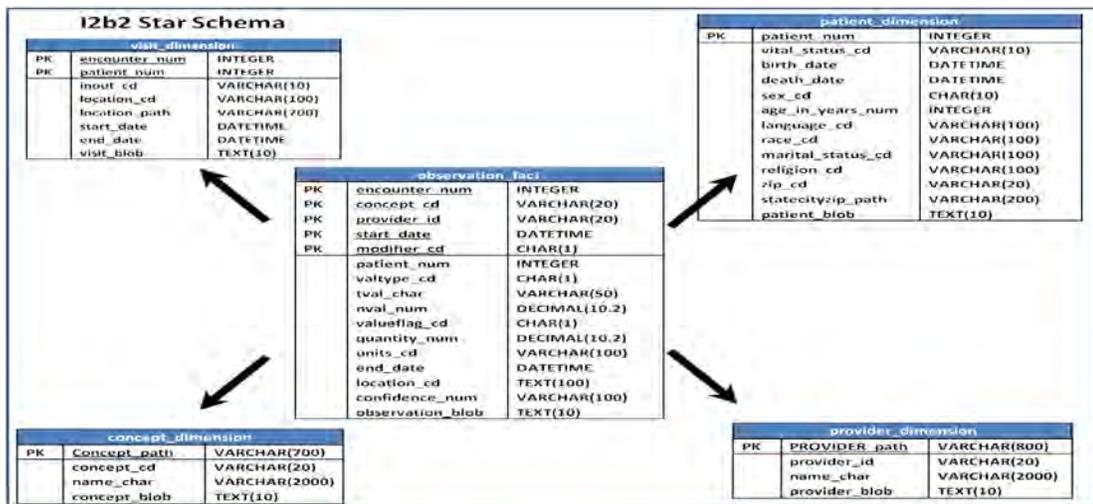
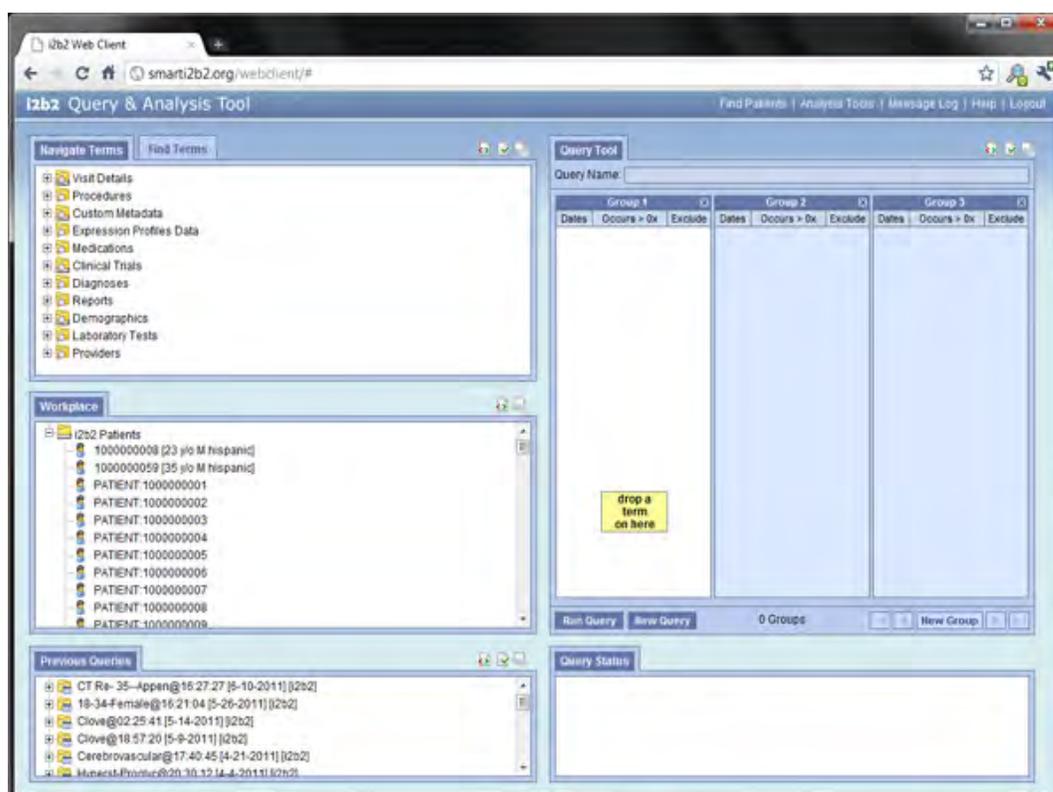


Figure 2.8: i2b2 screenshot



Use of Aggregated Clinical Data

To make use of aggregated clinical information, we must be able to recognize records that belong to patients with specific conditions. For example, it is necessary to identify records belonging to patients who have been diagnosed with breast cancer. A simple answer is to rely on billing codes, one of the most common forms of structured data in clinical records. However, as we saw in the case of e-patient Dave, one cannot simply rely on billing codes. Sometimes other structured data are available, problem lists are particularly useful. Unfortunately, problem lists are often out of date or incomplete.¹⁴ Thus, a great deal of interest has focused on extracting information from free text clinical notes.

Concept extraction refers to the problem of identifying concepts within unstructured data, such as discharge summaries or pathology reports. Usually, these concepts are mapped to a controlled vocabulary, such as ICD-9-CM, SNOMED-CT and others. While this may on the surface appear to be a trivial problem, there are

many ways in which a single concept might be expressed (for example high blood pressure and hypertension), and it is often the case that a single word or acronym may have multiple medically relevant meanings (for example DM may refer to Diabetes Mellitus or Depressed Mood) that cannot be teased apart without considering contextual cues. Consequently, much effort has been devoted toward the development of systems that aim to map between terms or phrases and controlled vocabularies with accuracy.

Multiple biomedical concept extraction systems exist including MetaMap¹⁵ and cTAKES.¹⁷ Broad-purpose medical language processing systems such as MedLEE,¹⁶ have also been adapted to this end. These systems can be tuned to perform well, but require re-tuning when applied to different corpora (e.g., changing institutions) or clinical problems (e.g., breast cancer vs. diabetes mellitus). Table 2.1 summarizes the published performance of these three concept extraction systems; note that the

results are not directly comparable to each other due to different tasks and gold standards (a common limitation).^{18,19}

Classification refers to the problem of categorizing data into two or more categories. For example, one might want to classify medical records as belonging to patients who have vs. have not been diagnosed with breast cancer. A variety of classification algorithms have been developed, most of which rely on statistical methods. These classification algorithms generally depend on the selection of a set of features, such as the presence or absence of particular terms, concepts or phrases. Once these features have been selected, either manually or through automated methods, medical records can be categorized on the basis of these features. A commonly utilized approach is supervised machine learning, in which an algorithm is used to learn a representation of the features that characterize annotated positive (patients with breast cancer) and negative (patients without breast cancer) cases. New cases can then be categorized automatically based on the extent to which their features are characteristic of previously encountered positive or negative examples.

What Makes Informatics Difficult?

Why are some domains highly computerized, while health care and biomedicine resist

computerization? Consider the banking system.⁴ It is clearly very complex and involves a vast quantities data and meaning. Why do all banks use computers? In contrast to health care, there are no arguments regarding the suitability of computers to track accounts. We argue that in the case of banking, there is a very narrow “semantic gap” between data and information. In other words, the correspondence between the data (numbers) and information (account balances) is very direct. As one manipulates the computational model, the meaning of these manipulations follows easily.

Consider the differences between banking data and health care data, such as an account at a bank versus a patient (Table 2.2). One difference is that concepts relevant to health are relatively poorly defined compared to banking concepts. The symbols require significant background knowledge to interpret properly. For example, there are multiple ways that a patient can be “sick” including derangements in vital signs (e.g., extremely high or low blood pressure), prognosis associated with a diagnosis (e.g., any patient with an acute aortic dissection is sick), or other factors. Two clinicians when asked to describe a “sick” individual may legitimately focus on different facts. In contrast, a bank account balance (e.g., \$1058.93) is relatively objective and is captured by the symbols. Thus, data-manipulating machines (IT) are much better suited to manipulating bank accounts than clinical descriptors.

Table 2.1: Published performance of three notable biomedical systems

Concept Extractor	Gold Standard	Precision	Recall	F-score (F_1)
cTAKES ¹⁷	Mayo clinic	0.80	0.65	0.72
MetaMap ²⁰	NLM 500 articles	0.32	0.53	0.40
MEDLEE ²¹	Proprietary	0.86	0.77	0.81

Table 2.2: Comparison of health and banking data

	Banking data	Health data
Concepts and descriptions	Precise <i>Example:</i> Account 123 balance = \$15.98	General, subjective <i>Example:</i> sick patient
Actions	Usually (not always) reversible <i>Example:</i> Move money A → B	Often not easily reversible <i>Example:</i> Give a medication Perform procedure
Context	Precise, constant <i>Example:</i> US \$	Vague, variable <i>Example:</i> Normal lab values differ by lab
User autonomy	Well-defined and constrained <i>Example:</i> What I can do with my checking account = what you can do	Variable and dependent on circumstance <i>Example:</i> Clinical privileges depend on training, change over time, depend on circumstances
Users	Clerical staff	Varied, including highly trained professionals
Time sensitivity	Few true emergencies (seconds)	Many time sensitive tasks, highly variable time sensitivity depending on context
Workflow	Well-defined	Highly variable, implicit

In general, if the problem relates strictly to form (data), or is easily reduced to a form-based problem, then computers can easily be applied to solve the problem. Retrieving all abstracts in PubMed containing the string “breast cancer” is a question related to data and is easily reducible to a form-based data query. On the other hand, retrieving all documents that report a positive correlation between beta blockers (a class of medications) and weight gain is an information retrieval question that depends on the meaning of the query and the meaning of the text in the documents. The latter question is not easily reducible to form and is therefore much harder to automate.

Concepts definable with necessary and sufficient conditions are usually relatively easy to reduce to form, and thereby permit some limited automated processing of meaning. However, concepts without necessary and sufficient

conditions (e.g., recognizing a sick patient, or defining pain) cannot be easily reduced to data and are much more difficult to capture computationally. Informatics is interesting (and difficult), in part, because many biomedical concepts defy definition via necessary and sufficient conditions.

Blois argued that, in order to compute upon a system, one must first determine the system’s boundaries.²² In other words, one must define all of the relevant components and assume that everything else is irrelevant. However, this is very difficult to do for biological (or human) systems. If the goal is to model the circulatory system, can the renal system be excluded? The endocrine system that includes the adrenal glands (releases epinephrine that constricts blood vessels and raises blood pressure)? The nervous system? And so on. With a bank account, it is easy to draw boundaries around

because it arises from a lack of knowledge of some underlying fact. This type of imperfection is addressed by probability and statistics.

- Example: how many female humans are in the US? Although there is a precise answer to this question at any given moment, we can only estimate the answer using statistics.
- Imprecise information: Information that is not as specific as it should be.
 - Example: Patient has pneumonia. This may be precise enough for some purposes, but is not sufficiently precise to determine treatment. For example, antibiotics can treat bacterial pneumonia, but are of little use to a patient with viral pneumonia.
- Vague information: Information that includes elements (e.g., predicates or quantifiers) that permit boundary cases (tall woman, may have happened, large bruise, big wound, elderly man, sharp radiating pain, etc.). Unlike uncertain information, with vague information there is no underlying matter of fact. Even if the age of every female human in the US was known, one could not precisely answer the question of how many mature women were in the US at that time, because “mature” is a term that has boundary cases; there are women who are clearly mature, those who clearly are not, and a number in between for whom one cannot be sure that term applies.
- Inconsistent information: Information that contains two or more assertions that cannot simultaneously hold.
 - Example: Birthdate: 8/29/66 AND 9/17/66

As illustrated in the above examples, all of these imperfections may be found in healthcare information. Humans can deal with these imperfections. For example, it can be decided that for clinical purposes, a difference in patient age of a little over two weeks (in itself a vague statement), is insignificant for clinical purposes.

Computers, on the other hand, must be explicitly programmed to make such “judgments.” However, the number of possible variances and exceptions is effectively infinite. Thus, they cannot all be anticipated and addressed in advance. This is one reason why clinical decision support often gives advice that is, to a clinician, obviously inappropriate to the current patient situation.

In addition, definitions in health care and biomedicine often change over time. Consider the definition of a gene.²⁵

Designing systems that adapt to changes in definition that, in turn, can affect other definitions is difficult. Our computers and programming languages process discrete symbols according to precise formal rules. They do not make sense of a highly ambiguous, noisy world or do meaning-based processing. With this background, one can now consider health IT and its various successes and failures in the real world.

Why Health IT Fails Sometimes

“To improve the quality of our health care while lowering its cost, we will make the immediate investments necessary to ensure that within five years all of America’s medical records are computerized. This will cut waste, eliminate red tape, and reduce the need to repeat expensive medical tests... it will save lives by reducing the deadly but preventable medical errors that pervade our health care system.”

– Barack Obama (Speech on the Economy, George Mason University, January 8, 2009)

Widespread dissatisfaction with health care in America and rapid advancement in information technology has focused attention on Health IT (HIT) as a possible solution. The need for HIT is one of the few topics upon which Democrats and Republicans agree. Both former President Bush and President Obama set 2014 as the goal date

for computerizing medical records. To many, HIT seems like an obvious solution to our health care woes. The government's HIT website says that HIT adoption will: improve health care quality, prevent medical errors, reduce health care costs, increase administrative efficiencies, decrease paperwork and expand access to affordable care.⁹ However, there is increasing evidence that HIT adoption does not guarantee these benefits. Unmitigated enthusiasm is dangerous for HIT adoption. Similar enthusiasm repeatedly threatens the field of artificial intelligence, resulting in cycles of excitement and disappointment (in artificial intelligence, these cycles are sometimes called "AI winters").

Effects of HIT

HIT is an "easy sell" to an American public increasingly dissatisfied with our health care system. Indeed, there is evidence that HIT can improve health care quality,²⁶ prevent medical errors,²⁷ and increase efficiency.²⁶ Thus, there is reason for optimism. With the American Recovery and Reinvestment Act (ARRA) of 2009, the US government made a multi-billion dollar investment in HIT.²⁸ Similar investments have been made by the governments of Australia,²⁹ Belgium,³⁰ Canada,³¹ Denmark,³² and the United Kingdom.³³

However, many and perhaps even most HIT projects fail.³⁴ There is also evidence that HIT can worsen health care quality to the point of increasing mortality,³⁵ increasing errors^{36,37} and decreasing efficiency.³⁵ In November 2011, the Institute of Medicine issued a report entitled "Health IT and Patient Safety: Building Safer Systems for Better Care" that concluded: "...some products have begun being associated with increased safety risks for patients."³⁸ There is even a term, "e-iatrogenesis," that refers to the unintended deleterious consequences of HIT.³⁹ Notably, systems that increase mortality at one institution³⁵, do not seem to have the same effect at another institution;⁴⁰ even though the clinical setting (pediatric intensive care) was similar. Thus, one cannot simply conclude that the system itself is wholly responsible. It is not just the system being implemented, but how it is

implemented and in what context that determines the clinical results.

We've Been Here Before: AI Winters

During the 1950s, we were faced with a different problem: the Cold War. Similarly, the government saw IT as a promising (at least partial) solution. If researchers could develop automated translation, we could monitor Russian communications and scientific reports in "real time." There was a great deal of optimism and "...many predictions of fully automatic systems operating within a few years."⁴¹

Although there were promising applications of poor-quality automated translation, the optimistic predictions of the 1950s were not realized. The fundamental problem of context and meaning remains unsolved. This made disambiguation difficult resulting in amusing failures. Humorous examples include: "the spirit is willing but the flesh is weak" translated English → Russian → English resulted in the phrase "the vodka is good but the meat is rotten."

In 1966, the influential Automatic Language Processing Advisory Committee (ALPAC) concluded that "there is no immediate or predictable prospect of useful machine translation."⁴² As a result, research funding was stopped and there was little automated translation research in the United States from 1967 until a revival in 1976-1989.⁴¹

Similarly, there is currently tremendous interest in HIT. Although there is good evidence that HIT can be useful, some will certainly be disappointed. A recent report by the National Research Council (the same body that published the ALPAC report) concluded that "...current efforts aimed at the nationwide deployment of health care IT will not be sufficient to achieve the vision of 21st century health care, and may even set back the cause if these efforts continue wholly without change from their present course."⁴³ Thus, there is reason for concern that HIT (and perhaps even informatics, in general) may be headed for a bust. Such an "HIT winter"

would be unfortunate, since there are real benefits of pursuing research and implementation of HIT.

The Problem: Health Information Technology is Really Health Data Technology

The fundamental problem is that existing technology stores, manipulates and transmits data (symbols), not information (data + meaning). Thus, the utility of HIT is limited by the extent to which data approximates meaning. Unfortunately, in health care, data do not fully represent the meaning. In other words, there is a large gap between data and information. Since the difference between data and information is meaning (semantics), this gap is referred to as the “semantic gap.”

Social and Administrative Barriers to HIT Adoption. Manipulating data and not information has many consequences for HIT. Note that there is no shortage of computers in hospitals. While most hospitals do not manage their clinical data electronically, all of them manage their financial data electronically. Just like any other organization, many hospitals have functioning e-mail systems and maintain a Web presence. Many clinicians used personal digital assistants,⁴⁴ some even communicate with patients using e-mail.

The social and administrative barriers to HIT adoption have been discussed by multiple authors in countless papers. Such barriers include a mismatch between costs and benefits, cultural resistance to change, lack of an appropriately trained workforce to implement HIT and multiple others.⁴⁵ To some, clinicians’ resistance to computerization appears irrational. However, caution seems increasingly reasonable given the mixed evidence regarding the benefits of poorly-implemented HIT. Thus, the clinical enterprise is not computerized because of rational skepticism regarding the benefit of current HIT, not an irrational resistance to IT or computerization.

Future Trends

Significant research problems must be addressed before HIT becomes more attractive to clinicians. Many of these are outlined in a recent National Research Council report.⁴³ First, there is a mismatch between what HIT can represent (data) and concepts relevant to health care (data + meaning). This is a very difficult and fundamental challenge that includes multiple long-standing challenges in artificial intelligence (e.g., how computers can be “taught” context or common sense) that have proven very difficult to solve. It seems that until one has true information processing, rather than data processing, technology, the benefits of HIT will be limited.

Second, HIT must augment human cognition and abilities. Friedman recently expressed this elegantly as the “fundamental theorem of informatics:” human + computer > human (humans working with computers should perform better than a human alone).⁴⁶ The theorem argues that there must be a clear and demonstrable benefit from HIT. In spite of the problems with current HIT, there are clearly situations where HIT can be beneficial. In some ways, human cognition and computer technology are very complementary. For example, monitoring (e.g., waveforms) is much easier for computers than for humans. In contrast, reasoning by analogy across domains is natural for humans but difficult for computers.

How Progress Will Be Made

Researchers are exploring multiple promising paradigm-shifting ideas. Examples of approaches that address some of the fundamental problems described in this chapter can be provided.

One approach is to recognize the complementary strengths of humans and computers. Humans are good at constructing and processing meaning. In contrast, computers are much better at processing data. Users can leverage this understanding to design systems that harness the data-processing power of computers

to present (display) data in ways that make it easier for humans to grasp and manipulate meaning. For example, a *word cloud visualization* shows the term frequency in text.⁴⁷ The size of the font is proportional to the frequency of the term.

Returning to HIT, one can apply these same principles. For example, Figure 2.10 shows an example of an EHR that integrates clinical decision support. This is not novel, but this example illustrates what could be done by combining multiple types of information on the same screen with an understanding of the user’s task.

Defining scenarios when HIT is beneficial with all relevant parameters and demonstrating that using HIT is *reliably* beneficial in these scenarios remains a research challenge. In its present form, HIT will not transform healthcare in the same way that IT has transformed other industries. This is due in part to the large semantic gap between health data and health information (concepts). In addition, many problems with healthcare require non-technological solutions, such as changes in healthcare policy and financing.

Figure 2.10: EHR screen (from John Halamka) showing integration of decision support into the EHR⁴⁸

Concise Synopsis of evidence-based imaging recommendations.

Jaundice

In patients with new-onset jaundice, the recommended initial imaging modality is abdominal ultrasound. US can distinguish between hepatic parenchymal damage and biliary obstruction. In very obese patients and those with bowel obstruction, US may be unreliable, in which case CT of the abdomen is suggested. In patients with an equivocal US, who do not show biliary duct dilation, and who are coagulopathic, ERCP is a reasonable diagnostic option. If ERCP is contraindicated (e.g., in acute pancreatitis), then magnetic resonance angiography and cholangiopancreatography may be considered. In patients with ductal dilation/obstruction, percutaneous transhepatic cholangiography (PTHC) may be both diagnostic and therapeutic, but may be contraindicated in patients with bleeding diatheses

Score	Imaging Study	Safety	Risk	mReis	Cost	CoPay	Comment
<input type="checkbox"/>	MRCP (MR Abdomen With and Without Contrast)	Allergy to iodine	1	0	1112	N/A	perform with MRA with or without contrast.
<input checked="" type="checkbox"/>	Ultrasound Abdomen Limited, Single Organ		0	0	136	N/A	N/A
<input type="checkbox"/>	CT Abdomen With Contrast	Allergy to iodine	3	1800	406	N/A	N/A
<input type="checkbox"/>	MRA Abdomen Without Contrast		1	0	574	N/A	perform with MRCP at the same time.
<input type="checkbox"/>	ERCP		4	10500	217	N/A	N/A
<input type="checkbox"/>	Percutaneous Transhepatic Choleang (PTHC)			000	610	N/A	N/A

Annotations:

- Specific attributes of this patient:** Patient coagulopathic, Azule pancreatitis suspected, Allergy to iodine.
- Evidence-based efficacy score (what is the best test for this patient?):** Points to the 'Score' column.
- Safety considerations – automatically based on known patient data, including lab values:** Points to the 'Safety' column.
- Cost and Patient Co-Pay and Insurer Realtime Authorization of Imaging Test:** Points to the 'Cost' and 'CoPay' columns.

Help And Information | 1. Select Scenario | 4. Test Selection

Please Select the imaging procedure you wish to perform by clicking the checkbox for the procedure's row.

Current Profile

Questions or Comments

Back | Order Test

Score: Highest value, to one square, the lowest value. "With" and "Without" mean with and without contrast. 5 highest risk (e.g. coronary angiogram), 0 low risk. Relative warnings and red items are absolute warnings. Usage for this particular imaging study. Retail cost for this procedure.

CoPay: Estimated insurance cost to patient, if available.

Comment: Any additional information regarding this scenario.

Key Points

- Data are observations reflecting differences in the world (e.g., “162.9”) while information is meaningful data or facts from which conclusions can be drawn and knowledge is information that is justifiably believed to be true
- Data are largely the domain of information technology (IT) professionals and computer scientists; information and knowledge are the domains of informatics and informaticians
- Vocabularies help convert data into information
- The transformation of data into information and knowledge is a core concern of informaticians
- When the real world, the conceptual model and the computational model match, we get useful answers from the computer
- Concepts relevant to health are relatively poorly defined compared to e.g. banking concepts
- There is a large “semantic gap” between health data and health information

Conclusion

Problems in healthcare are information and knowledge intensive. Current technology is centered on processing data. This mismatch, or semantic gap, between the problems healthcare IT tries to address and the available technology

explains the difficulties that informaticians face every day. It also explains the differences between Informatics and Computer Science. Informatics must advance our information and knowledge-processing capabilities in order to continue improving healthcare through technology.

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Chapter 3

Healthcare Data Analytics

WILLIAM R. HERSH

Learning Objectives

After reading this chapter the reader should be able to:

- Discuss the difference between descriptive, predictive and prescriptive analytics
- Outline the characteristics of “Big Data”
- Enumerate the necessary skills for a worker in the data analytics field
- List several limitations of healthcare data analytics
- Discuss the critical role electronic health records play in healthcare data analytics

Introduction

One of the promises of the growing critical mass of clinical data accumulating in electronic health record (EHR) systems is secondary use (or re-use) of the data for other purposes, such as quality improvement and clinical research.¹ The growth of such data has increased dramatically in recent years due to incentives for EHR adoption in the US funded by the Health Information Technology for Economic and Clinical Health (HITECH) Act.²⁻³ In the meantime, there has also seen substantial growth in other kinds of health-related data, most notably through efforts to sequence genomes and other biological structures and functions.⁴ The analysis of this data is usually called *analytics* (or *data analytics*). This chapter will define the terminology of this field, provide an overview of its promise, describe what work has been accomplished, and list the challenges and opportunities going forward.

Terminology of Analytics

The terminology surrounding the use of large and varied types of data in healthcare is evolving, but the term analytics is achieving wide use both in and out of healthcare. A long-time leader in the field defines analytics as “the extensive use of data, statistical and quantitative analysis, explanatory and predictive models, and fact-based management to drive decisions and actions.”⁵ IBM defines analytics as “the systematic use of data and related business insights developed through applied analytical disciplines (e.g. statistical, contextual, quantitative, predictive, cognitive, other [including emerging] models) to drive fact-based decision making for planning, management, measurement and learning. Analytics may be descriptive, predictive or prescriptive.”⁶

Adams and Klein have authored a primer on analytics in healthcare that defined different

levels and their attributes of the application of analytics.⁷ They noted three levels of analytics, each with increasing functionality and value:

- Descriptive – standard types of reporting that describe current situations and problems
- Predictive – simulation and modeling techniques that identify trends and portend outcomes of actions taken
- Prescriptive – optimizing clinical, financial, and other outcomes

Much work is focusing now on predictive analytics, especially in clinical settings attempting to optimize health and financial outcomes.

There are a number of terms related to data analytics. A core methodology in data analytics is *machine learning*, which is the area of computer science that aims to build systems and algorithms that learn from data.⁸ One of the major techniques of machine learning is *data mining*, which is defined as the processing and modeling of large amounts of data to discover previously unknown patterns or relationships.⁹ A subarea of data mining is *text mining*, which applies data mining techniques to mostly unstructured textual data.¹⁰ Another close but more recent term in the vernacular is *big data*, which describes large and ever-increasing volumes of data that adhere to the following attributes:¹¹

- Volume – ever-increasing amounts
- Velocity – quickly generated
- Variety – many different types
- Veracity – from trustable sources

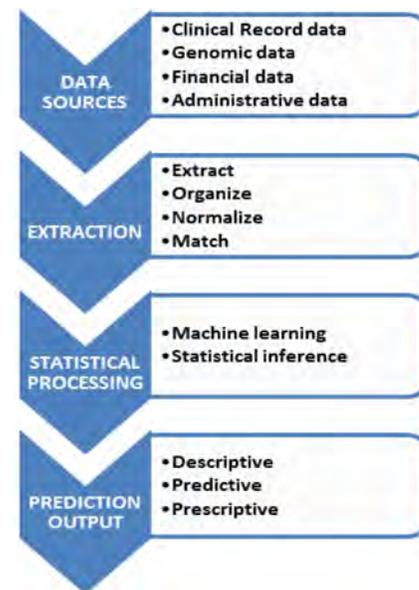
With the digitization of clinical data, hospitals and other healthcare organizations are generating an ever-increasing amount of data. In all healthcare organizations, clinical data takes a variety of forms, from structured (e.g., images, lab results, etc.) to unstructured (e.g., textual notes including clinical narratives, reports, and other types of documents). For example, it is estimated by Kaiser-Permanente that its current data store for its 9+ million members exceeds 30 petabytes of data.¹² Other

organizations are planning for a data-intensive future. Another example is the American Society for Clinical Oncology (ASCO) that is developing its Cancer Learning Intelligence Network for Quality (CancerLinQ).¹³ CancerLinQ will provide a comprehensive system for clinicians and researchers consisting of EHR data collection, application of clinical decision support, data mining and visualization, and quality feedback.

Another source of large amounts of data is the world’s growing base of scientific literature and its underlying data that is increasingly published in journals and other articles (see Chapter on online medical resources). One approach to this problem that has generated attention is the IBM Watson project, which started as a generic question-answering system that was made famous by winning at the TV game show Jeopardy!¹⁴ IBM has since focused Watson in the healthcare domain.¹⁵

Kumar et al. have noted that the process of big data analytics resembles a pipeline, and have developed an approach that specifies four major steps in this pipeline, to which one can place data sources and actions on it pertinent to healthcare and biomedicine.¹⁶ (Figure 3.1)

Figure 3.1: The Analytics Pipeline (Adapted from Kumar et al)¹⁶



The pipeline begins with input data sources, which in healthcare and biomedicine may include clinical records, financial records, genomics and related data, and other types, even those from outside the healthcare setting (e.g., census data). The next step is feature extraction, where various computational techniques are used to organize and extract elements of the data, such as linking records across sources, using natural language processing (NLP) to extract and normalize concepts, and matching of other patterns. This is followed by statistical processing, where machine learning and related statistical inference techniques are used to make conclusions from the data. The final step is the output of predictions, often with probabilistic measures of confidence in the results.

The growing quantity of data requires that its users have a good understanding of its *provenance*, which is where the data originated and how trustworthy it is for large-scale processing and analysis.¹⁷ A number of researchers and thought leaders have started to specify the path that will be required for big data to be applied in healthcare and biomedicine.¹⁸⁻²⁰ An edited volume was recently published about analytics applied in various aspects healthcare and life sciences.²¹

A more peripheral but related term is *business intelligence*, which in healthcare refers to the “processes and technologies used to obtain timely, valuable insights into business and clinical data.”⁷ Another relevant term is the notion promoted by the Institute of Medicine of the *learning health system*.²²⁻²³ Advocates of this approach note that routinely collected data can be used for continuous learning to allow the healthcare system to better carry out disease surveillance and response, targeting of healthcare services, improving decision-making, managing misinformation, reducing harm, avoiding costly errors, and advancing clinical research.²⁴

Another set of related terms come from the call for new and much more data-intensive approaches to diagnosis and treatment of disease variably called *personalized*

medicine,²⁵ *precision medicine*,²⁶ or *computational medicine*.²⁷ Advocates for these approaches note the inherent complexity of nonlinear systems in biomedicine, with large amounts and varied types of data that will need models to enable their predictive value. Technology thought leader O’Reilly notes that data science is transforming medicine, striving to solve its equivalent of the “Wanamaker Dilemma” for advertisers, named after the problem of knowing that half of advertising by merchants does not work, but that the half that does not work is not known.²⁸

One of the major motivators for data analytics comes from new models of healthcare delivery, such as *accountable care organizations* (ACOs), where reimbursement for conditions and episodes is bundled in a variety of ways, providing incentives to move to deliver high-quality care in cost-efficient ways.²⁹ ACOs require a focused IT infrastructure that provides data that can be used to predict and quickly act on excess costs.³⁰ One of the challenges for healthcare data is that patients often get their care and testing in different settings (e.g., a patient seen in a physician office, sent to a free-standing laboratory or radiology center, and also seen in the offices of specialists or being hospitalized). This has increased the need for development of *health information exchange* (HIE), where data is shared among entities caring for a patient across business boundaries.³¹ A well-known informatics blogger has succinctly noted that “ACO = HIE + analytics.”³²

Challenges to Data Analytics

There are, of course, challenges to data analytics. One concern is that data generated in the routine care of patients may be limited in its use for analytical purposes.³³ For example, such data may be inaccurate or incomplete. It may be transformed in ways that undermine its meaning (e.g., coding for billing priorities). It may exhibit the well-known statistical phenomenon of *censoring*, i.e., the first

instance of disease in record may not be when it was first manifested (left censoring) or the data source may not cover a sufficiently long time interval (right censoring). Data may also incompletely adhere to well-known standards, which makes combining it from different sources more difficult. Finally, clinical data mostly only allows observational and not experimental studies, thus raising issues of cause-and-effect of findings discovered.

Others have noted larger challenges around analytics and big data. Boyd and Crawford have expressed some “provocations” for the growing use of data-driven research.³⁴ They note that research questions asked of the data tend to be driven by what can be answered, as opposed to prospective hypotheses. They also note that data are not always as objective as one might like, and that “bigger” is not necessarily better. Finally, they raise ethical concerns over how the data of individuals is used, the means by which it is collected, and the possible divide between those who have access to data and those who do not. Similar concerns focused specifically on healthcare data by Neff, who describes a myriad of technical, financial, and ethical issues that must be addressed before one will be able to make use of big data routinely for clinical practice and other health-related purposes.³⁵ These challenges also create ethical issues, such as who owns data and who has privileges to use it.³⁶

Research and Application of Analytics

The research base around applying analytics to improve healthcare delivery is still in its early stages. There is an emerging base of research that demonstrates how data from operational clinical systems can be used to identify critical situations or patients whose costs are outliers. There is less research, however, demonstrating how this data can be put to use to actually improve clinical outcomes or reduce costs. Studies using EHR data for clinical prediction have been proliferating. One common area of

focus has been the use of data analytics to identify patients at risk for hospital readmission within 30 days of discharge. The importance of this factor comes from the US Centers for Medicare and Medicaid Services (CMS) Readmissions Reduction Program that penalizes hospitals for excessive numbers of readmissions.³⁷ This has led several researchers to assess EHR data in its value to predict patients at risk for readmission.³⁸⁻⁴⁰

A number of other critical clinical situations have been amenable to detection by analytics applied to EHR and other clinical data:

- Predicting 30-day risk of readmission and death among HIV-infected inpatients⁴¹
- Identification of children with asthma⁴²
- Risk-adjusting hospital mortality rates⁴³
- Detecting postoperative complications⁴⁴
- Measuring processes of care⁴⁵
- Determining five-year life expectancy⁴⁶
- Detecting potential delays in cancer diagnosis⁴⁷
- Identifying patients with cirrhosis at high risk for readmission⁴⁸
- Predicting out of intensive care unit cardiopulmonary arrest or death⁴⁹

Additional efforts have focused on helping to identify patients for participation in research protocols or improve diagnosis of disease:

- Identifying patients who might be eligible for participation in clinical studies⁵⁰
- Determining eligibility for clinical trials⁵¹
- Identifying patients with diabetes and the earliest date of diagnosis⁵²
- Predicting diagnosis in new patients⁵³

Other researchers have also been able to use EHR data to replicate the results of randomized controlled trials (RCTs). One large-scale effort has come from the Health Maintenance Organization Research Network’s Virtual Data Warehouse (VDW) Project.⁵⁴ Using the VDW, for example, researchers were able to demonstrate a link between childhood obesity and hyperglycemia in pregnancy.⁵⁵ Another demonstration of this ability has come from United Kingdom General Practice

Research Database (UKGPRD), a repository of longitudinal records of general practitioners. Using this data, Tannen et al. were able to demonstrate the ability to replicate the findings of the Women’s Health Initiative⁵⁶⁻⁵⁷ and RCTs of other cardiovascular diseases.⁵⁸⁻⁵⁹ Likewise, Danaei et al. were able to combine subject-matter expertise, complete data, and statistical methods emulating clinical trials to replicate RCTs demonstrating the value of statin drugs in primary prevention of coronary heart disease.⁶⁰

These large repositories have been used for other research purposes. For example, the UKGPRD has been used for determining risk factors for pancreatic cancer⁶¹ and gastroesophageal cancer.⁶² Another large data repository in the US allowed replication of prospective cohort studies for risks of venous thromboembolic events in a manner much more efficient than historical retrospective analyses.⁶³ In addition, the Observational Medical Outcomes Partnership (OMOP) was to apply risk-identification methods to records from ten different large healthcare institutions in the US, although with a moderately high sensitivity vs. specificity tradeoff.⁶⁴ Finally, a case report demonstrated a situation where a clinical research database was queried to help make a decision whether to anticoagulate a child with systemic lupus erythematosus

(SLE), a question for which no scientific literature existed to answer.⁶⁵ For an example of data analytics at a large healthcare system, see the Info box.

Another approach used more novel methods. Denny and colleagues have developed methods for carrying out genome-wide association studies (GWAS) that associate specific findings from the EHR (the “phenotype”) with the growing amount of genomic and related data (the “genotype”) in the Electronic Medical Records and Genomics (eMERGE) Network.⁶⁸ eMERGE has demonstrated the ability to validate existing research results and generate new findings,⁶⁹ being able to identify genomic variants, among others, associated with atrioventricular conduction abnormalities,⁷⁰ red blood cell traits,⁷¹ white blood cell count abnormalities,⁷² and thyroid disorders.⁷³ More recent work has “inverted” the paradigm to carry out phenome-wide association studies (PheWAS) that associated multiple phenotypes with varying genotypes.⁷⁴⁻⁷⁵ Genome-wide and phenome-wide association studies are also discussed in the chapter on bioinformatics.

Clearly a large and growing body of research demonstrates that EHR and other clinical data can be used to predict outcomes, including adverse ones, as well as diagnoses and eligibility for research studies. The next step in research is to find evidence that such method

Case Study: Veterans Health Administration (VHA)

The VHA is a large healthcare system with a long track record of EHR use (VistA). In 2013, the VHA had 30 million unique electronic patient records with 2 billion clinical notes (100,000 notes added daily). They also have had a corporate data warehouse (CDW) of structured data which allows them to analyze clinical and administrative data for patients at risk of hospital admission (from falls, coronary disease, PTSD, etc.). Analytics are run once weekly on all primary care patients looking for “at risk” patients who would likely require more coordinated care using care managers, home health and telehealth. In 2012, VHA researchers reported in the *American Journal of Cardiology* on the use of predictive analytics on heart failure patients. Specifically, using six categories of risk factors derived from the EHR they could successfully predict which patients were at risk of hospitalization and death.⁶⁶

According to Dr. Stephen Fihn, Director of Analytics and Business Intelligence for the VHA, the VHA is embarking on a 24-month pilot project to expand the use of healthcare data analytics. They will use natural language processing and machine learning to analyze patient records to aid in diagnosis, identify dangerous drug-drug interactions and optimally design treatment strategies.⁶⁷

to find evidence that such methods lead to improved patient outcomes. There are unfortunately a small number of studies, and their results are mixed. One study showed that a readmission tool applied to an existing case management approach helped reduce readmissions,⁷⁶ while another found that use of a Bayesian network model embedded in EHR to predict hospital-acquired pressure ulcers led to a tenfold reduction in such ulcers as well as a reduction by one-third in intensive care unit length of stay for such patients.⁷⁷ Another study found that a readmission risk tool intervention reduced risk of readmission for patients with congestive heart failure but not those with acute myocardial infarction or pneumonia.⁷⁸ Another study found that an automated prediction model integrated into an existing EHR was successful in identifying patients on admission who were at risk for readmission within 30 days of discharge, but its use had no effect on 30-day all-cause and 7-day unplanned readmission rates in the 12-month period after it was implemented.⁷⁹

Role of Informaticians in Analytics

Although much has been written extolling the virtues of analytics and big data analytics, little of it focuses on the human experts who will carry out the work, to say nothing of those who will support their efforts in building systems to capture data, put it into usable form, and apply the results of analysis. Many of those who collect, analyze, use, and evaluate data will come from the workforce of biomedical and health informatics. To this end, one must ask questions about the job activity as well as the education of those who work in this emerging area that some call *data science*.⁸⁰ Data analytics thought leader Davenport asserts that data science is the “sexiest job of the 21st century,” in that those who perform it have rare qualities in high demand.⁸¹

In the worlds of healthcare and biomedicine, the field poised to lead in data science is informatics. After all, informatics has led the charge in implementing systems that capture, analyze, and

apply data across the biomedical spectrum from genomics to health care to public health.⁸² From basic biomedical scientists to clinicians and public health workers, those who are researchers and practitioners are drowning in data, needing tools and techniques to allow its use in meaningful and actionable ways.

Data science is more than statistics or computer science applied in a specific subject domain. Dhar notes that a key aspect of data science, in particular what distinguishes it from statistics, is an understanding of data, its varying types, and how to manipulate and leverage it.⁸⁰ He points out that skills in machine learning are key, based upon a foundation of statistics (especially Bayesian), computer science (representation and manipulation of data), and knowledge of correlation and causation (modeling). Dhar also notes a challenge to organizational culture that might occur as organizations moved from “intuition-based” to “fact-based” decision-making.

It is also clear that there are two types of individuals working with analytics and big data. A report by the McKinsey consulting firm states that there will soon be a need in the US for 140,000-190,000 individuals who have “deep analytical talent”. Furthermore, the report notes there will be need for an additional 1.5 million “data-savvy managers needed to take full advantage of big data”.⁸³ Analyses from the UK find similar results. An analysis by SAS estimated that by 2018, there will be over 6400 organizations that will hire 100 or more analytics staff.⁸⁴ Another report found that data scientists currently comprise less than 1% of all big data positions, with more common job roles consisting of developers (42% of advertised positions), architects (10%), analysts (8%) and administrators (6%).⁸⁵ It was also found that the technical skills most commonly required for big data positions as a whole were NoSQL, Oracle, Java and SQL. While these estimates are not limited to healthcare, they also do not include other countries that will have comparable needs to the US and the UK for such talent.

A report from IBM Global Services noted healthcare organizations are lagging behind in

hiring individuals who are proficient in both “numerate” and business-oriented skills.⁸⁶ An additional report from IBM Global Services list “expertise” among the critical attributes in organizations that are needed to complement technology. This expertise includes the supplementation of business knowledge with analytics knowledge, establishing formal career paths for analytics professionals, and tapping partners to supplement skills gaps that may exist.⁸⁷ Another US-based report by PriceWaterhouseCoopers on health IT talent shortages noted that healthcare organizations wanting to keep ahead needed to acquire talent in Systems and data integration, data statistics and analytics, technology and architecture support, and clinical informatics.⁸⁸

The US National Institutes of Health (NIH) also recognizes that big data skills will be important for conducting biomedical research. In 2013, NIH convened a workshop on enhancing training in big data among researchers.⁸⁹ Similar to the healthcare domain, participants called for skills in quantitative sciences, domain expertise, and ability to work in diverse teams. The workshop also noted a need for those working in big data to understand concepts of managing and sharing data. Trainees should also have access to real-world data problems and real-sized data sets to solve them. Longer-term training would be required for those becoming experts and leaders in data science.

What do biomedical and health informaticians working in analytics and big data need to know? An emerging consensus can be drawn from the reports above indicates that a combination of skills will be required:

1. Programming - especially with data-oriented tools, such as SQL and statistical programming languages
2. Statistics - working knowledge to apply tools and techniques
3. Domain knowledge - depending on one's area of work, bioscience or health care

4. Communication - being able to understand needs of people and organizations and articulate results back to them

Thus to be relevant, informatics educational programs will need to introduce concepts of analytics, big data, and the underlying skills to use and apply them into their curricula. There will be a need for appropriate coursework for those who will become the “deep analytical talent” as well as higher breadth, perhaps with lesser depth, for the order of magnitude more individuals who will apply the results of big data analytics in healthcare and biomedical research.

Recommended Reading

The following are interesting references to expand your healthcare data analytics knowledge:

- *Mining Electronic Health Records in the Genomics Era*. A book chapter providing an overview of techniques for extracting structured and narrative text from EHRs, with a focus on genotype-phenotype correlations.⁶⁸
- *Caveats³³ And Recommendations⁹⁰ For Use Of Operational Clinical Data In Research*. A pair of papers noting challenges and overcoming them for use of EHR data in clinical research
- *Analytics in Healthcare and the Life Sciences: Strategies, Implementation Methods, and Best Practices*. A book describing tools and best practices for use of analytics for clinical care, pharmaceutical research, and patient engagement.²¹

Future Trends

As the volume of clinical data and the need for analytics continues to accelerate, systematic approaches will be required for sustained success. One recent analysis laid out recommendations for operational use of clinical data.⁹⁰ Although focused on comparative

effectiveness research, the recommendations can be applied for almost any data analytics task. The authors called for:

- Adherence to best practices for use of data standards and interoperability
- Processes to evaluate availability, completeness, quality, and transformability of data
- Toolkits and pipelines to manage data and its attributes
- Challenges and metrics for assessing “research grade” of operational data
- Standardized reporting methods for operational data and its attributes
- Adaptation of “best evidence” approaches to use of operational data
- Appropriate use of informatics expertise to assist with optimal use of operational data and to develop published guidelines for doing so

- Research agenda to determine biases inherent in operational data and to assess informatics approaches to improve data

The “best evidence” approach is modeled on the framework of evidence-based medicine (EBM), applying the four basic steps of EBM to clinical data instead of scientific studies: ⁹⁰

- Ask an answerable question – can question be answered by the data we have?
- Find the best evidence – in this case, the best evidence is the EHR data needed to answer the question
- Critically appraise the evidence – does the data answer the question? Are there confounders?
- Apply it to the patient situation – can the data be applied to this setting?

Key Points

- Healthcare data has proliferated greatly, in large part due to the accelerated adoption of EHRs
- Analytic platforms will examine data from multiple sources, such as clinical records, genomic data, financial systems, and administrative systems
- Analytics is necessary to transform data to information and knowledge
- Accountable care organizations and other new models of healthcare delivery will rely heavily on analytics to analyze financial and clinical data
- There is a great demand for skilled data analysts in healthcare; expertise in informatics will be important for such individuals

Conclusion

Clearly there is great promise ahead for healthcare driven by data analytics. The growing quantity of clinical and research data, along with methods to analyze and put it to use, can lead to improve personal health, healthcare delivery, and biomedical research. However there is also

a continued need to improve the completeness and quality of data as well as conduct research to demonstrate how to best apply it to solve real-world problems. In addition, human expertise, including in informatics, will be required to optimally carry out such work.

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Chapter 4

Electronic Health Records

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Learning Objectives

After reading this chapter the reader should be able to:

- State the definition and history of electronic health records (EHRs)
- Describe the limitations of paper-based health records
- Identify the benefits of electronic health records
- List the key components of an electronic health record
- Describe the ARRA-HITECH programs to support electronic health records
- Describe the benefits and challenges of computerized order entry and clinical decision support systems
- State the obstacles to purchasing, adopting and implementing an electronic health record
- Enumerate the steps to adopt and implement an EHR

Introduction

There is no topic in health informatics as important, yet controversial, as the electronic health record (EHR). Attempts at developing and promoting EHRs go back over 37 years. However, only in recent years have EHRs become firmly rooted in the US Healthcare system. Despite their widespread recent adoption, they are very much a work in progress. The Problem Oriented Medical Information System (PROMIS) was developed in 1976 by The Medical Center Hospital of Vermont in collaboration with Dr. Lawrence Weed, the originator of the problem oriented record and SOAP formatted notes. Ironically, the inflexibility of the concept led to its demise.¹ In

a similar time frame the American Rheumatism Association Medical Information System (ARAMIS) appeared. All findings were displayed as a flow sheet. The goal was to use the data to improve the care of rheumatologic conditions.² Other EHR systems began to appear throughout the US: the Regenstrief Medical Record System (RMRS) developed at Wishard Memorial Hospital, Indianapolis; the Summary Time Oriented Record (STOR) developed by the University of California, San Francisco; Health Evaluation Through Logical Processing (HELP) developed at the Latter Day Saints Hospital, Salt Lake City and The Medical Record developed at Duke University³, the Computer Stored Ambulatory Record (COSTAR)

developed by Octo Barnett at Harvard and the De-Centralized Hospital Computer Program (DHCP) developed by the Veterans Administration.⁴

In 1970 Schwartz optimistically predicted “clinical computing would be common in the not too distant future.”⁵ In 1991 the Institute of Medicine (IOM) recommended electronic health records as a solution for many of the problems facing modern medicine.⁶ Following the IOM recommendation, little progress was made for multiple reasons. As Dr. Donald Simborg stated, the slow acceptance of electronic health records is like the “wave that never breaks.”⁷

The American Recovery and Reimbursement Act (ARRA) of 2009 was a major game changer for electronic health records, with reimbursement by Medicare and Medicaid for the Meaningful Use of certified EHRs, as well as other programs that supported EHR education and health information exchange. Reimbursement details will be discussed in more detail later in this chapter.

The authors will primarily discuss outpatient (ambulatory) electronic health records. Inpatient EHRs share many similarities to ambulatory EHRs but the scope, price and complexity are different. The logical steps to selecting and implementing an EHR are found later in the chapter.

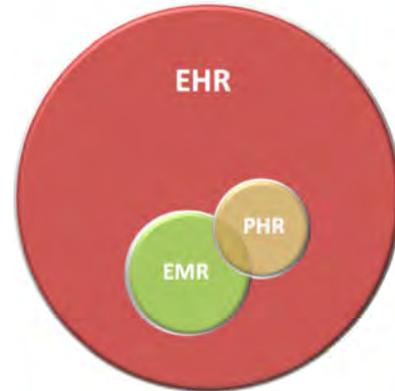
Electronic Health Record Definitions

There is no universally accepted definition of an EHR. As more functionality is added the definition will need to be broadened. Importantly, EHRs are also known as electronic medical records (EMRs), computerized medical records (CMRs), electronic clinical information systems (ECIS) and computerized patient records (CPRs). Throughout this book electronic health record as the more accepted and inclusive term will be used.

Figure 4.1 demonstrates the relationship between EHRs, EMRs and personal health records (PHRs).⁸ As indicated in the diagram,

PHRs can be part of the EMR/EHR system which may cause confusion.

Figure 4.1: Relationship between EHR, PHR and EMR



In 2008 the National Alliance for Health Information Technology released the following definitions in an effort to standardize terms used in HIT:

Electronic Medical Record: “An electronic record of health-related information on an individual that can be created, gathered, managed and consulted by authorized clinicians and staff within one healthcare organization.”⁹

Electronic Health Record: “An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed and consulted by authorized clinicians and staff across more than one healthcare organization.”⁹

Personal Health Record: “An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared and controlled by the individual.”⁹

Need for Electronic Health Records

The following are the most significant reasons why our healthcare system would benefit from

the widespread transition from paper to electronic health records

Paper Records Are Severely Limited

Much of what can be said about handwritten prescriptions can also be said about handwritten office notes. Figure 4.2 illustrates the problems with a paper record. In spite of the fact that this clinician used a template, the handwriting is illegible and the document cannot be electronically shared or stored. It is not structured data that is computable and hence sharable with other computers and systems. Other shortcomings of paper: expensive to copy, transport and store; easy to destroy; difficult to analyze and determine who has seen it; and the negative impact on the environment. Electronic patient encounters represent a quantum leap forward in legibility and the ability to rapidly retrieve information. Almost every industry is now computerized and digitized for rapid data retrieval and trend analysis. Look at the stock market or companies like Walmart or Federal Express. Why not the field of medicine?

Figure 4.2: Outpatient paper-based patient encounter form



With the relatively recent healthcare models of pay-for-performance, patient centered medical home model and accountable care organizations there are new reasons to embrace technology in

order to aggregate and report results in order to receive reimbursement. It is much easier to retrieve and track patient data using EHRs and patient registries than to use labor intensive paper chart reviews. EHRs are much better organized than paper charts, allowing for faster retrieval of lab or x-ray results. It is also likely that EHRs will have an electronic problem summary list that outlines a patient’s major illnesses, surgeries, allergies and medications. How many times does a physician open a large paper chart, only to have loose lab results fall out? How many times does a physician re-order a test because the results or the chart is missing? It is important to note that paper charts are missing as much as 25% of the time, according to one study.¹⁰ Even if the chart is available; specifics are missing in 13.6% of patient encounters, according to another study.¹¹

Table 4.1 shows the types of missing information and its frequency. According to the President’s Information Technology Advisory Committee, 20% of laboratory tests are re-ordered because previous studies are not accessible.¹² This statistic has great patient safety, productivity and financial implications.

Table 4.1: Types and frequencies of missing information

Information Missing During Patient Visits	% Visits
Lab results	45%
Letters/dictations	39%
Radiology results	28%
History and physical exams	27%
Pathology results	15%

EHRs allow easy navigation through the entire medical history of a patient. Instead of *pulling paper chart volume 1 of 3* to search for a lab result, it is simply a matter of a few mouse clicks.

Another important advantage is the fact that the record is available 24 hours a day, seven days a week and doesn't require an employee to pull the chart, nor extra space to store it. Adoption of electronic health records has saved money by decreasing full time equivalents (FTEs) and converting records rooms into more productive space, such as exam rooms. Importantly, electronic health records are accessible to multiple healthcare workers at the same time, at multiple locations. While a billing clerk is looking at the electronic chart, the primary care physician and a specialist can be analyzing clinical information simultaneously. Moreover, patient information should be available to physicians on call so they can review records on patients who are not in their panel. Furthermore, it is believed that electronic health records improve the level of coding. Do clinicians routinely submit a lower level of care for billing purposes because they know that handwritten patient notes are short and incomplete? Templates may help remind clinicians to add more history or details of the physical exam, thus justifying a higher level of coding (templates are disease specific electronic forms that essentially allow a user to point and click a history and physical exam). A study of the impact of an EHR on the completeness of clinical histories in a labor and delivery unit demonstrated improved documentation, compared to prior paper-based histories.¹³ Lastly, EHRs provide clinical decision support such as alerts and reminders, which will be covered later in this chapter.

Need for Improved Efficiency and Productivity

The goal is to have patient information available to anyone who needs it, when they need it and where they need it. With an EHR, lab results can be retrieved much more rapidly, thus saving time and money. It should be pointed out however, that reducing duplicated tests benefits the payers and patients and not clinicians so there is a misalignment of incentives. Moreover, an early study using computerized order entry showed that simply displaying past results

reduced duplication and the cost of testing by only 13%.¹⁴ If lab or x-ray results are frequently missing, the implication is that they need to be repeated which adds to this country's staggering healthcare bill. The same could be said for duplicate prescriptions. It is estimated that 31% of the United States \$2.3 trillion dollar healthcare bill is for administration.¹⁵ EHRs are more efficient because they reduce redundant paperwork and have the capability of interfacing with a billing program that submits claims electronically. Consider what it takes to simply get the results of a lab test back to a patient using the old system. This might involve a front office clerk, a nurse and a physician. The end result is frequently placing the patient on hold or playing *telephone tag*. With an EHR, lab results can be forwarded via secure messaging or available for viewing via a portal. Electronic health records can help with productivity if templates are used judiciously. As noted, they allow for point and click histories and physical exams that in some cases may save time. Embedded clinical decision support is one of the newest features of a comprehensive EHR. Clinical practice guidelines, linked educational content and patient handouts can be part of the EHR. This may permit finding the answer to a medical question while the patient is still in the exam room. Several EHR companies also offer a centralized area for all physician approvals and signatures of lab work, prescriptions, etc. This should improve work flow by avoiding the need to pull multiple charts or enter multiple EHR modules. Although EHRs appear to improve overall office productivity, they commonly increase the work of clinicians, particularly with regard to data entry. We'll discuss this further in the Loss of Productivity section.

Quality of Care and Patient Safety

As previously suggested, an EHR should improve patient safety through many mechanisms: (1) Improved legibility of clinical notes, (2) Improved access anytime and anywhere, (3) Reduced duplication, (4) Reminders that tests or preventive services are overdue, (5) Clinical decision support that

reminds clinicians about patient allergies, correct dosage of drugs, etc., (6) Electronic problem summary lists provide diagnoses, allergies and surgeries at a glance. In spite of the before mentioned benefits, a study by Garrido of quality process measures before and after implementation of a widespread EHR in the Kaiser Permanente system, failed to show improvement.¹⁶

To date there has only been one study published the authors are aware of that suggested use of an EHR decreased mortality. This particular EHR had a disease management module designed specifically for renal dialysis patients that could provide more specific medical guidelines and better data mining to potentially improve medical care. The study suggested that mortality was lower compared to a pre-implementation period and compared to a national renal dialysis registry.¹⁷

It is likely that healthcare is only starting to see the impact of EHRs on quality. Based on internal data Kaiser Permanente determined that the drug Vioxx had an increased risk of cardiovascular events before that information was published based on its own internal data.¹⁸ Similarly, within 90 minutes of learning of the withdrawal of Vioxx from the market, the Cleveland Clinic queried its EHR to see which patients were on the drug. Within seven hours they deactivated prescriptions and notified clinicians via e-mail.¹⁹

Quality reports are far easier to generate with an EHR compared to a paper chart that requires a chart review. Quality reports can also be generated from a data warehouse or health information organization that receives data from an EHR and other sources.²⁰ Quality reports are the backbone for healthcare reform which are discussed further in another chapter.

Public Expectations

According to a 2006 Harris Interactive Poll for the Wall Street Journal Online, 55% of adults thought an EHR would decrease medical errors; 60% thought an EHR would reduce healthcare costs and 54% thought that the use of an EHR

would influence their decision about selecting a personal physician.²¹ The Center for Health Information Technology would argue that EHR adoption results in better customer satisfaction through fewer lost charts, faster refills and improved delivery of patient educational material.²² Patient portals that are part of EHRs are likely to be a source of patient satisfaction as they allow patients access to their records with multiple other functionalities such as online appointing, medication renewals, etc.

Governmental Expectations

EHRs are considered by the federal government to be transformational and integral to healthcare reform. As a result, EHR reimbursement is a major focal point of the HITECH Act. It is the goal of the US Government to have an interoperable electronic health record by 2014. In addition to federal government support, states and payers have initiatives to encourage EHR adoption. Many organizations state that healthcare needs to move from the *cow path* to the *information highway*. CMS is acutely aware of the potential benefits of EHRs to help coordinate and improve disease management in older patients.

Financial Savings

The Center for Information Technology Leadership (CITL) has suggested that ambulatory EHRs would save \$44 billion yearly and eliminate more than \$10 in rejected claims per patient per outpatient visit. This organization concluded that not only would there be savings from eliminated chart rooms and record clerks; there would be a reduction in the need for transcription. There would also be fewer callbacks from pharmacists with electronic prescribing. It is likely that copying, faxing and mail expenses, chart pulls and labor costs would be reduced with EHRs, thus saving full time equivalents (FTEs). More rapid retrieval of lab and x-ray reports results in time/labor saving as does the use of templates. It appears that part of the savings is from improved coding. More efficient patient encounters mean more patients

could be seen each day. Improved savings to payers from medication management is possible with reminders to use the *drug of choice* and generics. It should be noted that this optimistic financial projection assumed widespread EHR adoption, health information exchange, interoperability and change in workflow.²³

EHRs should reduce the cost of transcription if clinicians switch to speech recognition and/or template use. Because of structured documentation with templates, they may also improve the coding and billing of claims.

It is not known if EHR adoption will decrease malpractice, hence saving physician and hospital costs. A 2007 Survey by the Medical Records Institute of 115 practices involving 27 specialties showed that 20% of malpractice carriers offered a discount for having an EHR in place. Of those physicians who had a malpractice case in which documentation was based on an EHR, 55% said the EHR was helpful.²⁴

Technological Advances

The timing seems to be right for electronic records partly because the technology has evolved. The internet and World Wide Web make the application service provider (ASP) concept for an electronic health record possible. An ASP option means that the EHR software and patient data reside on a remote web server that users can access via the internet from the office, hospital or home. Computer speed, memory and bandwidth have advanced such that digital imaging is also a reality, so images can be part of an EHR system. Personal computers (PCs), laptops and tablets continue to add features and improve speed and memory while purchase costs drop. Wireless and mobile technologies permit access to the hospital information system, the electronic health record and the internet using a variety of mobile technologies. The chapter on health information exchange will point out that health information organizations can link EHRs together via a web-based exchange, in order to share information and services.

Need for Aggregated Data

In order to make evidence based decisions, clinicians need high quality data that should derive from multiple sources: inpatient and outpatient care, acute and chronic care settings, urban and rural care and populations at risk. This can only be accomplished with electronic health records and discrete structured data. Moreover, healthcare data needs to be combined or aggregated to achieve statistical significance. Although most primary care is delivered by small practices, it is difficult to study because of relatively small patient populations, making aggregation necessary.²⁵ For large healthcare organizations, there will be an avalanche of data generated from widespread EHR adoption resulting in “big data” requiring new data analytic tools.

Need for Integrated Data

Paper health records are standalone, lacking the ability to integrate with other paper forms or information. The ability to integrate health records with a variety of other services and information and to share the information is critical to the future of healthcare reform. Digital, unlike paper-based healthcare information can be integrated with multiple internal and external applications:

- Ability to integrate for sharing with health information organizations (another chapter)
- Ability to integrate with analytical software for data mining to examine optimal treatments, etc.
- Ability to integrate with genomic data as part of the electronic record. Many organizations have begun this journey. There is more information in the chapter on bioinformatics²⁶
- Ability to integrate with local, state and federal governments for quality reporting and public health issues
- Ability to integrate with algorithms and artificial intelligence. Researchers from the Mayo Clinic were able to extract Charlson

Comorbidity determinations from EHRs, instead of having to conduct manual chart reviews²⁷

EHR as a Transformational Tool

It is widely agreed that US Healthcare needs reform in multiple areas. To modernize its infrastructure healthcare would need to have widespread adoption of EHRs. Large organizations such as the Veterans Health Administration and Kaiser Permanente use robust EHRs (VistA and Epic) that generate enough data to change the practice of medicine. In 2009 Kaiser Permanente reported two studies, one pertaining to the management of bone disease (osteoporosis) and the other chronic kidney disease. They were able to show that with their EHR they could focus on patients at risk and use all of the tools available to improve disease management and population health.²⁸⁻²⁹ In another study reported in 2009 Kaiser-Permanente reported that electronic visits that are part of the electronic health record system were likely responsible for a 26.2% decrease in office visits over a four year period. They posited that this was good news for a system that aligns incentives with quality, regardless whether the visit was virtual or face-to-face.³⁰ Other fee-for-service organizations might find this alarming if office visits decreased and e-visits were not reimbursed. Kaiser also touts a total joint registry of over 100,000 patients with data generated from its universal EHR. As a result of their comprehensive EHR (KP HealthConnect) and visionary leadership they have seen improvement in standardization of care, care coordination and population health. They also have been able to experience advanced EHR data analytics with their Virtual Data Warehouse, use of artificial intelligence and use of computerized simulation models (Archimedes). In addition they have begun the process of collecting genomic information for future linking to their electronic records.³¹⁻³²

Need for Coordinated Care

According to a Gallup poll it is very common for older patients to have more than one physician: no physician (3%), one physician (16%), two physicians (26%), three physicians (23%), four physicians (15%), five physicians (6%) and six or more physicians (11%).³³

Having more than one physician mandates good communication between the primary care physician, the specialist and the patient. This becomes even more of an issue when different healthcare systems are involved. O'Malley et al. surveyed 12 medical practices and found that in-office coordination was improved by EHRs but the technology was not mature enough to improve coordination of care with external physicians.³⁴ Electronic health records are being integrated with health information organizations (HIOs) so that inpatient and outpatient patient-related information can be accessed and shared, thus improving communication between disparate healthcare entities. Home monitoring (telehomecare) can transmit patient data from home to an office's EHR also assisting in the coordination of care. It will be pointed out in a later section that coordination of care across multiple medical transitions is part of Meaningful Use.

Institute of Medicine's Vision for EHRs

The history and significance of the Institute of Medicine (IOM) is detailed in chapter 1. They have published multiple books and monographs on the direction US Medicine should take, including *The Computer-Based Patient Record: An Essential Technology for Health Care*. This visionary work was originally published in 1991 and was revised in 1997 and 2000.⁶ In this book and their most recent work *Key Capabilities of an Electronic Health Record System: Letter Report* (2003) they outline eight core functions all EHRs should have:

- Health information and data: In order for the medical profession to make evidence based decisions, clinicians need a lot of accurate data and this is accomplished much

better with EHRs than paper charts; *if you can't measure it, you can't manage it.*

- **Result management:** Physicians should not have to search for lab, x-ray and consult results. Quick access saves time and money and prevents redundancy and improves care coordination.
- **Order management:** CPOE should reduce order errors from illegibility for medications, lab tests and ancillary services and standardize care.
- **Decision support:** Should improve overall medical care quality by providing alerts and reminders.
- **Electronic communication and connectivity:** Communication among disparate partners is essential and should include all tools such as secure messaging, text messaging, web portals, health information exchange, etc.
- **Patient support:** Recognizes the growing role of the internet for patient education as well as home telemonitoring.
- **Administrative processes and reporting:** Electronic scheduling, electronic claims submission, eligibility verification, automated drug recall messages, automated identification of patients for research and artificial intelligence can speed administrative processes.
- **Reporting and population health:** Healthcare needs to move from paper-based reporting of immunization status and biosurveillance data to an electronic format to improve speed and accuracy.³⁵

Electronic Health Record Key Components

Many current EHRs have more functionality than the eight core functions recommended by IOM and this will increase as time goes by. The following components are desirable in any EHR system. One of the advantages of certification for Meaningful Use is that it helped standardize what features were important. The following are features found in most current EHRs:

- Clinical decision support systems (CDSS) to include alerts, reminders and clinical practice guidelines. CDSS is associated with computerized physician order entry (CPOE). This will be discussed in more detail in this chapter and the patient safety chapter.
- Secure messaging (e-mail) for communication between patients and office staff and among office staff. EHRs will likely include messaging that is part of the Direct Project, explained in the chapter on health information exchange. Telephone triage capability is important.
- An interface with practice management software, scheduling software and patient portal (if present). This feature will handle billing and benefits determination. This will be discussed further in another section.
- Managed care module for physician and site profiling. This includes the ability to track Health plan Employer Data and Information Set (HEDIS) or similar measurements and basic cost analyses.
- Referral management feature
- Retrieval of lab and x-ray reports electronically
- Retrieval of prior encounters and medication history
- Computerized Physician Order Entry (CPOE). Primarily used for inpatient order entry but ambulatory CPOE also important. This will be discussed in more detail later in this chapter.
- Electronic patient encounter. One of the most attractive features is the ability to create and store a patient encounter electronically. In seconds one can view the last encounter and determine what treatment was rendered.
- Multiple ways to input information into the encounter should be available: free text (typing), dictation, voice recognition and templates.
- The ability to input or access information via a smartphone or tablet PC
- Remote access from the office, hospital or home

- Electronic prescribing discussed in a section to follow
- Integration with a picture archiving and communication system (PACS), discussed in a separate chapter
- Knowledge resources for physician and patient, embedded or linked
- Public health reporting and tracking
- Ability to generate quality reports for reimbursement, discussed in the chapter on quality improvement strategies
- Problem summary list that is customizable and includes the major aspects of care: diagnoses, allergies, surgeries and medications. Also, the ability to label the problems as acute or chronic, active or inactive. Information should be coded with ICD-9/10 or SNOMED CT so it is structured data.
- Ability to scan in text or use optical character recognition (OCR)
- Ability to perform evaluation and management (E & M) determination for billing
- Ability to create graphs or flow sheets of lab results or vital signs
- Ability to create electronic patient lists and disease registries. Discussed in more detail in the chapter on disease management
- Preventive medicine tracking that links to clinical practice guidelines
- Security and privacy compliance with HIPAA standards
- Robust backup systems
- Ability to generate a Continuity of Care Document (CCD) or Continuity of Care Record (CCR), discussed in the data standards chapter
- Support for client server and/or application service provider (ASP) option³⁶

Computerized Physician Order Entry (CPOE)

CPOE is an EHR feature that processes orders for medications, lab tests, imaging, consults and other diagnostic tests. The majority of articles

written about CPOE have discussed medication ordering only, possibly giving readers the impression that CPOE is the same as electronic prescribing. The reality is that CPOE has a great deal more functionality as will be pointed out later in this and other chapters. Many organizations such as the Institute of Medicine and Leapfrog see CPOE as a powerful instrument of change. There is limited evidence that CPOE will reduce medication errors, cost and variation of care. This is discussed in the following sections.

Reduce Medication Errors

CPOE has the potential to reduce medication errors through a variety of mechanisms.³⁷ Because the process is electronic, users can embed rules (clinical decision support) that check for allergies, contraindications and other alerts. Koppel et al. lists the following advantages of CPOE compared to paper-based systems for patient safety: overcomes the issue of illegibility, fewer errors associated with ordering drugs with similar names, more easily integrated with decision support systems than paper, easily linked to drug-drug interaction warning, more likely to identify the prescribing physician, able to link to adverse drug event (ADE) reporting systems, able to avoid medication errors like trailing zeroes, creates data that is available for analysis, can point out treatment and drugs of choice, can reduce under and over-prescribing, prescriptions reach the pharmacy quicker.³⁸

Inpatient CPOE: This functionality was recommended by the IOM in 1991. Most studies so far have looked primarily at inpatient CPOE and not ambulatory CPOE. A 1998 study by David Bates in JAMA showed that CPOE can decrease serious inpatient medication errors by 55% (relative risk reduction). This frequently cited article did not show reduction of potential adverse drug events (ADEs), however.³⁹ Many of the studies showing reductions in medication errors by the use of technology were reported by a limited number of academic institutions with a home grown EHR and robust technology support. Other hospital systems with

commercial EHRs are unlikely to experience the same optimistic results. A 2008 systematic review of CPOE with CDSS by Wolfstadt et al. only found 10 studies of high quality and those dealt primarily with inpatients. Only half of the studies were able to show a statistically significant decrease in medication errors, none were randomized and seven were homegrown systems, so results are difficult to generalize.⁴⁰

With the inception of CPOE new errors that result from technology have arisen. A 2005 article reported that the mortality rate increased 2.8%-6.5% after implementing a well-known EHR.⁴¹ In a 2006 article, also from a children's hospital implementing the same EHR, they found no increase in mortality; perhaps due to better planning and implementation. One of the authors stated that the CPOE system eliminated handwriting errors, improved medication turnaround time and helped standardize care.⁴² Nebeker reported on substantial ADEs at a VA hospital following the adoption of CPOE that lacked full decision support, such as medication alerts.⁴³ On the other hand, another inpatient study showed a reduction in preventable ADEs (46 vs. 26) and potential ADEs (94 vs. 35) compared to pre-EHR statistics.⁴⁴ To summarize, clinicians and staff must be properly trained in CPOE; otherwise errors will likely increase, at least in the short term.

Outpatient CPOE: Americans made 906.5 million outpatient visits in the year 2000. By sheer numbers there is more of a chance for a medication error written for outpatients. According to an optimistic report by the Center for Information Technology Leadership, adoption of an ambulatory CPOE system (ACPOE) will likely eliminate about 2.1 million ADEs per year in the USA. This could potentially prevent 1.3 million ADE-related visits, 190,000 hospitalizations and more than 136,000 life-threatening ADEs.²³ However, a systematic review by Eslami was not as optimistic as he concluded that only one of four studies demonstrated reduced ADEs and only three of five studies showed decreased medical costs. Most showed improved guideline compliance, but it took longer to electronically

prescribe and there was a high frequency of ignored alerts (alert fatigue).⁴⁵ Kuo et al. reported medication errors from primary care settings. He concluded that 70% of medication errors were related to prescribing and that 57% of errors might have been prevented by electronic prescribing.⁴⁶

Reduce Costs

Several studies have shown reduced length of stay and overall costs in addition to decreased medication costs with the use of CPOE.⁴⁷ Tierney was able to show in 1993 an average savings of \$887 per admission when orders were written using guidelines and reminders, compared to paper-based ordering that was not associated with clinical decision support.⁴⁸

Reduce Variation of Care

One study showed excellent compliance by the medical staff when the drug of choice was changed using decision support reminders.⁴⁹ Study conclusions should be interpreted with some note of caution. Many of the studies were conducted at medical centers with well-established health informatics programs where the acceptance level of new technology was unusually high. Several of these institutions such as Brigham and Women's Hospital developed their own EHR and CPOE software. Compare this experience with that of a rural hospital trying CPOE for the first time with potentially inadequate IT, financial and leadership support. It is likely that smaller and more rural hospitals and offices will have a steep learning curve.

On the surface CPOE seems easy, just replace paper orders with an electronic format. The reality is that CPOE represents a significant change in work flow and not just new technology. An often repeated phrase is "*it's not about the software, dummy,*" meaning, regardless which software program is purchased, it requires change in work flow and extensive training.

Adoption of CPOE has been slow, partly because of cost and partly because inputting is slower than scribbling on paper.⁵⁰ Although physicians have been upset by new changes that do not shorten their work day, many authorities feel EHRs greatly improve numerous hospital functions. There has been less resistance traditionally in teaching hospitals with a track record of good informatics support. Also, young house staff who work in teaching hospitals and who write the majority of orders are more likely to be tech savvy and amenable to change. It does require great forethought, leadership, planning, training and the use of physician champions in order for CPOE to work. According to some, CPOE should be the last module of an EHR to be turned on and alerts should be phased in to bring about change more gradually. Others have recognized nurses as more accepting of change and willing to teach docs *one-on-one* on the wards.

For more information on CPOE readers are referred to a monograph “A Primer on Physician Order Entry” and an article “CPOE: benefits, costs and issues.”⁵¹⁻⁵²

Clinical Decision Support Systems (CDSS)

Traditionally, CDSS meant computerized drug alerts and reminders to perform preventive tests as part of computerized physician order entry (CPOE) applications. Most of the studies in the literature evaluated those two functions. However, according to Hunt, CDSS is “*any software designed to directly aid in clinical decision making in which characteristics of individual patients are matched to a computerized knowledge base for the purpose of generating patient specific assessments or recommendations that are then presented to clinicians for consideration.*”⁵³ Therefore, CDSS should have a broader definition than just alerts and reminders.

Two 2005 papers addressed the effects of CDSS on clinical care. Garg and co-authors concluded that overall, CDSS improved performance in

64% of the 97 studies but only 13% of the 52 studies analyzed reported improvement in actual patient outcomes.⁵⁴ Kawamoto et al. looked at those factors that contributed to the success of CDSS: automatic CDSS that was part of clinician work flow; recommendations and not just assessments; provision of CDSS at the point of care and computer-based CDSS (not paper-based). When these four features were present, CDSS improved clinical care about 94% of the time.⁵⁵

According to a 2009 article, clinical decision support by nine commercial EHRs was extremely variable and tended not to offer choices.⁵⁶ Clearly, the most sophisticated CDSS are developed at medical centers with home grown EHRs and a long record of extensive HIT adoption. With Meaningful Use criteria, certified EHRs will have to conform to CDSS standards which may reduce variability.

Sheridan and Thompson have discussed various levels of CDSS: (level 1) all decisions by humans, (level 2) computer offers many alternatives, (level 3) computer restricts alternatives, (level 4) computer offers only one alternative, (level 5) computer executes the alternative if the human approves, (level 6) human has a time line before computer executes, (level 7) computer executes automatically, then notifies human, (level 8) computer informs human only if requested, (level 9) computer informs human but is up to computer and (level 10) computer makes all decisions.⁵⁷ Most EHR systems may offer alternatives and provide reminders but make no decisions on their own. With artificial intelligence and natural language processing becoming more sophisticated, this could change in the future.

Table 4.2 outlines some of the clinical decision support available today. Calculators, knowledge bases and differential diagnoses programs are primarily standalone programs but they are slowly being integrated into EHR systems.

Knowledge support. Numerous digital medical resources are being integrated with EHRs. As an example, the American College of Physician’s PIER resource is integrated into

Allscript's Touch Chart.⁵⁸ The comprehensive online reference UpToDate has been integrated into six EHRs and has an option to connect to other EHRs via an API.⁵⁹ iConsult (offered by Elsevier) is a primary care information database available for integration into EHRs. Diagnostic (ICD-9) codes can be hyperlinked to further information or users can use *infobuttons*. Other products such as Dynamed, discussed in the chapter on online medical resources are available as *infobuttons*. Figure 4.3 shows an example of iConsult integrated with the Epic EHR.⁶⁰ Another interesting integrated knowledge program is the Theradoc Antibiotic Assistant. The program integrates with an inpatient EHR's lab, pharmacy and radiology sections to make suggestions as to the antibiotic of choice with multiple alerts. Clinicians can be alerted via cell phones, pagers or e-mail. Other modules include Adverse Drug Event (ADE) Assistant, Infection Control Assistant and Clinical Alerts Assistant.⁶¹ A study in the New England Journal of Medicine (NEJM) using this product showed considerable improvement in the prescription of appropriate antibiotics resulting in cost saving, reduced length of stay and fewer adverse drug events.⁶²

Table 4.2: Clinical decision support

Type of CDSS	Examples
Knowledge	iConsult®, Theradoc®
Calculators	Medcalc 3000®, eCalcs
Trending/Patient tracking	Flow sheets, graphs
Medications	CPOE and drug alerts
Order sets/protocols	CPGs and order sets
Reminders	Mammogram due
Differential diagnosis	Dxplain®
Radiology CDSS	What imaging studies to order?
Laboratory CDSS	What lab tests to order
Public health alerts	Infection disease alerts

Figure 4.3: iConsult integrated with Epic EHR (Courtesy iConsult)

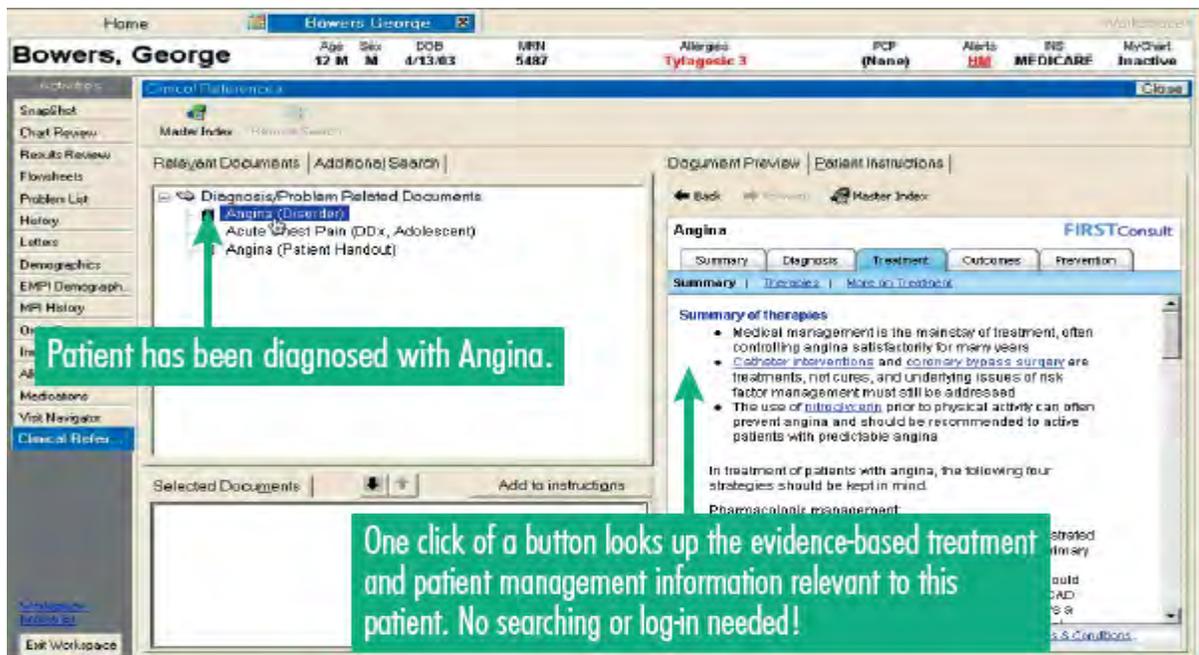


Figure 4.4: eCalcs (Courtesy eCalcs)

The screenshot displays the eCalcs application interface. At the top, there is a navigation bar with tabs for 'Daily', 'Provider Schedules', 'Appointments', 'Clinical Desktop', 'Note', and 'eCalcs'. Below this, a patient information header shows 'Test, Cardiology' and various fields: MRN: 031226095332733, Sex: M, H Phone: (802)985-0932, Alerts: No Restricted Data, DOB: 01/01/1970, Age: 42 Years, AKA: Medici, James, Allergies: Yes, Pri Ins: [Select], and FYI: [FYI].

On the left side, there is a 'Select Patient' dropdown and a list of calculation tools including ADA Diabetes Risk, Breast Cancer Risk, CAGE Alcohol Screening, CHADS2 for Risk of Stroke, Child-Pugh Score, Chron's Activity Index, Creatinine Clearance, Framingham Risk for General CVD (highlighted), Framingham Risk for Heart Attack, MELD Score for Liver Disease, PHQ, Pneumonia Severity Index, Predicted Peak Flow, Pregnancy Due Dates, and Reynolds Risk Score.

The main area displays the 'Framingham Risk for General Cardiovascular Disease' calculation. It includes input fields for Sex (Male), Age (42), Total Cholesterol (180 mg/dL), HDL Cholesterol (50 mg/dL), and Systolic BP (120 mmHg). There are checkboxes for 'Patient has diabetes' (checked), 'Patient smokes' (unchecked), and 'Being treated for hypertension' (unchecked). The results shown are: Heart/Vascular Age: 48 Years, 10 Year CVD Risk: 6.7%, and Normal 10 Year CVD Risk: 4.6%. There are 'Add to Chart' and 'Calculate' buttons.

At the bottom of the window, the status bar shows 'User: dsurrell Site: New World Health Enc Date: 12 Mar 2012 10:00 AM Enc Type: Appointment' and a 'Done' button.

Calculators. It is likely with time calculators will be embedded into all EHRs, particularly in the medication and lab ordering sections. Figure 4.4 shows a calculator program that integrates more than 30 common calculations into a commercial EHR (Allscripts). The fields are automatically calculated and results can be added to the encounter note.⁶³ Note that the figure shows a Framingham cardiovascular risk score determination. Important calculations, such as kidney function (creatinine clearance) should be calculated and available on all patients, particularly when prescribing drugs that are excreted by the kidneys or imaging contrast agents that can be toxic to the kidneys.

Flow sheets, graphs, patient lists and registries. The ability to track and trend lab results and vital signs, for example, in diabetic patients will greatly assist in their care. Furthermore, the ability to use a patient list to contact every patient taking a recalled drug will improve patient safety. Registries will be covered in more detail in the disease management chapter.

Medication ordering support. Decision support as part of CPOE possesses several rules

engines to detect known allergies, drug-drug interactions, drug-condition and drug-food allergies, as well as excessive dosages. As EHRs and CPOE mature, they will factor in age, gender, weight, kidney (renal) and liver (hepatic) function of the patient, known contraindications based on known diagnoses, as well as the pregnancy and lactation status. Incorporation of these more robust features is complicated and best implemented at medical centers with an established track record of CDSS and CPOE development. As has been pointed out, there are programs that improve antibiotic ordering based on data residing in the EHR.⁶⁴ Computerized drug alerts have obvious potential in decreasing medication errors but have not been universally successful to date. According to a systematic review by Kawamoto et al., successful alerts need to be automatic, integrated with CPOE, require a physician response and make a recommendation.⁵⁵ Four studies have been published from the Brigham and Women's Hospital showing mediocre compliance, even for black-box type warnings.⁶⁵⁻⁶⁸ An excellent review by Kuperman et al. describes basic and advanced medication-related

CDSS.⁶⁹ Further information about alerts is included in the chapter on patient safety.

Reminders. Computerized reminders that are part of the EHR assist in tracking the yearly preventive health screening measures, such as mammograms. Shea performed a meta-analysis and concluded that there was clear benefit for vaccinations, breast cancer and colorectal screening, but not cervical cancer screening.⁷⁰ A well-designed system should allow for some customization of the reminders as national recommendations change. Reminders are not always heeded by busy clinicians who may choose to ignore them. As a possible solution, preventive reminders could be reviewed by the office nurse and overdue tests ordered prior to the visit with the physician.

Order sets and protocols. Order sets are groups of pre-established inpatient orders that are related to a symptom or diagnosis. For instance, users can create an order set for pneumonia that might include the antibiotic of choice, oxygen, repeat chest x-ray, etc. that saves keystrokes and time. Order sets can also reflect best practices (clinical practice guidelines), thus offering better and less expensive care. Over one hundred clinical practice guidelines are incorporated into the electronic health record at Vanderbilt Medical Center.⁷¹ For more information on order sets readers are referred to this reference.⁷²

Differential Diagnoses. Dxpain is a differential diagnosis program developed at Massachusetts General Hospital. When clinicians input the patient's symptoms it generates a differential diagnosis (the diagnostic possibilities). The program has been in development since 1984 and is currently web-based. A licensing fee is required to use this program. At this time it cannot be integrated into an EHR.⁷³ In spite of the potential benefit, an extensive 2005 review of CDSSs revealed that only 40% of the 10 diagnostic systems studied showed benefit, in terms of improved clinician performance.⁷⁴ Artificial intelligence continues to improve so it is likely that EHRs will have the ability to assist with differential diagnosis in the future.

Radiology CDSS. Physicians, particularly those in training, may order imaging studies that are either incorrect or unnecessary. For that reason, several institutions have implemented clinical decision support to try to improve ordering. Appropriateness criteria have been established by the American College of Radiologists. Massachusetts General Hospital has had radiology order entry since 2001 and studied the addition of decision support. They noted a decline in low utility exams from 6% down to 2% as a result of decision support.⁷⁵

Laboratory CDSS. It should be no surprise that clinicians occasionally order inappropriate lab tests, for a variety of reasons. It would be helpful if clinical decision support would alert them to the indications for a test, as well as the price. A Dutch study of primary care demonstrated that 20% fewer lab tests were ordered when clinicians were alerted to lab clinical guidelines.⁷⁶

Public Health Alerts. The New York Department of Health and Mental Hygiene used Epic EHR's "Best Practice Advisory" to alert New York physicians about several infectious disease issues. The EHR-based alert also hyperlinked to disease specific order sets for educational tips, lab and medication orders.⁷⁷

How well clinicians use CDSS programs such as those discussed, remains to be seen. They will have to be intelligently designed and rigorously tested in order to be accepted. For more information on CDSS, readers are referred to the resources cited in these references.⁷⁸⁻⁸²

Electronic Prescribing

Approximately five billion prescriptions are written annually in the United States and until about 2009 the majority were still paper-based.⁸³ This trend has changed dramatically, due to increased EHR adoption; such that by the end of 2012, 87% of electronic prescribing was EHR based, 69% of office-based prescriptions were electronic and 93% of community pharmacies were connected to the Surescripts

network.⁸⁴ The potential multiple advantages of e-prescribing are as follows:

- Legible and complete prescriptions that help eliminate handwriting errors and decrease pharmacy “callbacks” and rejected scripts
- Abbreviations and unclear decimal points are avoided
- The wait to pick up prescriptions potentially is reduced
- Fewer duplicated prescriptions
- Better compliance with fewer drugs not filled or picked up
- Potential to reduce workload for pharmacists
- Timely notification of drug alerts and updates
- Better use of generic or preferred drugs
- The ability to check plan-level and patient-level formulary status and patient copays
- E-prescribing can interface with practice and drug management software.
- The process is secure and HIPAA compliant.
- It is the HIT platform for future clinical decision support, alerts and reminders. It could integrate decision support related to both disease states and medications.
- Digital records improve data analysis of prescribing habits.
- Programs offer the ability to look up drug history, drug-drug interactions, allergies and compliance.
- While entering an e-script is slower than writing a paper script, clinicians have options to speed up the process like batch refills and choosing from lists of drugs most commonly prescribed in a practice.
- Provides a single view of prescriptions from multiple clinicians

- Applications have the ability to check eligibility, co-pays and it can file drug insurance claims.
- Overall, e-prescribing is associated with reduced cost of prescribing.⁸⁵

It is not thought that simply switching from paper to electronic prescriptions will improve patient safety; it will require clinical decision support systems (CDSS) that alert and educate potential medication issues.

Perhaps the most important CDSS is the reminder that a patient has a confirmed allergy to a drug, thus preventing a potential serious reaction. It is most helpful if the actual details of the allergy are listed (e.g. Sulfa family, anaphylaxis 2012). The next important CDSS feature is drug-drug interaction determination. In elderly patients on multiple medications it is particularly important to understand the effect of one drug on another. Notification of an interaction will usually cause the prescribing physician to reduce the dose of one drug or make another safer choice. There are many other types of CDSSs that might be important associated with e-prescribing. Drug-condition/disease alerts might remind a physician that drug A is not safe in a pregnant woman. Reminders about dosages out of range (too high or too low), age or BMI extremes would be very valuable, particularly with toxic drugs such as chemotherapy medications. Reminders about duplicate drugs and drugs prescribed by other physicians are also very important.

As electronic health records become smarter by using rules engines and artificial intelligence users can expect alerts about potential prescribing problems based on liver or kidney problems and other considerations. Eventually, there may be summary alerts based on age, gender, BMI, liver/kidney function, etc., such as “This patient is at risk of drug side effects, recommend Lisinopril dose reduction by 50%.” Another example would a reminder about medications with sedating properties in the elderly.

As noted previously, the vast majority of e-prescribing now takes place as part of the electronic health record. There is evidence that e-prescribing as part of an EHR reduces medication errors but many questions remain.⁸⁶ Some of the issues with CPOE in this chapter and the chapter on patient safety have been addressed. They following are some of the issues or challenges associated with e-prescribing:

- Alerts, in general, are viewed as nuisances by physicians, unless they are very specific, highly important and are educational.⁸⁷
- One study evaluated the pharmacist's perspective and disclosed unique new e-prescribing issues: incorrect drugs, doses and patient instructions continue to occur; in spite of an electronic process prescribing delays persisted. They recommended that only clinicians forward e-prescriptions, clinical decision support should be used, scripts should be sent together (bundled); software standardization would be helpful and there should be a mechanism to message physicians about issues.⁸⁸
- A study of 3850 outpatient electronic prescriptions reported in 2011 revealed an error rate of 11.7%, with about a third having the potential to cause adverse drug events (ADEs). Two thirds of the prescribing errors were due to omissions of drug dose, instructions, etc. Actual ADEs were not reported.⁸⁹
- A qualitative study of e-prescribing was reported in 2011 and recorded some of the existing issues physicians and pharmacists are facing:⁹⁰
 - The refill process had more problems and errors than the initial new prescription process and resulted in workarounds for both physicians and pharmacies.
 - Some pharmacies don't accept electronic scripts because they don't want to pay Surescripts fees.

- Mail order pharmacies still lack consistent e-prescribing capabilities. Most of their refills are still done by fax.
- Physicians write sigs (instructions) that aren't patient friendly and pharmacists have to rewrite them.
- Physicians often receive duplicate requests from pharmacies for a variety of reasons.

Practice Management Integration

Most medical offices have had computerized practice management (PM) systems for many years, regardless of whether that office maintains paper medical records, electronic health records (EHRs) or a hybrid of these two. As will be pointed out, there are many reasons why PM systems have become so prevalent but one of the main reasons is for more rapid claims submission and adjudication. Without an electronic system, time and money would be lost on faxes, phone calls and snail mail. The American Medical Association estimated that inefficient claims submission systems lead to about \$210 billion annually in unnecessary costs.⁹¹ A PM system is designed to capture all of the data from a patient encounter necessary to obtain reimbursement for the services provided. This data is then used to:

- Generate claims to seek reimbursement from healthcare payers
- Apply payments and denials
- Generate patient statements for any balance that is the patient's responsibility
- Generate business correspondence
- Build databases for practice and referring physicians, payers, patient demographics and patient encounter transactions (i.e., date, diagnosis codes, procedure codes, amount charged, amount paid, date paid, billing messages, place and type of service codes, etc.)

Additionally, a PM system provides routine and ad hoc reports so that an administrator can

analyze the trends for a given practice and implement performance improvement strategies based on the findings. For example, a medical office administrator is able to use the PM system to compare and contrast different payers with regards to the amount reimbursed for each given service or the turnaround time between claims submission and payment. The results lead to deciding which managed care plans the practice will participate in versus those plans that the practice may want to consider not accepting in the future. Another example is to analyze all payers for a given service performed in the practice to determine if that service is a good use of the practice's clinical time. This analysis provides one aspect of whether or not the practice should consider continuing to offer a certain service such as case management of a patient who is receiving home health services through an agency. Of course, the administrator has to weigh services that aren't profitable against any negative impact on overall patient satisfaction but the PM system provides a means of analyzing payment performance.

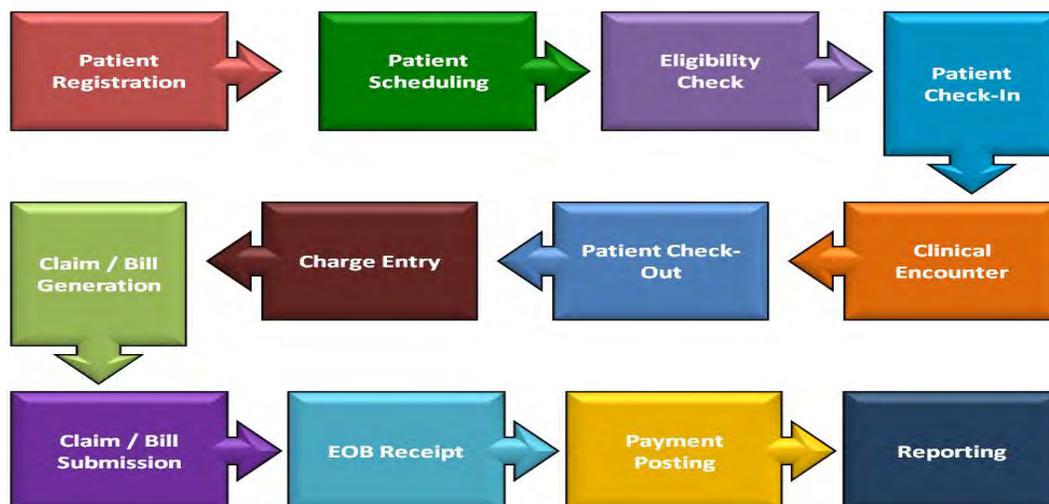
Most PM systems also offer patient scheduling software that further increases the efficiency of the business aspects of a medical practice. Finally, some PM systems offer an encoder to assist the coder in selecting and sequencing the correct diagnosis (International Classification of Diseases, Current revision, clinically modified for use in the United States, or ICD-XX-CM) and

procedure (Current Procedural Terminology, fourth edition or CPT-4® and Healthcare Common Procedure Coding System or HCPCS) codes. Even when a physician determines the appropriate codes using a *superbill*, (a list of the common codes used in that practice along with the amount charged for each procedure), there are times when a diagnosis or procedure is not listed on the superbill and an encoder makes it efficient to do a search based on the main terms and select the best code. Furthermore, some encoders are packaged with tools such as a subscription to a newsletter published by the American Medical Association (AMA) known as "CPT® Assistant" that help the practice comply with correct coding initiatives which in turn optimize the reimbursement to which the practice is legally and ethically entitled and avoids fraud or abuse fines for improper coding.

Clinical and Administrative Workflow in a Medical Office

Several steps are common to almost any medical practice with regards to treating patients and getting reimbursed properly for the services provided. The steps are subdivided based on whether or not the patient has been to this practice previously for any type of service. The first step is to get the patient registered. This can be accomplished via a practice website or by the patient calling the office to schedule an appointment. Figure 4.5 demonstrates typical outpatient office workflow.

Figure 4.5: Typical Outpatient office workflow (EOB = explanation of benefits)



Patient Registration. This step includes obtaining demographic information, including any healthcare plan or plans the patient has and establishing which member of the patient's household is financially responsible for any balances due either at the time of the visit or after claims adjudication by any healthcare payer(s) the practice agrees to bill for the patient.

Patient Scheduling. The patient is then scheduled for an appointment. If the patient had a previous encounter with the physician, the office receptionist simply has to update any changes to the patient information already on file.

Eligibility Check. For a new patient the insurance information must be verified to ensure that the patient is currently covered by a plan accepted by the practice and the planned services are a covered benefit. If not, the patient must be notified in advance of the visit to determine if they are willing to accept full financial responsibility for the services (i.e. full payment then attempt to get reimbursement from their healthcare plan on their own) or cancel the appointment and find a participating physician. If a practice offers web-based patient registration, there are some choices ranging from designing the website and all applicable online forms internally to contracting with a forms services company. Based on the amount of money the practice is willing to spend, a forms company offers basic forms design for use on the practice's own website. Alternately, they can subcontract to use the company's server and website for forms design, updating, processing and transmitting information to the practice's EHR or PM system. See Medical Web Office services for a sample range of forms and communications services available for medical practices.⁹²

Patient Check-In. The patient checks in for the scheduled visit. If already established with the practice the receptionist simply verifies/updates the patient information. If the patient is new, and the data gathered to schedule an appointment was obtained via telephone, the patient is asked to complete a registration form

and provide a copy of his or her insurance card(s). Any information not previously obtained is keyed into the computer system for use by the PM system and the source document is added to the paper medical record, if applicable. Scanning the information is an option with an EHR. Most practices that have a PM system that is integrated with an EHR can scan the documents (including bubble sheets completed by the patient at time of registration) into the system once and the information is posted to the appropriate places in both the EHR and the PM system. Sometimes the data that is used by both the EHR and the PM software, such as patient name, is saved to a common database in an integrated system. At other times, however, the shared data is communicated electronically between the EHR and the PM system even though the databases are separate. It is important to know that when the systems have a shared database, this database only contains the part of the clinical record that is used to obtain reimbursement such as the patient demographics, diagnoses and procedures, dates of service, etc. However, the purely financial information is only found in the PM system – such as amount billed and amount paid or information about health plans. This is because it is not advisable to combine the business aspects of health information with clinical aspects. What procedure is done on a given date and the diagnosis that justifies the medical necessity of a procedure is both clinical and financial but how much the procedure costs and how much the patient paid out-of-pocket, etc., is purely financial.

Clinical Encounter. The patient is generally first seen by a nurse or medical assistant, to have vitals taken, collect blood and urine samples, if needed, and update the patient's subjective history. The patient is then examined by the physician who takes additional history and completes the objective physical exam and updates the clinical notes in SOAP order – Subjective, Objective, Assessment and Plan. In a paper system, the physician dictates either during the visit or as soon afterward as possible and a transcriptionist creates a paper copy of the notes. Alternately, some physicians use voice

recognition technology to dictate directly into a laptop or other device then print out the report generated by the software to file in the paper record.

As discussed previously, in an EHR system clinicians have several options for inputting patient information into the clinical record. They can use voice recognition software, standard dictation or templates. Therefore, when the physician is face-to-face with the patient, the EHR would have already been started for that encounter by a nurse or other physician extender who would have entered the patient's chief complaint, vital signs and possibly any updates to the patient's subjective history (the subjective portion of the SOAP note).

The physician will continue building the encounter notes by using a series of drop-down menus to indicate body systems examined, tests performed, tests or prescriptions ordered, (the objective portion of the SOAP note), the assessment and the plan. Each selection made by the physician adds to the clinical notes. Clinical notes are a good example of data that is maintained in the EHR but not shared with a PM system. However, EHRs that use computer assisted coding (CAC) technology can convert the standardized notes into codes and the codes are used by both the EHR and the PM system. For example, many EHRs can run the office notes through logic to assign CPT evaluation and management (E&M) codes based on either the 1995 or 1997 guidelines. The EHR system can pass these codes plus many ICD-XX-CM codes over to integrated (same vendor) or interfaced (different vendors) PM system when the systems are compatible. The physician concludes the clinical aspects of the encounter by giving the patient discharge/follow-up instructions and patient education literature. Any lab samples are sent to the lab and, if the patient needs a prescription and the practice uses e-prescribing, a prescription is sent from the EHR to the pharmacy electronically or via Fax. If not, the patient is given a paper copy of the prescription.

Patient Check-Out. The patient is discharged after a receptionist collects any money due and schedules any follow-up visits. If the practice

has chosen this feature, the EHR can interface with the PM system scheduler so the physician can schedule a follow-up visit and the patient can take home a printout of the office notes, any education material, the next appointment, plus a paper copy of physician orders or prescriptions for facilities not linked with the EHR.

Charge Entry Claims-Bill Generation. In a standalone PM system, the charges are entered, often from a superbill but sometimes the services are coded from the information in the medical record. In an integrated PM with EHR system, the information needed is sent directly from the EHR to the PM system and a claim is built as described above. However, a person responsible for correct coding and billing must still verify that all applicable codes were brought over to the PM system, add any codes that the system did not assign automatically and scrub codes which means to link the diagnoses to the correct procedures that justify medical necessity and check for obvious errors in order to get them ready to submit as claims to payers.

Claims-Bill Submission. The claims are sent electronically in all but rare cases but they are sent in cycles so once the PM system is updated, the claim is in queue waiting for transmission to a clearinghouse or directly to the payer, such as Medicare.

Remittance Advice (RA) and Explanation of Benefits (EOB) Receipt. Once the claim is sent, the payer electronically (again, there are some exceptions in which the practice will actually get a paper check in the mail) sends a remittance advice (RA) containing the details for each charge paid or denied in that cycle. The RA contains an EOB (payments, denials, denial reason, reduced payments and reasons, patient responsibility, whether or not the claim was sent automatically to a secondary payer, etc.) for each charge by patient.

Payment Posting. The money is electronically deposited into the practice's account. The payer generally mails a paper copy of each individual explanation of benefits to the patient. Billing personnel also have to follow-up when a person has more than one payer, to determine that the

claim was transmitted to the appropriate secondary payer. If there is still a balance after the biller has applied payments and written off any charges in excess of the allowed amount for a particular payer, the system moves the balance into a queue to await patient billing. The biller is also responsible for tracking claims and initiating the collections process if a balance due by the patient is not paid in a timely fashion.

Reporting. Daily reports are run and verified to ensure deposits match, all patients who were seen that day have charges in the system, etc. There are both routine reports (daily, weekly, monthly and end-of-year) and ad hoc reports used by the practice.

Electronic Health Record Adoption

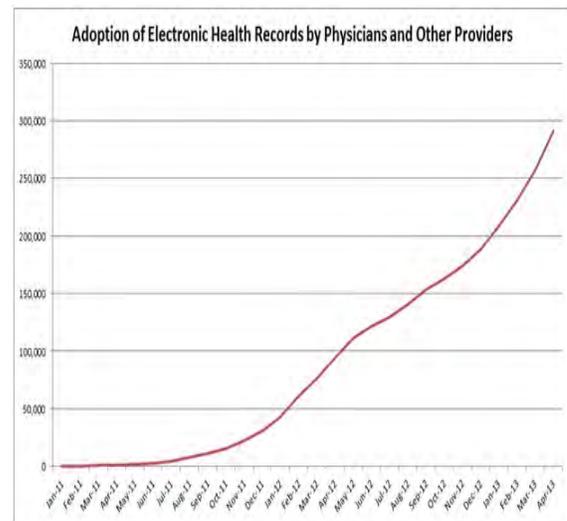
Outpatient (Ambulatory) EHR Adoption

In 2006 the adoption rate of ambulatory EHRs was reported to be in the 10% to 20% range, depending on which study is read and what group was studied.⁹³ Many of the commonly quoted statistics came from surveys, with their obvious shortcomings. It is also important to realize that many outpatient practices may have EHRs but continue to run dual paper and electronic systems or may use only part of the EHR. Furthermore, a significant concern is that small and/or rural practices are more likely to lack the finances and information technology support to purchase and implement EHRs.

In 2008, a seminal article reported on the adoption rate of outpatient EHRs. In this study a sample of 5000 physicians was selected from the AMA master file but Osteopaths, residents and federal physicians were excluded. The most significant finding was that only 4% of respondents reported using a comprehensive EHR (order entry capability and decision support), whereas 13% reported using a basic

EHR system. As has been reported before, the adoption rate was higher for large medical groups or medical centers. Responding physicians did report multiple beneficial effects of using EHRs.⁹⁴ The National Ambulatory Medical Care Survey (2012) reported that 72% of office-based respondents had an EHR, compared to 48% reported in 2009. The percentage varied by state from a low of 54% to a high of 89%.⁹⁵ Figure 4.6 shows HHS statistics for EHR adoption by physicians as of April 2013.⁹⁶

Figure 4.6: EHR Adoption by physicians in the United States (Courtesy HHS Press Office)



Adoption of an EHR does not necessarily indicate that the end-user is using the advanced capabilities of an EHR, as indicated in Figure 4.7 from HIMSS Analytics. HIMSS looked at data from over 5,000 US hospitals to determine the actual level of EHR adoption by stages of cumulative capabilities. In the first quarter of 2013, only 1.9% of hospitals surveyed had a complete EHR capable of CCD transactions, data warehousing and data continuity. The results indicate that very few hospital systems have achieved an advanced level of EHR sophistication.⁹⁷

Figure 4.7: US Ambulatory EMR Adoption Model (Courtesy HIMSS Analytics)

US Ambulatory EMR Adoption Model SM		
Stage	Cumulative Capabilities	2013 Q1
Stage 7	HIE, data sharing with community based EHR, robust business and clinical intelligence	0.96%
Stage 6	Advanced CDS, proactive care management, population health management	1.2%
Stage 5	Patient engagement	5.17%
Stage 4	CPOE, physician documentation with CDS, external data exchange	0.69%
Stage 3	E-prescribing, nursing documentation, medication reconciliation, CDS	10.06%
Stage 2	CDR, access to results from outside facilities	27.67%
Stage 1	Access to clinical information, unstructured data, multiple data sources	4.51%
Stage 0	Paper chart based	49.75%

Data from HIMSS Analytics Database ©2013

N =
18,318

Inpatient EHR Adoption

In 2009 a study showed that 7.6% of the respondents reported a basic EHR system and only 1.5% reported a comprehensive EHR. Again, large urban and/or academic centers had the highest adoption rates. User satisfaction rates were not reported.⁹⁸ The Office of the National Coordinator reported on EHR adoption to meet meaningful use and noted that as of 2012 there was a lot of progress. Specifically, of 24 meaningful use objectives examined, 16 had adoption rates of at least 80%.⁹⁹

As anticipated, EHR adoption by rural or small non-teaching hospitals continues to be lower than by larger, urban hospitals and academic medical centers.¹⁰⁰

International EHR Adoption

Until recently, the US lagged behind many other developed countries in its adoption of EHRs. In fact, a 2006 study indicated the US were as much as a dozen years behind other industrialized countries in HIT adoption.¹⁰¹ A 2009 study showed that the US continued to lag in EHR adoption among primary care physicians in developed countries.¹⁰² A 2012 survey of the same countries demonstrated increases in the United States, from 46 to 69 percent and an increase in Canada from 37 to 56 percent.

However, many of the EHR systems were basic so that the percent adoption of “multi-functional” EHRs is considerably lower, particularly in small medical practices.¹⁰³ A major difference between the US and these high EHR adopter countries has been, until recently, the degree of government involvement. Other countries’ governments invested heavily in HIT. The United Kingdom, with 20% of the population of the US, committed \$17 billion through its National Program for IT (NPfIT). Australia has provided subsidies to adopting physicians and has the National E-Health Transition Authority (NEHTA). Germany has a public-private partnership involved in promoting interoperability standards and certifying EHRs called Gematik. Denmark, long thought to be the international leader in health IT, has a very high EHR adoption rate and the most interoperable system of any country.¹⁰⁴

All is not wonderful in other countries however. In 2011 UK officials announced that they planned to dismantle their \$17 billion health IT project. They stated that some of the nearly \$10 billion that they had invested to date was wasted and that their main vendor, Computer Sciences Corporation would not be able to provide the software that was promised.¹⁰⁵

The HITECH Act of 2009, which created the EHR Incentives Programs in the US, is helping

the United States catch up, which will be discussed further in another section.

Electronic Health Record and Meaningful Use Challenges

Many of the same barriers to HIT adoption discussed in Chapter 1 also pertain to EHR adoption and successful attainment of meaningful use.

Financial Barriers

Although there are models that suggest significant savings after the implementation of ambulatory EHRs, the reality is that it is expensive. Multiple surveys report lack of funding as the number one barrier to EHR adoption.¹⁰⁶ In a 2005 study published in *Health Affairs*, initial EHR costs averaged \$44,000 (range \$14-\$63,000) per FTE (full time equivalent) and ongoing annual costs of \$8,500 per FTE. These costs included the purchase of new hardware, etc. Financial benefits averaged about \$33,000 per FTE provider per year. Importantly, more than half of the benefit derived was from improved coding.¹⁰⁷ This is not a surprise given the fact that studies have shown that physicians often *under-code* for fear of punishment or lack of understanding what it takes to code to a certain level.¹⁰⁸ A 2008 survey reported about one-third of physicians paid between \$500-\$3,000 per clinician, one-third paid between \$3,001-\$6,000 and about one-third paid more than \$6,000.¹⁰⁹

A 2011 study reported on the financial and nonfinancial costs of implementing a commercial EHR in a healthcare network in Texas. They calculated that implementation for a five physician primary care practice would be about \$162,000 with \$85,500 in maintenance expenses in the first year. They also estimated that the average end-user would require 134 hours to train and prepare for implementation.¹¹⁰ Another study reported on 5-year return on investment from 49 practices that were part of the Massachusetts eHealth

Collaborative, before and after EHR implementation. The study was prior to CMS reimbursement under the HITECH Act but was similar in that the eHealth Collaborative paid for the majority of costs related to purchase and implementation. They found only 27 percent of practices would achieve a positive five year return and that a majority would experience a loss. The average projected loss over five years was \$43,473 per physician. There were striking differences between the winners and losers of EHR adoption.¹¹¹

It is important to consider that integration with other disparate systems such as practice management systems can be very expensive and hard to factor into a cost-benefit analysis. The web-based application service provider (ASP) option is less expensive in the short term and perhaps in the long term, when one factors in the expenses to maintain and upgrade an office client-server network. According to many studies EHR adoption was far higher in large physician practices that could afford the initial high cost.¹¹²

Physician Resistance

Prior to EHR reimbursement lack of support by medical staff was consistently the second most commonly perceived obstacle to adoption.¹¹³ Physicians have to be shown a new technology makes money, saves time or is good for their patients. None of these can be proven for certain for every practice. Although physicians should not expect to go paperless from the beginning, at some point it can no longer be optional. It seems clear that CPOE does take longer than written orders but offers multiple advantages over paper as pointed out previously.¹¹⁴ Implementation will not fix old work flow issues and will not work if several physicians in a group are opposed to going electronic. It is now known that some practices have opted to change or discontinue their use of an EHR. A 2007 survey demonstrated fewer than 20% of respondents had uninstalled their EHR in an effort to step down to a less expensive alternative and 8% had returned to paper.¹¹⁵ According to a 2013 Deloitte survey of US

physicians 63% of physicians were satisfied with their EHR (48% were somewhat satisfied and 15% were very satisfied).¹¹⁶

Physicians may resist some aspects of the EHR reimbursement program. For example, the American Academy of Family Physicians analyzed CMS meaningful use data and determined that 21% fewer family physicians attested for meaningful use in 2012, compared to 2011. Rates for the specialties were about the same. They theorized that physicians had to attest for 12 months of meaningful use which is onerous and they may have missed the attestation period.¹¹⁷

EHRs are not the only important issue for most physicians. They face increases in overhead while reimbursement wanes, along with ICD-10, HIPAA 5010, new healthcare reform and Red Flag rules, just to mention several looming challenges.

Loss of Productivity

It is likely physicians will have to work at reduced capacity for several months with gradual improvement depending on training, aptitude, etc. This is a period when physician champions can help maintain morale and momentum with a positive attitude. According to one systematic review CPOE used on central station desktops for CPOE was not time efficient; the weighted average relative time difference across these studies reported an increase in documentation time of 238.4%.¹¹⁴

Loss of productivity is, in part, due to the change in workflow discussed in the next section.

Work Flow Changes

Everyone in the office will have to change the way they route information compared to the old paper system. If planning was well done in advance everyone should know how work flow will change. As an example, many offices place the patients chart in the exam room door to indicate that the patient is ready to be seen. How will that be accomplished with an electronic system? Initially, one will have to

maintain a dual system of paper and electronic records. Work flow analysis will also determine where computer terminals will be placed in an office or hospital setting for easy access.

Reduced Physician-Patient Interaction

Clinicians will have to maintain eye contact as often as possible and learn to incorporate the EHR into the average patient visit. Use of a movable monitor or tablet PC may help diminish the time the clinician spends not looking at the patient. There are several studies that report computers (EHR access) implemented in the office exam room do not detract from the physician-patient relationship. Some believe that the overall effect of exam room technology depends on the skill of the physician integrating the technology appropriately with the patient.¹¹⁸⁻¹²⁰

Because CPOE and inpatient documentation entry takes longer to complete (on average), compared to the paper process there is a concern that attendings or housestaff will be forced to spend more time documenting on the computer and less time with the patient. A study reported in 2013 showed that interns spent only 12% of their time in direct patient-related care, but 40% on the computer.¹²¹ A second report in 2013 reported that emergency room physicians spent 28% of their time in direct patient care but 43% of time with data entry. On average, the total number of mouse clicks for a 10 hour shift approached 4,000.¹²² These findings further strain the already negative perception of many patients that they don't have enough face time with their physician.

Usability Issues

Usability has been defined as the "effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment."¹²³ Is the software well organized and intuitive such that the user can find what they are looking for with a minimal number of mouse clicks? This is more complicated than what one would expect

because there are multiple sub-specialties with unique needs, as well as multiple clinicians who are used to working in a set sequence. Based on several surveys included in this chapter, usability does not necessarily correlate with the amount of money paid for the software. HIMSS now has an EHR usability task force and it is predicted that eventually all certified EHRs will need to pass usability testing.¹²⁴ At this time CCHIT is the only certification body that includes usability testing, but for 2014 limited usability testing will be a requirement.¹²⁵

In early 2013 the American Medical Informatics Association (AMIA) published their recommendations to improve EHR usability. They recommended further research and new policy recommendations as well as recommendations to vendors and end-users of EHR systems.¹²⁶ An article by DesRoches et al. published in 2013 looked at the achievement of meaningful use and the ability to manage patient populations as of early 2012. Ease of use for panel management was subjectively measured and was listed as “easy” by only 43.8% for the ability to generate a list of patients by laboratory results and as high as 75.7% for the ability to provide patients with an after visit summary.¹²⁷

Integration with Other Systems

Hopefully, integration with other systems like practice management software was already solved prior to implementation. Users should be prepared to pay significantly for programmers to integrate a new EHR with an old legacy system. An average cost is about \$3-\$15,000 per interface.¹²⁸ Most office and hospitals have multiple old legacy systems that do not talk to each other. Systems are often purchased from different vendors and written in different programming languages. If either the EHR or practice management system’s software is upgraded, then interfaces need to be checked and possibly changed. It is now popular to purchase an EHR already integrated with practice management, billing and scheduling software programs.

Quality Reporting Issues

EHRs have the potential to generate a variety of data necessary for compliance with meaningful use objectives, to include quality reports. Quality reports have been tied to physician reimbursement in several situations. New York City considered basing a physician’s pay on evidence of high quality, but obstacles remain. In early 2013, two reports from Weill-Cornell Medical College in New York City highlighted issues with quality measure reporting. In one study the accuracy of reporting was low, compared to manual chart review. In another study that examined quality reporting in the Primary Care Information Project in New York it was noted that within the first two years of using an EHR there was no improvement in overall quality, even with high levels of technical assistance.¹²⁹⁻¹³⁰

Lack of Interoperability Standards

Data standards and medical vocabularies are necessary for interoperability. The initial standards have been proposed by ONC and will be covered in more detail in another chapter. Reimbursement for Meaningful Use will mandate that EHRs demonstrate the ability to exchange information. Although numerous standards have already been accepted (separate chapter) they will likely need to be updated and new standards added based on use cases. Furthermore, computers are based on data and not information, as discussed in the chapter on healthcare data, information and knowledge.

Privacy Concerns

The HITECH Act of 2009 introduced a new certification process for EHRs sponsored by ONC, in addition to CCHIT certification. This new certification ensures that EHRs will be able to support Meaningful Use and that they also will be HIPAA compliant. ONC certification includes requirements on database encryption, encryption of transmitted data, authentication, data integrity, audit logs, automatic log off, emergency access, access control and accounting of HIPAA releases of information. The HITECH

Act also strengthened the prior HIPAA requirements as they relate to EHRs, particularly in the areas of enforcement of HIPAA and notification of breaches. Both civil and criminal penalties for Business Associates (as well as covered entities) were introduced. Civil penalties in their harshest form can range up to 1.5 million dollars. If a data breach of PHI (protected health information) occurs, all affected individuals must be notified. If more than 500 individuals are affected, HHS must be notified as well. Sale of PHI is prohibited.¹³¹ Users of EHRs must:

- Use HIPAA compliant technology
- Provide physical and software security of data systems
- Provide physical and software security of their network(s) including mobile and remote computing
- Provide access control with defined user roles, passwords and user authentication and auditing
- Monitor and manage user behavior
- Have written security policies and procedures
- Have an effective disaster recovery plan¹³²

EHRs pose new potential privacy and security threats for patient data, but with proper technology as well as proper health entity and user behavior, these risks can be mitigated. On the bright side, EHRs offer new safeguards unavailable in the paper record world, like audit trails, user authentication, and back-up copies of records. Further details are available in the chapter on privacy and security.

Legal Aspects

A 2010 Health Affairs article estimated that malpractice costs in the US are around \$55 billion dollars annually (in 2008 dollars) or 2.4% of what the US spends on health care.¹³³ Will EHRs increase or decrease that number? Unfortunately the answer isn't in yet. Most studies suggesting lower malpractice claims after EHR implementation are not designed to prove cause and effect and may not be generalizable to other practices or regions.¹³⁴ Arguments can be

made for either outcome. On one hand, by increasing the quality of care, theoretically EHRs should reduce malpractice risk. Yet that assumes that quality and malpractice are related in a linear fashion, which may well not be the case. On the other hand, EHRs that are poorly designed, or that contain bugs, could promote inadvertent errors. This risk points to a need for monitoring and corrective action related to EHR-generated errors. The Office of the National Coordinator (ONC) for Health IT understands that a system of monitoring and corrective action for EHR-related errors needs to be implemented. ONC outlined its plans for this in a December 2010 statement.¹³⁵ As a first step, one can currently report EHR-generated errors to AHRQ-recognized Patient Safety Organizations like PDR Secure.¹³⁶

Two important areas of potential risks and benefits include documentation of clinical findings and clinical decision support. One might expect that the more comprehensive documentation produced by EHRs will improve a physician's defense against malpractice. It certainly may. However the automated way that EHRs carry information forward from one note to the next can also promote errors and potential liability, if a piece of data is recorded incorrectly from the start, yet never corrected.¹³⁷ Guidance on proper coding with EHRs is beginning to appear.¹³⁸ E-discovery laws now allow electronically stored data related to patient records to be considered discoverable for the purpose of malpractice, so the metadata and audit trails that supplement EHR documentation can be used both to defend and to impeach a physician in a malpractice case.¹³⁹ Will that be a net benefit or liability for physicians? Decision support alerts and guidelines embedded into EHRs could potentially provide a defense against malpractice claims if their advice is followed. But what if alerts or guidelines are overridden? There may be very appropriate reasons to do so, but will physicians be expected to document the reason for each and every alert they override? Will they run the risk of being penalized if they don't?

Improved access to information provided by health information exchanges (HIEs) should improve the coordination of care, the quality of medical information that is available, and thus the quality of medical decision making. But, will clinicians have a tendency to overlook key nuggets of clinical information simply because they are overwhelmed by the volume of information they receive? Will ready access to outside information on a patient make a physician more liable if he or she doesn't always actively search for every piece of potentially relevant information? In addition, user errors can arise as users climb a steep learning curve to become proficient with EHRs. Care needs to be taken particularly during the implementation of an EHR to guard against user error.

Finally, as EHRs become the standard of care, will practicing without an EHR become a medicolegal liability? At this point in time it is still undetermined whether EHRs will significantly impact the incidence and expense of malpractice in a positive or a negative way.¹⁴⁰

Inadequate Proof of Benefit

Successful implementation of HIT at a medical center with a long standing history of systemic IT support does not necessarily translate to another healthcare organization with less IT support and infrastructure. A systematic review by Chaudry is often cited as proof of the benefits of HIT, but in his conclusion he states “four benchmark institutions have demonstrated the efficacy of health information technologies in improving quality and efficiency. Whether and how other institutions can achieve similar benefits and at what costs, are unclear.”¹⁴¹

There have been five recent articles in the medical literature that failed to demonstrate a significant impact of EHRs on medical quality in the US and in Europe.¹⁴²⁻¹⁴⁶ A more positive study was published in 2011 of more than 25,000 diabetics in 46 practices that showed achievement of diabetic care was significantly better for practices with EHRs, compared to paper-based practices. They measured intermediate outcomes and not actual patient

outcomes, so the impact on morbidity or mortality is not known.¹⁴⁷ Following the publication of the fifth edition of this textbook, three other articles related to diabetic care and electronic health records were published. All three studies were observational in nature and measured intermediate outcomes such as hemoglobin A1c levels. Only one study showed significant benefit and that was experienced by Kaiser-Permanente, an advanced integrated delivery network.¹⁴⁸⁻¹⁵⁰

A systematic review published in 2012 that looked at the economics of HIT and medication management could find little evidence that CPOE or CDSS were cost effective. Importantly, they noted that the quality of the literature was heterogenous and of poor quality.¹⁵¹ Another systematic review evaluated the impact of point-of-care computer reminders, as part of CPOE/CDSS on physician behavior and found a very small positive effect. Specifically, the review found that the reminders improved adherence to care by a median of only 4.2%.¹⁵² There has also been a hope and perception that having prior test results readily available in the EHR would reduce testing duplication. In a large retrospective study of before and after EHR implementation, having access to electronic results of lab and imaging results resulted in increased, rather than decreased ordering.¹⁵³

Patient Safety, EHRs and Unintended Consequences

Patient Safety. Unfortunately, with implementation of most technologies new problems and issues arise that were not considered initially. EHRs are no exception to this observation and a variety of unintended consequences have been reported. Weiner coined the term *e-iatrogenesis* to mean “*patient harm caused at least in part by the application of health information technology.*”¹⁵⁴ Several studies have shown increased errors as a result of implementing CPOE.^{41,43,72,155-157} Campbell et al. outlined nine examples of unintended consequences related to CPOE implementation:

1. “More work for clinicians
2. Unfavorable workflow changes
3. Never ending demands for system changes
4. Conflicts between electronic and paper-based systems
5. Unfavorable changes in communication patterns and practices
6. Negative user emotions
7. Generation of new kinds of errors
8. Unexpected and unintended changes in institutional power structure
9. Overdependence on technology”¹⁵⁸

Alert fatigue is another common unintended consequence related to CPOE, discussed in more detail in the chapter on patient safety.

The US federal government is keenly aware of the unintended consequences associated with HIT and EHRs after reports by the Joint Commission and the Institute of Medicine.¹⁵⁹⁻¹⁶⁰ Furthermore, the Pennsylvania Patient Safety Authority published a report on errors related to use of default values in 2013. They reported that wrong-time, wrong-dose, inappropriate auto-stops and wrong-route errors were often related to default values that should have been changed.¹⁶¹

In response to concerns AHRQ released the monograph *Guide to Reducing Unintended Consequences of Electronic Health Records* in 2011. This Guide discusses unanticipated and undesirable consequences of EHR implementation.¹⁶² In mid-2013, ONC released the report *HIT Patient Safety and Surveillance Plan*. The plan will make EHR error reporting easier, to include allowing the EHR to generate the report to patient safety organizations (PSOs). More details are discussed in the patient safety chapter.¹⁶³

Reliability. In spite of successful EHR implementations, several dramatic failures were seen in 2013, with EHR shutdowns from 1 to 10 days.¹⁶⁴⁻¹⁶⁵ Healthcare organizations must develop backup plans to include temporarily relying on paper-based processes until the EHR is re-established.

With better training or re-design some of the technology-related errors are likely to be overcome. More research is needed to obtain a balanced opinion of the impact of EHRs on quality of care, patient safety and productivity. Furthermore, there is a need to study the impact on all healthcare workers and not just physicians.

The HITECH Act and EHR Reimbursement

Arguably, the most significant EHR-related initiative occurred in 2009 as part of the American Recovery and Reinvestment Act (ARRA). Two major parts of ARRA, Title IV and Title XIII are known as the Health Information Technology for Economic and Clinical Health or HITECH Act. Approximately \$20-30 billion was dedicated for Medicare and Medicaid reimbursement for EHRs to clinicians and hospitals. In this chapter the focus will primarily be on reimbursement to eligible professionals (EPs) and not hospitals or Medicare Advantage organizations, even though they are also potentially reimbursable. The Centers for Medicare and Medicaid Services (CMS) established a comprehensive web site to explain the EHR Incentive Program, summarized in the following sections.¹⁶⁶

In order for clinicians to participate in this program they must be: (1) eligible, (2) register for reimbursement, (3) use a certified EHR, (4) demonstrate and prove Meaningful Use, and (5) receive reimbursement.

Eligible Professionals (EPs)

Medicare: Medicare defines EPs as doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry and chiropractors. Hospital-based physicians such as pathologists and emergency room physicians are not eligible for reimbursement. Hospital-based is defined as providing 90% or more of care in a hospital setting. The exception is if more than 50% of a physician’s total patient

encounters in a six-month period occur in a federally qualified health center or rural health clinic. Physicians may select reimbursement by Medicare or Medicaid, but not both. They cannot receive Medicare EHR reimbursement and federal reimbursement for e-prescribing. They can receive Medicare reimbursement as well as participate in the Physicians Quality Reporting System (PQRs). If they participate in the Medicaid EHR incentive program they can participate in all three programs.

Medicaid: Medicaid EPs are defined as physicians, nurse practitioners, certified nurse midwives, dentists and physician assistants (physician assistants must provide services in a federally qualified health center or rural health clinic that is led by a physician assistant). Medicaid physicians must have at least 30% Medicaid volume (20% for pediatricians). If a clinician practices in a federally qualified health center (FQHC) or rural health clinic (RHC), 30% of patients must be *needy individuals*. The Medicaid program will be administered by the states and physicians can receive a one-time incentive payment for 85% of the allowable purchase and implementation cost of a certified EHR in the first year, even before Meaningful use is demonstrated. Medicaid is also different from Medicare in the following: payment over six years does not have to be consecutive and there are no penalties for non-participation.¹⁶⁶

Registration: Registration began in January 2011. Medicare physicians must have a National Provider Identifier (NPI) and be enrolled in the CMS Provider Enrollment, Chain and Ownership System (PECOS) and National Plan and Provider Enumeration System (NPPES) to participate.¹⁶⁶

Certified EHRs: An EHR has to be certified by a recognized certifying organization in order for a physician or hospital to receive reimbursement. As of mid-2013 there were six organizations that can provide certification.¹⁶⁷ Standards and certification criteria are listed on the HHS site, as are the currently certified EHRs. Users can view ambulatory and inpatient EHR categories and search by product name. The search should review who certified the EHR,

whether it was for a complete or modular EHR and the EHR certification ID number they would need for reimbursement. The newest 2014 certification is for stage 2 meaningful use. A search in September 2013 of all complete EHRs, ambulatory and inpatient for *all versions* by vendors reported 1792 offerings.¹⁶⁸

Meaningful Use (MU): The goals of MU are the same as the national goals for HIT: (a) improve quality, safety, efficiency and reduce health disparities; (b) engage patients and families; (c) improve care coordination; (d) ensure adequate privacy and security of personal health information; (e) improve population and public health. Three processes stressed by ARRA to accomplish this are: e-prescribing, health information exchange and the production of quality reports. As planned, Meaningful Use will occur in three stages. The intent is for stage 1 to begin the basic process of data capturing and sharing; stage 2 will require advanced data processes and sharing and stage 3 will examine actual patient outcomes. Figure 4.3 shows the proposed timeline for Meaningful Use.

- Stage 1 (2011): Meaningful Use mandates a *core set* and a *menu set* of objectives. To be a Meaningful Use Stage 1 user, participants must meet all 15 of the core objectives and select five out of 10 menu objectives. They must choose at least one population and public health measure. Appendix 4.1 compares stage 1 with stage 2 for EPs, not hospitals. For each objective there are reporting measures that must be met to prove Meaningful use. In 2011 the results of all objectives and measures, to include clinical quality measures were reported by clinicians and hospitals to CMS and Medicaid clinicians reported to states by attestation. Quality measures are derived from the Physician Quality Reporting System (PQRS) and the National Quality Forum (NQF). Each EP must submit information on three core quality measures in 2011 and 2012 (tobacco use, blood pressure measurement and adult weight screening). They must also choose three other measures that are ready for

incorporation into EHRs. Physicians must fill in numerators and denominators for Meaningful Use objectives and indicate if they qualify for exclusions and attest that they have met Meaningful use. Details about Meaningful Use and attestation for Medicare and Medicaid are available on the CMS web site.¹⁶⁶

- Stage 2 (2014): The final rule for stage 2 was published in September 2012 with the intent of implementation in 2014. The proposed changes include increasing the percent compliance with Stage 1 objectives, moving several menu objectives to core and adding new objectives (e.g. secure messaging).¹⁶⁸ Specifically, stage 2 will require 17 core objectives and 3 out of 6 menu objectives. In the 2014 reporting period all EPs and EHs need to upgrade to 2014 certified EHR technology and EPs should remember that 2014 is the last year to start the Medicare Meaningful Use program.¹⁶⁶ For reporting periods during or after fiscal or calendar year 2014 EPs will need to have EHRs certified by the 2014 standards. In late 2013 the reporting period was extended to 2016
- Stage 3 (2017): In mid-2013 the HIT Policy Committee (Meaningful Use Workgroup) proposed basic functionality and health outcomes goals one might expect with stage 3. Stage 3 will begin in 2017 and only for those who have completed 2 years of stage 2. Appendix 4.2 lists these proposed goals for stage 3 Meaningful Use.¹⁷⁰

Reimbursement

Tables 4.4 and 4.5 list the Medicare and Medicaid reimbursement levels for EHRs. Payments will be held until the Medicare physician meets the \$24,000 threshold for allowed charges. Medicare physicians may earn an additional 10% if they practice in a healthcare professional shortage area (HPSA). Payments are based on the calendar year. It is important to note that no monies are paid upfront and contrary to what is published by EHR vendors and others, the amount listed yearly in Table 4.4

is a maximum. Physicians will be reimbursed 75% of allowable Part B charges or up to, for example, \$18,000 in the first year. Clinicians are paid in a single annual payment and have to demonstrate Meaningful Use for 90 days of continuous EHR use in the first year and the entire calendar year thereafter.

Medicare physicians who do not use a certified EHR nor demonstrate Meaningful Use will receive penalties of 1% in 2015, 2% in 2016 and 3% in 2017 when they bill Medicare. Penalties could reach 5% in 2018 and beyond if fewer than 75% of physicians are using EHRs at that point. In addition, late adoption might mean that more complex Meaningful Use (Stage 2 or 3) will be required, likely to make purchase and implementation more difficult. The timeline was changed in late 2013 such that stage 2 was extended through 2016 with stage 3 beginning in 2017. Other changes are likely to occur so EPs and EHs should closely monitor the ONC and CMS web sites.

Medicaid is administered by states and will use the same Meaningful Use criteria. In addition to the states being given the reimbursement money by the federal government to give to clinicians and hospitals, they will also receive 90% reimbursement for the cost of administering the program. Medicaid EPs and hospital-based physicians are not subject to possible payment reductions. Unlike Medicare, Medicaid physicians can be paid the first year just to adopt, implement or upgrade an EHR and not yet meaningfully use the EHR. Medicaid EPs must demonstrate Meaningful Use in years two through six. Medicaid physicians are not eligible for the 10% HPSA bonus but can receive the e-prescribing and PQRI (also known as PQRS) bonuses. PQRS and Meaningful Use are not aligned well and this is discussed in the chapter on quality improvement strategies. The last year to begin participation in the Medicaid program is 2016.

Hospitals can also be reimbursed for the purchase of EHRs and can share this technology with the known limits of the *Safe Harbor Act* discussed elsewhere in this chapter. Hospitals will start at a base of \$2 million annually with

decreasing amounts over five years, plus an additional amount dependent on patient volume. Hospitals may receive reimbursement from both Medicare and Medicaid.¹⁶⁶ Critical access hospitals and small rural hospitals have shown a definite increase in meeting meaningful use criteria but there is still concern that rural physicians lag behind urban doctors in terms of adoption of EHRs.

EHR Incentive Program Update: June 2013

The Office of the National Coordinator for HIT submitted a Report to Congress on the adoption of HIT in June 2013. The following are some of the salient findings of the report:

- Roughly 394,000 eligible physicians and hospitals have registered for reimbursement and 291,000 eligible professionals have received incentive payments, representing more than half of the eligible candidates. Over 3800 hospitals have received incentive

payments, representing more than 80% of eligible hospitals.

- Among eligible professionals receiving reimbursement, 90% were from metropolitan areas.
- There has been steady growth in the use of the Regional HIT extension centers (RECs), but only 38% of the primary care clinicians who used RECs, demonstrated meaningful use.
- The percent of non-federal hospitals capable of meeting core and menu meaningful use measures varied from a low of 55% to a high of 94% in 2012.
- The percent of physicians using EHR-based e-prescribing increased from 7% in 2008 to 54% in 2012.
- As of December 2012, thirty-nine states participated in the Direct (push) exchange of medical information and 25 states were participating in the query (pull) exchange of medical information.¹⁷¹

Table 4.3: Meaningful Use Stages 1-3 Timeline for EPs

Meaningful Use Stages by Year											
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Start 2011	1	1	1	2	2	2	3	3	TBD	TBD	TBD
Start 2012		1	1	2	2	2	3	3	TBD	TBD	TBD
Start 2013			1	1	2	2	3	3	TBD	TBD	TBD
Start 2014				1	1	2	2	3	3	TBD	TBD
Start 2015					1	1	2	2	3	3	TBD
Start 2016						1	1	2	2	3	3
Start 2017							1	1	2	2	3

Table 4.4: Maximum Medicare reimbursement for EHR adoption EPs

Year	2011 (year 1)	2012 (year 1)	2013 (year 1)	2014 (year 1)	2015 (year 1)
2011	\$18,000				
2012	\$12,000	\$18,000			
2013	\$8,000	\$12,000	\$15,000		
2014	\$4,000	\$8,000	\$12,000	\$12,000	
2015	\$2,000	\$4,000	\$8,000	\$8,000	\$0
2016	\$0	\$2,000	\$4,000	\$4,000	\$0
Total	\$44,000	\$44,000	\$39,000	\$24,000	\$0

Table 4.5: Maximum Medicaid reimbursement for EHR adoption for EPs

Eligible Clinician	Base Year: Max 85% of EHR cost	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Physician	\$21,250	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$63,750
Dentist	\$21,250	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$63,750
Nurse mid-wife	\$21,250	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$63,750
Physician assistant	\$21,250	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$63,750
Nurse practitioner	\$21,250	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$8,500	\$63,750
Pediatrician	\$14,167	\$5,667	\$5,667	\$5,667	\$5,667	\$5,667	\$5,667	\$42,500

Electronic Health Record Examples

There are more than 300 EHRs available in the United States that vary in price from free to about \$40,000 with features that range from basic to comprehensive. Importantly, not all have been certified for Meaningful Use. Also, very few EHR vendors have price transparency so only a minority actually post their charges on their web sites. The EHR market has changed rapidly due to Meaningful Use requirements, in

addition to advances in technology and user demands.

Examples of EHRs in three categories based on size and target audience will be discussed. Small practice is defined by having one to four physicians and typically do best with subscription service (cloud computing, ASP model, SaaS) where they only need an internet connection. A medium medical practice is defined as having five to 20 physicians that might use a subscription service or have the

client-server model with onsite servers which would normally mandate either onsite IT support or contract support services to manage the network. A large practice is defined as having 20 to 99 physicians and most likely will have onsite servers and their own IT staff. A very large practice is defined as having 100+ physicians and will typically utilize the client-server model with their own data center and IT staff as well as programmers and database administrators.

Small Medical Practice

Amazing Charts: This simple and intuitive EHR is ONC ATCB certified and has scored high in usability by multiple reviewers which will be discussed later in the chapter. They offer a three month free trial which is unique among vendors. In 2013 they claimed more than 25,000 clinicians in 6300 practices.

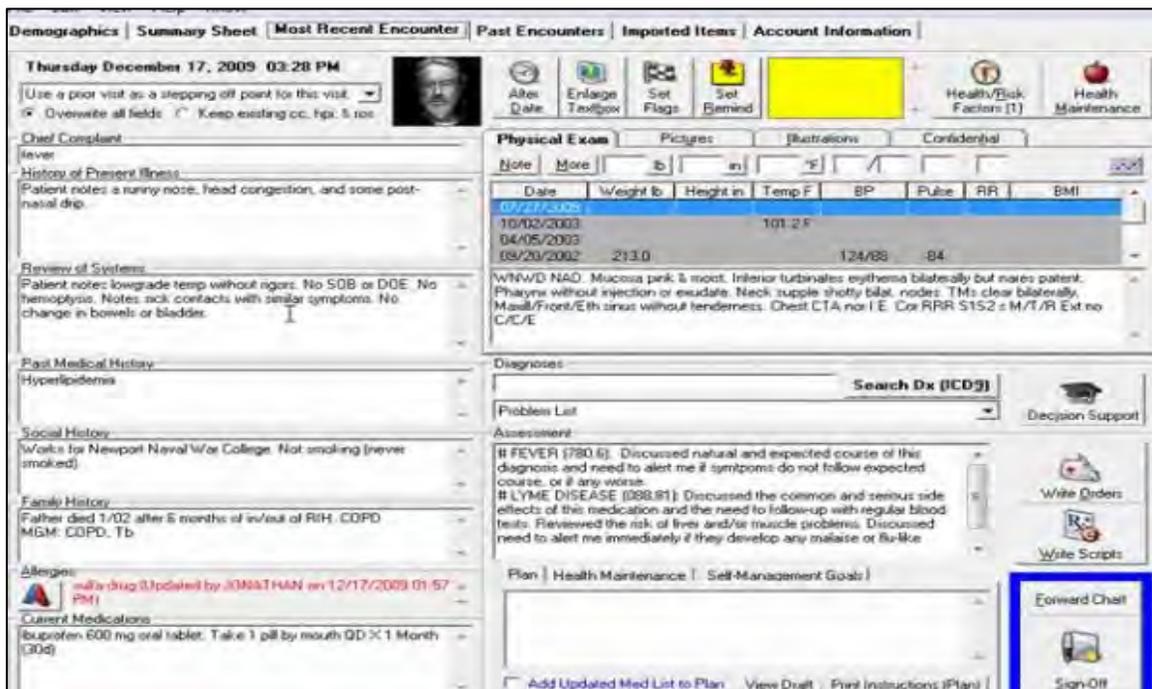
- Standard package: scheduling, internal secure messaging, charting (template

driven), e-prescribing, billing (superbills) and ad hoc reporting are included.

- Practice management: a practice management system or web-based model at this time.
- Remote access: physicians can access their computers remotely with services such as LogMeIn and they can view but not modify records remotely using an iPhone app.
- They offer an ASP or hosted solution for \$39/month/connection.
- Pricing: the standard charge is \$1,995 per physician (includes training and support for physician and staff) for first year, followed by \$995 per physician per year after that for software updates and tech support. For a separate fee they offer offsite backup (\$250) and a low cost interface to practice management systems and medical devices.

Figure 4.8 shows a typical screen shot of a patient encounter from Amazing Charts.¹⁷²

Figure 4.8: Amazing Charts patient encounter screen shot (Courtesy AmazingCharts)

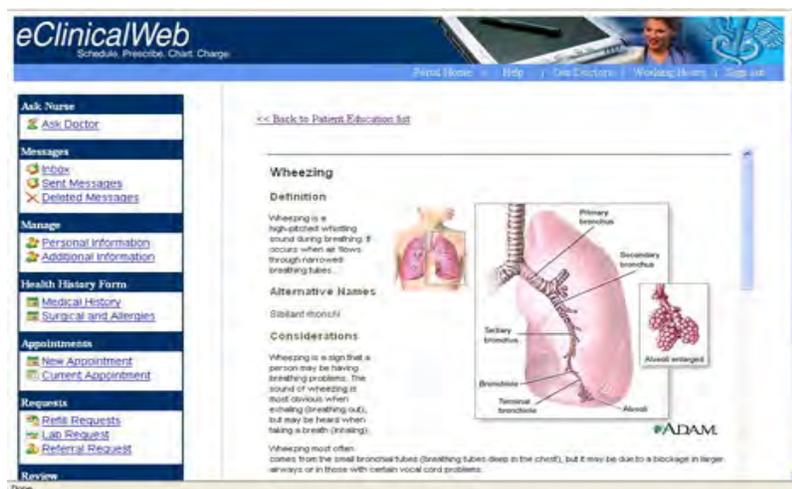


Medium Size Medical Practice

eClinicalWorks: This EHR was selected by the Massachusetts Medical Society because it is multi-featured and well designed with excellent physician acceptance. In 2013, they claimed 472,000 users in 27,000 practices. Their modules are fully integrated and not standalone. The system will operate on Windows or Linux-based servers and is compatible with SQL or MySQL databases. They offer both a web-based and client-server model. It is also one of the few that lists its pricing schedule on their web site. Current modules include:

- EMR module: multiple means of inputting data such as templates, handwriting recognition, voice recognition and free text; tab to access the resource UpToDate; Continuity of Care Record (electronic patient summary) available; patient/disease registries with customizable alerts; referral letters can be automatically generated; e-visit capability.
 - Practice management: scheduling, billing management, claims scrubbing, business analytics and reporting.
 - Patient portal: online registration, secure messaging, web consults, prescription refills, online appointing, view of billing statements, lab results, patient education, receive alerts and complete consent forms. (Figure 4.9)
- Clinical messenger: communication with patient via email, text messaging or Voice over IP (VoIP). Patients can confirm appointment with one phone key, receive (normal) lab results and receive individual or group alerts. This is a hosted eClinicalWorks function.
 - Interoperability: eEHX community health exchange can connect disparate offices, labs and hospitals. Provides master patient index, integration engine, push/pull capability and quality measure reporting and public health alerts.
 - Care Coordination Medical Record is a special packaged for accountable care organizations and the patient centered medical home model.
 - Mobile: iPhones or BlackBerry smartphones and iPad applications to access EHR works are available.
 - Pricing:
 - Option 1: Cloud based EHR begins at \$375/month/clinician
 - Option 2: EHR only package is \$499/clinician/month. The EHR/PMS combined system is \$599/clinician/month.
 - Option 3: Revenue cycle management (RCM) the EHR is free, but the vendor receives 2.9% of monthly collected revenue.¹⁷³

Figure 4.9: Patient portal module eClinicalWorks (Courtesy eClinicalWorks)



Large to Very Large Medical Practice

Epic: Epic is the most popular and highest rated EHR for large to very large healthcare organizations like Kaiser Permanente, Geisinger Clinic, Group Health Cooperative and the Cleveland Clinic. They offer an ambulatory EHR for medical practices and an inpatient EHR for hospitals or a system that will work for both. It is interesting that this very intuitive comprehensive EHR is based on early MUMPs programming that is also found in VistA the EHR used by the Veterans Health Administration. The following are their main services:

- EpicCare EHR: approximately 50% of clinicians are specialists so they offer 40 specialty modules that have specialty specific workflow, templates and order sets. Inpatient EHR modules include flow sheets, electronic medication administration record (eMAR), interdisciplinary care plans, hospital outpatient support, clinical pathways, ICU support, ED department, operating room integration, anesthesia and pathology integration, radiology and laboratory information system integration, health information management, nurse triage, home health integration, barcode administration, pharmacy integration and enterprise reporting.
- Practice management: registration, scheduling, billing and call management
- Personal Health Record:
 - My Chart is an integrated personal health record (PHR) with the following services: view test results, view upcoming & past appointments, schedule appointments, pay bills securely, get automated health maintenance reminders, view problem-based education materials, request refills, send & receive secure messages with physicians, view a child's records and print growth charts and manage the care of elderly parents.
 - *Lucy* is a standalone PHR not integrated with the EHR.

- Information Exchange: EpicCare Link provides a secure web-based portal for read-only access to limited sections of the EHR to community physicians, in addition to secure messaging.
- Physician Portal: Epic Web is a physician portal for remote access to the EHR.
- Interoperability: Care Everywhere is an interoperability capability for disparate EHRs and can pull in data from *Lucy*.
- Mobile: Epic *Haiku* is an iPhone app that provides authorized users of Epic's EHR with secure access to clinic schedules, hospital patient lists, health summaries, test results and notes. *Haiku* also supports dictation and access to inbox. *Cantu* is an iPad app that also provides access to the EHR.¹⁷⁴

Logical Steps to Selecting and Implementing an EHR

EHR implementations are complex affairs. They are not simply IT projects. They are practice transformation projects that should be considered socio-technical-economic initiatives. If approached as simply software to be installed and users to be trained in using the software, an EHR implementation will undoubtedly falter or even fail. Thus, health care organizations involved in implementing an EHR are wise to spend a lot of time planning. A few of the many questions an organization needs to both ask and answer prior to implementing an EHR are: Why are is the practice doing this? Who should be involved? How will this impact end-users and how should they be prepared? What will be the major barriers? What should the practice start doing now to overcome identified barriers and is it ready for change? How will the change be managed?

Implementation of an EHR can be divided into three separate, yet intertwined phases: Pre-implementation, implementation and post-implementation.¹⁷⁵ While each phase is distinct, the success of subsequent phases depends upon the thorough planning and execution of the prior stages.

Pre-implementation begins with deciding whether to purchase an EHR (it is rare for a health care organization to create one themselves these days) and ends with signing a contract with a vendor for a specific EHR. This requires a thorough understanding not only of the organization's needs and current state but also of the selected software's abilities and limitations. The main activity in pre-implementation is choosing the EHR that will be used, but several steps that might be done during implementation, such as workflow mapping, may be done and some say should be done, during pre-implementation. Workflow mapping involves a detailed step-by-step description, typically utilizing a flowchart of how a particular process is accomplished. For example, how are notes created or how are patient messages handled or how are prescription refills managed?¹⁷⁶

Implementation of the EHR starts with the signing of the contract and ends with the go-live date. Experts in IT implementations often categorize facets of implementation into People, Process, or Technology issues.¹⁷⁷ Alternatively, they can be termed: Team, Tactics and Technology.

People issues are particularly important in an EHR implementation. Unless the people issues are managed well from the start, later adoption of the varied functionality inherent in an EHR will likely suffer. Key people issues are leadership, change management, goal establishment and expectation setting. An implementation will have three key types of leaders: a project manager, a senior administrative sponsor, and a clinical champion. The clinical champion will invariably be a physician, but hospital settings will typically have a nurse champion as well. The need for a project manager, someone knowledgeable and experienced in managing a complex IT project with overlapping timelines and multiple stakeholders, is obvious. Senior leadership sponsorship and support is also essential, because an EHR implementation will affect nearly all aspects of a hospital or clinic's operations and thus consistent support from the

organization's leader or leaders will be required as inevitable bumps in the road are encountered.

Some healthcare organizations have learned the hard way that implementing an EHR without one or more physician champions can be disastrous. When it comes to clinical matters, physicians rely on other physicians. Because an EHR affects clinical practice in so many ways, respected, supportive, influential clinicians are needed to encourage other physicians to accept and utilize the system effectively.¹⁷⁸

In inpatient settings, a nurse or clinical champion is essential to ensure that decisions made incorporate all disciplines within the facility. When implementing an EHR it is important to view operations from all perspectives (e.g. physicians, nurses, medical assistants, pharmacists, other support personnel and administrators). Without a nurse champion, decisions made might be solely physician-focused. Additionally, nurses commonly drive the change process in hospitals. Commitment to success, engagement of everyone, and a shared interest in improvement is paramount, so attitude is everything.¹⁷⁹

Because of the degree of change involved in implementing an EHR for the first time, change management skills are needed. This topic is beyond the scope of this book but many good resources can be found on it. One good introductory and classic resource is Kotter's book *Leading Change*.¹⁸⁰ An important part of change management is setting goals and establishing expectations. Be realistic, look at the EHR myths and sins, noted in the info box.

Many specific process (or tactical) decisions are determined during implementation. How will the EHR be used to redesign our workflows? What is the data entry strategy? Which data will be entered discretely, which will be scanned and which (if any) will be left out of the EHR? Who will do this data entry and when? What order sets will be created? What other information systems will the EHR connect to and what kind of interfaces will it require? Will the practice follow a *big bang* (all personnel/sites and EHR functions at once) or a phased implementation



EHR Myths and Deadly Sins

Myths:

- A new EHR will fix everything
- Brand A is the best
- Our software needs to work the way the practice works
- Software will eliminate errors
- Discrete data is always best
- The more templates the better
- Mobile is best
- The practice must have a detailed plan and stick to it
- Planning can stop

Deadly Sins:

- Not doing your homework
- Assuming the EMR is a magic bullet
- Not including nurses in the planning stages
- Not participating in training
- Thinking one can implement the same processes as paper
- Not asking for extra help
- Being short sighted ¹⁸¹⁻¹⁸³

approach (certain user groups and/or certain sites/departments and or certain EHR functions in sequential order)? How will user training be conducted? What about note templates? How much customization will be allowed? How will super-users be utilized? What about the technology? EHR software does vary in its complexity. Software designed for larger practices tends to be more customizable but also more complex, requiring more IT support.

Small practices may adopt EHRs as a subscription service (SaaS) where they only need to maintain an internet connection and user terminals and everything else is done for them remotely. Large practices may be completely self-contained with their own servers, intranet, backup, terminals and IT staff. Large practice and hospital IT departments will often maintain three software environments for the EHR – production (live), test, and training.

Implementation of the EHR is followed by the post-implementation phase which remains in effect for the duration of EHR use. This phase involves maintaining, reassessing and improving the EHR's content and capabilities, facility workflows/processes, and staff training with a focus on continuous improvement and patient safety. In a sense, EHR implementation is never done. As clinical sites learn more about the software from using it, they often learn how to use the software in previously unanticipated ways. And certainly as the EHR software is periodically upgraded, new functionality is added that increases efficiencies or opens up new possibilities. Post-implementation can also be referred to as maintenance, sustainment or optimization.

Logical Steps

In the next section the logical steps towards selection and implementation of EHRs are presented:

- Develop an office strategy. List priorities for the practice. Is the goal to save time and/or money or just go paperless? Is the practice looking to be more competitive by offering patient satisfaction-related features like secure messaging, virtual visits, a portal and connectivity with the medical community? Is remote access to computing needed by the clinicians? Is the practice seeking improved workflow to expedite chart pulls and provide easier refills? Is more reporting capability needed? Is better integration with your practice management system needed? Is there a need to integrate disparate programs? Now is the time to study work flow and see how it will change

your practice. This is when frequent conferences with the front office staff will be critical to get their input about the processes that need to improve. Make sure physicians are committed to using the EHR. Look for at least one physician champion and be sure your staff is onboard. Do not proceed if there are hold-outs. Do not proceed if your only goal is to receive federal money. Factor in your future requirements. Will more partners or offices or specialties be added? Plan for initial decreased productivity.

- Research the EHR topic:
 - Take a short EHR course at a community college or university
 - Utilize expertise from regional extension centers (RECs) (see Chapter 1)¹⁸⁴
 - Read an EHR textbook¹⁸⁵⁻¹⁸⁹
 - Read important articles, monographs and surveys¹⁹⁰
 - Network with information on web sites such as the 2013 HealthIT XChange where there are articles and discussions about each stage of EHR planning and implementation sponsored by all of the major informatics organizations.¹⁹¹ Also consider the National Learning Consortium hosted by ONC that covers multiple topics related to EHR implementation.¹⁹²
 - The 2012 EHR User Satisfaction Survey received 3,088 responses from family physicians, reporting on 160 EHR systems (129 were used by 12 or fewer respondents). Thirty one EHRs were used by the majority of respondents (87%) and this served as the corner stone of the survey. The EHRs for the VA, DOD and Indian Health Service were included. A chart correlated the top EHRs by practice size and the number of respondents using the specific EHR. Another chart ranked the 31 EHRs based on 19 dimensions. A third chart ranked EHRs based on whether they were easy and intuitive to use (usability). A fourth chart rated training and support. A fifth chart evaluated whether the EHR enables the user to practice higher quality medicine compared to paper charts and a sixth chart rated the level of overall satisfaction. An average for *all respondents* was included for benchmarking. Only 38% of respondents agree or strongly agree that they are satisfied with their system. Clearly, cost and EHR size did not correlate with user satisfaction.¹⁹³
- The 2012 Black Book Rankings of the top 20 EHR vendors for family physicians had similar results to the AAFP.¹⁹⁴
- Utilize HIT Consultants:
 - Consulting firms such as AC Group provide consulting for EHR purchase. In addition they have several fee-based monographs on the subject.¹⁹⁵
 - KLAS is an independent HIT rating service that vendors pay to join and end-users pay to receive reviews. Their reviews cover EHRs and components based on practice size and include letter grades on implementation, service and product. Their input usually comes from office managers or IT specialists and not necessarily end-users. Physicians can evaluate survey data on individual vendors free if they are willing to complete an online questionnaire.¹⁹⁶⁻¹⁹⁷
- List EHR features needed in the practice. Review the key components section of this chapter. Choose the method of inputting: keyboard, mouse, stylus, touch-screen or voice recognition? Don't forget backup systems, e.g. *dual failover*.
- Analyze and re-engineer workflow. Processes such as prescriptions, telephone triage, lab ordering, appointments, scheduling, registration and billing will change with the use of an electronic health record. Healthcare workers must embrace

business process engineering (BPR) and business process automation (BPA) to create a digital office. It is wise to map the various processes to see what changes must occur and where computer terminals to execute the process electronically should be added. Some choose to use workflow software to map office workflow. HIMSS offers a toolkit “Workflow Redesign in Support of the Use of Information Technology within Healthcare” for its members.¹⁹⁸ Other resources on workflow and process mapping related to EHRs are available.¹⁹⁹⁻²⁰⁰

- Use Project Management Tools. A variety of tools exist that improve organizational skills during the planning process. Consider using standard matrices that are glorified checklists and timelines that help organize your efforts.²⁰¹⁻²⁰³
- Decide on client-server or the application service provider (ASP) option. One early decision that must be made is whether the practice wants to purchase a standard client-server EHR package which means having the software on your own computers. The other choice is an ASP model which uses a remote server that hosts the EHR software and your patient data. Each has its merits and shortcomings. Almost all EHR vendors now offer both models. Features of an ASP Model:¹⁸⁶
 - Vendor charges monthly fees to provide access to patient data on a remote server. Fees will usually include maintenance, software upgrades, data backups and help desk support. Monthly fee may be a fixed amount or based on number of users.
 - Lease agreement commitments range from one to five years.
 - ASP may charge a fixed amount or charge for the number of users.
 - ASP can be completely web-based or can require a small software program (thin client) to help share processing tasks.
 - Pros: Lower start-up costs; ASP maintains and updates software; saves money by eliminating or reducing need for local tech support; generally a better choice for small practices with less IT support; enables remote log-ons, for example, from home or satellite offices.
- Cons: If your ISP is out of service, then your practice is stalled; security and HIPAA concerns; concerns about who owns the data and cost of monthly cable fees; slower speeds compared to a client-server model; need a fast internet connection, preferably a cable modem, DSL or T1 line.
- Decide on an inputting strategy. Different types of inputting are necessary because clinicians have different specialties, personal preferences and document requirements:
 - Dictation. In spite of the desire by most people who purchase an EHR to avoid dictation, many physicians will not want to give this up because it is part of their routine or they practice in a specialty where the historical narrative is best told with a dictation. Besides cost (10 to 20 cents per line), the disadvantages are the fact it is non-structured data, the physician must proof read and someone must cut and paste the narrative into the EHR, thus causing some delay.
 - Speech recognition. Speech recognition is an attractive alternative to standard dictation for many but not all physicians. The cost to purchase, example Dragon Naturally Speaking (DNS) 12®, is approximately \$1,600 per physician (on-site training not included) and includes a choice of multiple medical specialty vocabularies. DNS is available for the iPhone and wireless platforms.²⁰⁴ There is preliminary evidence to suggest speech recognition improves the patient narrative and has a reasonable return on investment.²⁰⁵ While it is true that speech recognition has improved dramatically in the last few years, it will not be satisfactory for all users. In 2010, Hoyt and Yoshihashi

reported a failure rate of 31% in a large scale implementation of voice recognition in a military treatment facility.²⁰⁶

- Handwriting recognition. A few EHRs utilizing the tablet PC platform will allow a clinician to write on the tablet and have the information converted to text.
- Digital Pens. Smart (digital) pens are being used as another means of inputting that fits physician workflow.
- Templates. Most EHRs offer a template or point and click option to facilitate inputting history and physical exam data into the EHR. In addition to saving time, templates input data as structured data so it is machine and human readable. Practices can create templates ahead of time before going live and thereby, try to standardize care within a practice. Multiple template designs are available. With MEDCIN every phrase must be located and selected for inputting. Others *document-by-exception* which means there is standard language for most exams; if verbiage does not pertain to a patient, it can be deleted. Most templates can be customized (some on the fly) and shared. Many are disease specific such as *low back pain* or *headache* templates. One concern with templates, besides a potential *robotic note*, is the over use of options such as *auto-negative* where the review of systems can be performed rapidly with the potential for false documentation. Clicking history or physical exam choices that the clinician did not ask or examine is considered fraud. Conversely, submitting an overly detailed history or physical exam that is not justified by the diagnosis could be considered abuse.²⁰⁷
- Typing. A minority of physicians will be happy to input their data by typing, particularly if they are tech savvy and

excellent typists. Most physicians, however, will complain that typing notes is not why they went to medical school.

- Scribes. Emergency rooms were the first hospital area to hire scribes to shadow physicians and in addition to multiple duties were responsible for inputting information into the EHR by typing, templates, dictation or transcription.²⁰⁸
- A blended approach. Medical practices would be wise to offer multiple means to input patient data. As an example, for simple patient encounters for flu, templates may be adequate. For more complex visits dictation or voice recognition may be necessary. Organizations will have to balance the need for productivity by finding better ways to input into an EHR with the needs to have discrete or structured data. As an example, hospitals rated as stage 6 by HIMSS used templates 35%, dictation/transcription 62% and speech recognition 4% for inputting into EHRs. Newer software, using natural language processing, will extract discrete data known as *narradata* from dictations that can be used secondarily for decision support, reporting and billing. This approach is known as discrete reportable transcription (DRT) and may be important for Meaningful Use of EHRs.²⁰⁹
- Discuss mobility. Will clinicians need to be wireless? Will they benefit from access of the EHR remotely using a smart phone? Multiple vendors, like Epic, offer their software on, example an iPhone or iPad.
- Decide on EHR / PM Approach. Is a combined EHR and Practice Management System needed? Will a combined EHR and practice management system be purchased or will there be a need for an interface to be created?
- Survey hardware and network needs. How many more computers are needed for purchase? What about a network and/or wireless? Is the plan to use an in-house

server with its dedicated closet, air conditioning and backup? What about a network switch and commercial grade firewall? Will the practice require short term or long term IT staff? What is the data back up and disaster plan. Plan for a commercial grade uninterruptible power supply. Also, plan for a service level agreement if the practice opts for the ASP model.

- What interfaces are needed? What about interfaces to external laboratory, pharmacy and radiology services or is that part of the package purchased?
- Will the practice need third party software? As an example: patient education material, ICD-9 codes, CPT codes, HCPCS database, SNOMED, drug database, voice recognition, etc. Ask if that is part of the purchased package.
- Develop your vendor strategy.
 - Write a simple Request for Proposal (RFP) or Request for Information (RFI). This will cause the practice to put on paper all of your requirements and will provide the vendor with all of the important details regarding your practice. This formal request will standardize the responses from vendors as they will need to respond in writing how they plan to address your EHR requirements. Exact pricing should be part of the RFP. Sample RFPs are available on the Web.²¹⁰
 - Consider using a web tool to compare EHR vendors. One free web site offers EHR resources, readiness assessments, detailed search engine and vendor comparisons, vendor profiles, EHR top 10 ratings (11 categories).²¹¹
 - Obtain several references from each vendor and visit each practice if possible. Be sure to select similar practices to yours.
 - The following comprehensive reference by Adler provides an EHR demonstration rating form, questions to ask vendors, RFP advice, EHR references and a vendor rating tool.²¹² Create a scoring matrix to compare vendors.
 - The following reference also has a scoring sheet with sections for vendor software, interfaces, third party software, conversion services, implementation services, training services, data recovery services, annual support and maintenance, financing alternatives and terms. It also includes red flags and FAQ's. This reference is intended to compare costs and not EHR functionality between candidate vendors.²¹³
 - Obtain in writing commitments for implementation and technical support, including data conversion from paper records; interfacing with practice management (PM) software; exact schedule and time line for training.
- Look for funding:
 - The most obvious choice is Medicare or Medicaid reimbursement under the HITECH Act.
 - As noted before, hospitals can donate EHR systems to physician offices under the *safe harbor* with physicians having to pay 15% of costs.
 - *Physician Quality Reporting System (PQRS)* will reward physicians for quality reports that can be generated by an EHR. This will be covered in more detail in the chapter on quality improvement strategies.²¹⁴
 - Check to see if your state has incentive programs
- Select a vendor and develop a contract. Most practices will need to create a contract with legal help. This will ensure the vendor meets their obligations and will define the contract period, duties and obligations, license stipulations, scope of license,

payment schedules, termination clauses, upgrades, support, warranties, liabilities, downtime clauses, etc. ONC developed a 2013 Guide to EHR contracts so adopters could better understand contract terms and pitfalls.²¹⁵

- Decide on a strategy to convert paper encounters to electronic format. Most experts advise that key information (medications, allergies, major illnesses, immunizations, lab results, etc.) be keyed in by staff on active patients several months before going live. Decide what documents such as prior encounters, consultations, discharge summaries, etc., will be needed to upload into the EHR. Several resources will help the practice develop a strategy.²¹⁶⁻²¹⁸ One vendor posts an approximate charge of 15 cents per page for less than 30,000 pages to scan in paper forms. As an example, for 5000 pages this would amount to a charge of \$825.²¹⁹
- Training. It can be said that one cannot train too much. Determine if your vendor has an electronic training database clinicians and staff can use before going live. Assess IT competencies of the clinicians and staff and train for gaps in knowledge.
- Implementation. Consider a phased in approach where clinicians and staff begin with processes such as e-prescribing, internal messages and laboratory retrieval before tackling patient encounters. Develop a go-live plan to determine reduced schedules and frequent debriefs. For more information about roll out and turnover strategies readers are referred to these references.^{187,220}

Recommended Reading

The following are several articles readers might consider to augment their understanding on the potential impact of EHRs.

- *Do Electronic Health Records Improve Processes Of Care And Outcomes Of Preventive Care?* In an editorial Lin discusses the controversy surrounding the

potential impact of EHRs on preventive care. The results are mixed and comparing the success by one organization with an entirely different organization's failure is difficult.²²¹

- *Implementation Of An Outpatient Electronic Health Record And Emergency Department Visits, Hospitalizations And Office Visits With Diabetes.* Authors from Kaiser Permanente studied the impact of implementing a system wide EHR into their integrated delivery network. They reported a modest reduction in ED visits, hospitalizations but no change in office visits. This was a before and after study so cause and effect are difficult to prove.²²²
- *Electronic Health Records And Quality Of Diabetes Care.* Authors compared diabetes care in greater Cleveland that included 38% safety net clinics. They reported composite standards for diabetes and improvements were greater for clinics with EHRs, compared to paper based clinics, regardless of insurance status. This study was not randomized and while controlling for co-variants it is probably still difficult to prove cause and effect.²²³
- *E-Measures: Insight Into The Challenges And Opportunities Of Automating Publicly Reported Quality Measures.* This early 2014 study by Kaiser Permanente scientists explains how they automated their quality measures generated by their enterprise EHR. The note that this is a very expensive process with ROI occurring in four years. Currently, automated quality measures save 5-14 minutes per measure compared to standard manual extraction.²²⁴
- *Mining Electronic Health Records in the Genomic Era.* Excellent summary of the potential of the electronic health record to store phenotypic information that can be used to compare with genomic information. Author discusses the types of data within the EHR, as well as the technological challenges to making the EHR a robust research tool.²²⁵

Future Trends

One doesn't need a crystal ball to determine the direction that EHRs in the US will take over the next several years. The potent force shaping that direction will be the Meaningful Use (MU) criteria of the EHR Incentive Programs. The developer of these criteria is the Health Information Technology Policy Committee (HITPC), a Federal Advisory Committee that advises the Office of the National Coordinator (ONC) and the Department of Health and Human Services (HHS). So far those agencies have closely followed HITPC's recommendations, and it is likely that they will continue to do so in the future. ONC in turn is responsible for creating the EHR certification criteria that ensure that EHRs can perform to specifications that allow for Meaningful Use.

The Meaningful Use program is currently in its first stage (2011-2013), will start its second stage in 2014, and then move to its third stage in 2017 (proposed).

So what direction is HITPC headed? HITPC has designed the MU criteria around five policy areas:

- Improving quality, safety, efficiency and reducing health disparities – goals set out by the Institute of Medicine (IOM)
- Engaging patients and families in their care – another IOM goal
- Improving care coordination
- Improving population and public health
- Ensuring adequate privacy and security protections for personal health information

The Stage 2 criteria, and early suggestions about Stage 3 from HITPC, point to increased care coordination, increased reliance on electronic ordering, more patient portal use, and a greater focus on clinical measurements and quality reporting. Thus clinicians can expect to see EHRs that have more sophisticated analytics, increased standardization, enhanced interoperability, and tight linkages with more sophisticated patient portals than now exist. A

desired outcome is that data and information will no longer remain locked in the plethora of EHR silos built by physicians and hospitals, but will electronically flow from one to the other.²²⁶ It can also be expected there will be more integration between hospital EHRs and the myriad of pumps, medical devices, monitors, etc.

Beyond 2016, when the CMS EHR Incentives for the Medicare program end, the direction that EHRs will take is less clear. Will some groups revert to paper and new medical groups decline EHR adoption? Without robust funding will ONC and CMS be able to continue monitoring meaningful progress? What will be the impact of fines on physicians who failed to meet meaningful use?

ONC and CMS will continue to monitor adoption, meaningful use progress, certification and EHR use and misuse. It is estimated that 5% of attesters for meaningful use will be audited in 2013 for compliance.²²⁷ The federal government will also be looking for evidence of over-coding and other potential abuses.²²⁸ It is likely there will be new coding guidelines in the near future as a result of multiple questions about legitimate EHR billing practices. IT vendors are also being scrutinized, evidenced by the revocation of two EHR certifications in 2013.²²⁹

Experts suggest a number of trends, including an increased reliance on cloud computing,²³⁰ large shared databases used for comparative effectiveness research²³¹⁻²³² increasing use of natural language processing²³³ more pervasive use of telehealth (virtual visits and consultations),²³⁴ improved clinical decision support, more use of patient registries built into EHR workflow,²³⁵ and greater use and integration of wireless remote outpatient monitoring of patients.²³⁶⁻²³⁷

Of course, down the road, one or more unforeseen health IT technologies breakthroughs could alter EHRs in ways that one can currently only barely imagine.

Key Points

- Electronic health records are central to creating health information organizations and a nationwide health information network
- The current paper-based system is fraught with multiple shortcomings
- Reimbursement by the federal government for electronic health records use has greatly increased adoption
- In spite of the potential benefits of electronic health records, obstacles and controversies persist
- Clinical decision support is still in its infancy and will likely improve in the future with artificial intelligence
- Advance planning and training is mandatory for successful implementation of EHRs

Conclusion

In spite of the initial slow acceptance of EHRs by clinicians and healthcare organizations, they continue to proliferate and improve over time. Electronic health records have been transformational for large organizations like the VA, Kaiser-Permanente and the Cleveland Clinic, but the reality is that medicine in this country is mostly practiced by small medical groups, with limited finances and IT support. As a new trend, some outpatient clinicians opt to re-engineer their business model based on an EHR. Their goal is to reduce overhead by having fewer support staff and to concentrate on seeing fewer patients per day but with more time spent per patient. When this is combined with secure messaging, e-visits and e-prescribing the goal of the *e-office* is achievable.²³⁸

Buyers have a wide choice of features and cost to choose from. At this time cost is a major obstacle as well as the lack of high quality economic studies demonstrating reasonable return on investment. As more studies show cost savings, medical groups that have been sitting on the fence will make the financial commitment.

Without doubt, Medicare and Medicaid reimbursement for EHRs and e-prescribing is the most significant impetus to jump start EHR adoption. Preliminary studies have shown a significant increase in EHR adoption as a result of reimbursement programs. It is too early to know how well received Stage 1

Meaningful Use objectives and measures will be received, implemented and reported. Detailed data regarding EHR failure rates are lacking as well as lessons learned from stage 1 and yet, stage 2 Meaningful Use is planned for 2014. For those practices that can afford and need complexity, multiple high-end vendors exist. For smaller, rural, primary care practices, simpler alternatives exist.

Potential obstacles to achieving stage 2 early on might include: vendor not achieving 2014 certification; not enough patients using the portal, inability or failure to do electronic referrals, failure to achieve adequate CPOE and ability to see images within the EHR. Therefore, multiple challenges loom. It is also worth noting that purchasing EHRs is only one of multiple difficult challenges facing clinicians and their staff. According to a mid-2009 Medical Group Management Association (MGMA) survey implementing an EHR was ranked third in difficulty preceded by rising operating costs and maintaining clinician salaries in the face of decreasing reimbursement.²³⁹

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Appendix 4.1

Stage 1 and 2 Meaningful Use Core Objectives and Measures

Stage I Meaningful Use		Stage 2 Meaningful Use	
Description	Goal/Type	Description	Goal/Type
CPOE: Use Computerized Physician Order Entry (CPOE) for unique patients with at least one medication on their medication list.	> 30% of orders Core	Use Computerized Physician Order Entry (CPOE) for medication, laboratory and radiology orders.	> 60% of medication > 30% of Laboratory > 30% of Radiology/imaging Core
Demographics: Record the following demographics as structured data: • Preferred language • Gender • Race • Ethnicity • Date of birth.	> 50% of patients Core	Record the following demographics as structured data: • Preferred language • Gender • Race • Ethnicity • Date of birth.	> 80% of patients Core
Vital signs: Record and chart changes in vital signs as structured data: • Height/length • Weight • Blood pressure (BP) (age 3+) • Calculate and display BMI • Plot and display growth charts for children 0–20 years, including BMI.	> 50% of patients Core	Record and chart changes in vital signs as structured data: • Height/length • Weight • Blood pressure (BP) (age 3+) • Calculate and display BMI • Plot and display growth charts for children 0–20 years, including BMI.	> 80% of patients Core
Clinical Decision Support: Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.	1 rule Core	Implement 5 clinical decision support rules relevant to specialty or high clinical priority along with the ability to track compliance with that rule.	5 rules plus drug-drug interaction drug allergy interaction Core
Smoking: Record smoking status as structured data for patients 13 years old or older.	> 50% of patients Core	Record smoking status as structured data for patients 13 years old or older.	> 80% of patients Core
Patients by Condition: Generate a list of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.	> 1 report Menu	Generate a list of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.	> 1 report *Now a Core Measure

Stage I Meaningful Use		Stage 2 Meaningful Use	
Description	Goal/Type	Description	Goal/Type
Patient Reminders: Unique patients 65 years and older or 5 years or younger seen with the EHR are sent an appropriate reminder per patient preference for preventative/follow up care.	> 20% of patients 65+ or 5- Menu	More than 10% of all unique patients who have had two or more office visits with the EP within the previous 24 months are sent a reminder per patient preference, if available.	> 10% of patients *Now a Core Measure
Patient Education: Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	> 10% of patients Menu	Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	> 10% of patients *Now a Core Measure
Transitions of Care: Provide a summary record of care for each patient in transition of care or referral.	> 50% of patients Menu	Provide a summary record of care for each patient in transition of care or referral.	> 50% of patients >10% electronically *Now a Core Measure
eRx: Generate and transmit permissible prescriptions electronically for patients whom the EHR was used.	> 40% of prescription Core	Generate and transmit permissible prescriptions electronically for patients whom the EHR was used.	> 50% of prescriptions Core
Medication Reconciliation: Performs medication reconciliation for instances of new patients in care transition or referral.	> 50% of patients Menu	Performs medication reconciliation for instances of new patients in care transition or referral.	> 50% of patients *Now a Core Measure
Lab Results: Incorporate clinical lab results into CEHRT as structured data.	> 40% of results Menu	Incorporate clinical lab results into CEHRT as structured data.	> 55% of results*Now a Core Measure
Health Information Protection: Protect privacy and security of electronic health information through appropriate technical capabilities.	Yes Core	Conduct or review security analysis of electronic health information and incorporate a risk management process.	Yes Core
Patient Portal: Provide patients with the ability to access online, download, and transmit their health information within 4 business days of availability.	> 10% of patients within 4 days Menu	Provide patients with the ability to access online, download, and transmit their health information within 4 business days of availability.	> 50% of patients > 5% actually accessing within 4 days *Now a Core Measure
Clinical Summaries: Provide patients with a clinical summary within 3 <i>business days</i> .	> 50% of patients within 3 days Core	Provide patients with a clinical summary within 1 business day .	> 50% of office visits within 1 day Core
Immunization Registries: Capability to submit electronic data to immunization information systems.	Yes Menu	Capability to successfully submit electronic data to immunization information systems.	Yes *Now a Core Measure

Stage I Meaningful Use		Stage 2 Meaningful Use	
Description	Goal/Type	Description	Goal/Type
		Provide patients with secure electronic messaging about relevant health information.	> 5% of patients Core
Syndromic Surveillance: Capability to submit electronic syndromic surveillance data to public health agencies.	> 1 test Menu	Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency.	> 1 test Menu
		Record electronic notes in patient records. They must be searchable and may contain drawings and other content.	> 30% of patients Menu
		Imaging results, explanations, or any other accompanying information are accessible through CEHRT.	> 10% of all images/results Menu
		Record patient family health history as structured data.	> 20% of patients Menu
		Successful ongoing submission of cancer cases to a public health central cancer registry from CEHRT to a public health agency.	Yes Menu
		Successful ongoing submission of specific cases (other than cancer) to a public health central cancer registry from CEHRT to a public health agency.	Yes Menu
Drug Formulary Checks: Implement drug formulary check with access to at least one internal or external drug formulary.	Yes Menu		
Medication Allergy List: Patients have at least one entry or an indication that patient has no known allergies.	> 80% of patients Core		
Medication List: Patients have at least one entry or an indication that patient is not currently prescribed any medications.	> 80% of patients Core		
Problem List: Establish and maintain an up to date problem list of current and active diagnosis recorded as structured data.	> 80% of patients Core		

Appendix 4.2

Proposed Stage 3 Meaningful Use Goals (Courtesy Government Health IT)

Functional Goals	MU Outcome Goals
<p>All relevant data accessible through EHR</p> <p>CDS supports timely, effective, safe, efficient care and prevention</p> <p>CDS helps avoid inappropriate care. access to health information</p>	<p>Patients receive evidence based care</p> <p>Patients are not harmed by their care</p> <p>Patients do not receive inappropriate care</p>
<p>Provide patient and caregivers online access to health information</p> <p>Provide ability to contribute information in the record</p> <p>Patient preferences recorded and used</p>	<p>Patients understand their disease and treatments</p> <p>Patients participate in shared decision making</p> <p>Patient preferences honored across care teams</p>
<p>Relevant patient information is shared among healthcare team and patient, especially during transitions</p> <p>Goals, care plans, and interventions are shared and tracked</p>	<p>All members of a patients care team participate in implementing a coordinated care plan</p>
<p>Efficient and timely means of defining and reporting on patient populations to identify areas for improvement</p> <p>Shared information with public health agencies</p>	<p>Providers know the status of their patient's health</p> <p>Bidirectional public health data exchange</p>
<p>CDS support to avoid duplicative care</p> <p>CDS support to avoid unnecessary or inappropriate care</p>	<p>Eliminate duplicative testing</p> <p>Use cost-effective diagnostic testing and treatment</p> <p>Minimize inappropriate care (overuse, underuse, and misuse)</p>
<p>Patient conditions are treated appropriately (e.g age, race, socio-economic status, education, sexual orientation)</p>	<p>Eliminate gaps in quality of health and healthcare across racial, ethnic, sexual orientation and socioeconomic groups</p>

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Chapter 5

Health Information Exchange

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Learning Objectives

After reading this chapter the reader should be able to:

- Identify the need for and benefits of health information exchange (HIE) and interoperability
- Describe the concept of health information organizations (HIOs) and how they integrate with the national strategy
- Compare and contrast the differences between Direct and eHealth Exchange
- Enumerate the basic and advanced features offered by HIOs
- Detail the obstacles facing HIOs
- Understand the future direction of HIOs and the impact of Meaningful Use

Introduction

Health information exchange (HIE) is a critical element of Meaningful Use (MU) and integral to the future success of healthcare reform at the local, regional and national level. Exchange of health-related data is important to all healthcare organizations, particularly federal programs such as Medicare or Medicaid for several reasons. The federal government determined that HIE is essential to improve: the disability process, continuity of medical care issues, bio-surveillance, research and natural disaster responses.¹ As a result, the federal government has been a major promoter of HIE and the development of data standards to achieve interoperability. Electronic transmission of data results in faster and less expensive transactions, when compared to standard mail and faxes. If the goal of the federal government was only to promote electronic health records, then the end result would be electronic,

instead of paper silos of information. Instead, they have created a comprehensive game plan to share health information among disparate partners.

Chapter 1 discusses multiple HITECH programs that support HIE and interoperability. HIE is an important part of meaningful use, particularly stage 2 and is also integral to accountable care organizations (ACOs) and patient centered medical homes (PCMH) that are supported by the Affordable Care Act. This will be discussed more in the chapter on quality improvement strategies.

In reality, exchange of patient information is an international issue and not limited to just the United States. A 2012 survey of 10 high income countries asked if physicians could electronically exchange patient summaries and test results outside their own practices. Canada reported a

low of 14% and New Zealand reported a high of 55%; the US reported 31%. Furthermore, they found that fewer than 25% of US physicians were notified when one of their patients visited the emergency department and only 16% received information from specialists when changes were made to medications or a care plan.²

HIE most commonly involves the exchange of clinical results, images and documents. It should be pointed out that it is also important to share financial and administrative data among disparate entities as well. Table 5.1 lists some of the common types of health related data that are important to exchange among the many healthcare partners.

Table 5.1: Common types of health-related data exchanged

Data	Examples
Clinical results	Lab, pathology, medication , allergies, immunizations and microbiology data
Images	Radiology reports; scanned images of paper documentation
Documents	Office notes, discharge notes, emergency room notes
Clinical Summaries	Continuity of Care Documents (CCDs), personal health record extracts
Financial information	Claims data, eligibility checks
Medication data	Electronic prescriptions, formulary status, history
Performance data	Quality measures like blood pressure, cholesterol levels
Case management	Management of the underserved/emergency room utilization
Public health data	Infectious diseases outbreak data, immunization records
Case management	Management of the underserved/emergency room utilization
Referral management	Management of referrals to specialists

This chapter will begin with important HIE-related definitions and then chronicle of the evolution of local, state and national organizations created for HIE.

Definitions

The following are commonly cited definitions related to health information exchange.

- Health Information Exchange (HIE) is the “*electronic movement of health-related information among organizations according to nationally recognized standards.*”³
- Health Information Organization (HIO) is “*an organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.*”³
- Health Information Service Provider (HISP) is an organization that provides services and support for the electronic exchange of health information.⁴
- Interoperability is defined as “the ability of two or more systems or components to exchange information and to use the information that has been exchanged”. This implies that the data is computable and that standards exist that permit interoperability.⁵
- eHealth Exchange (formerly NwHIN) is a *network-of-networks* that establishes standards, services and policies that define how HIOs will engage in the secure exchange of health information over the internet.
- Opt-In and Opt-Out refers to patient consent policies; the ability for *content creators* to determine whether or not the personal health record data they create can be shared as well as with whom. Under an opt-in scenario, no health information can be exchanged unless the patient signs a specific informed consent document permitting the sharing of data. Opt-out assumes that consumers grant permission for the exchange of personal health information as part of the broader informed consent that they sign when they receive care from a clinician and the halting of

data sharing must be triggered by an action from the patient.

- Push and Pull technology relates to the process by which health information is exchanged through the internet. Push technology refers to clinicians sending (pushing) information to another provider mostly by email or other secure messaging process. On the other hand, pull technology is used whenever a clinician sends an electronic request for health information to a server (for example, a server maintained by a HISP), the server performs a query for the data, and then responds with any matches.
- Regional Extension Centers (RECs) were created under the HITECH Act for the purpose of providing technical assistance, best practice information, and education to support providers' implementation and Meaningful Use of electronic health records. Secondly, RECs are tasked with supporting and enabling nationwide health information exchange.
- Regional Health Information Organization (RHIO) is "*a health information organization that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.*"¹
- Semantic interoperability is the sharing of discrete data which also contains information about the meaning of the data (metadata) in a manner that both the data and meaning can be appropriately consumed by the other system.

Note that the term RHIO is inexact because HIOs do not have to be regional; they can include only one city or an entire state. Furthermore, HIOs are being created for specific populations such as those on Medicaid or the uninsured. In keeping with these new definitions the acronym HIO will be used when addressing health information organizations and RHIO when addressing specific defined regional HIOs. HIE will be used to describe the act of moving or exchanging health information.

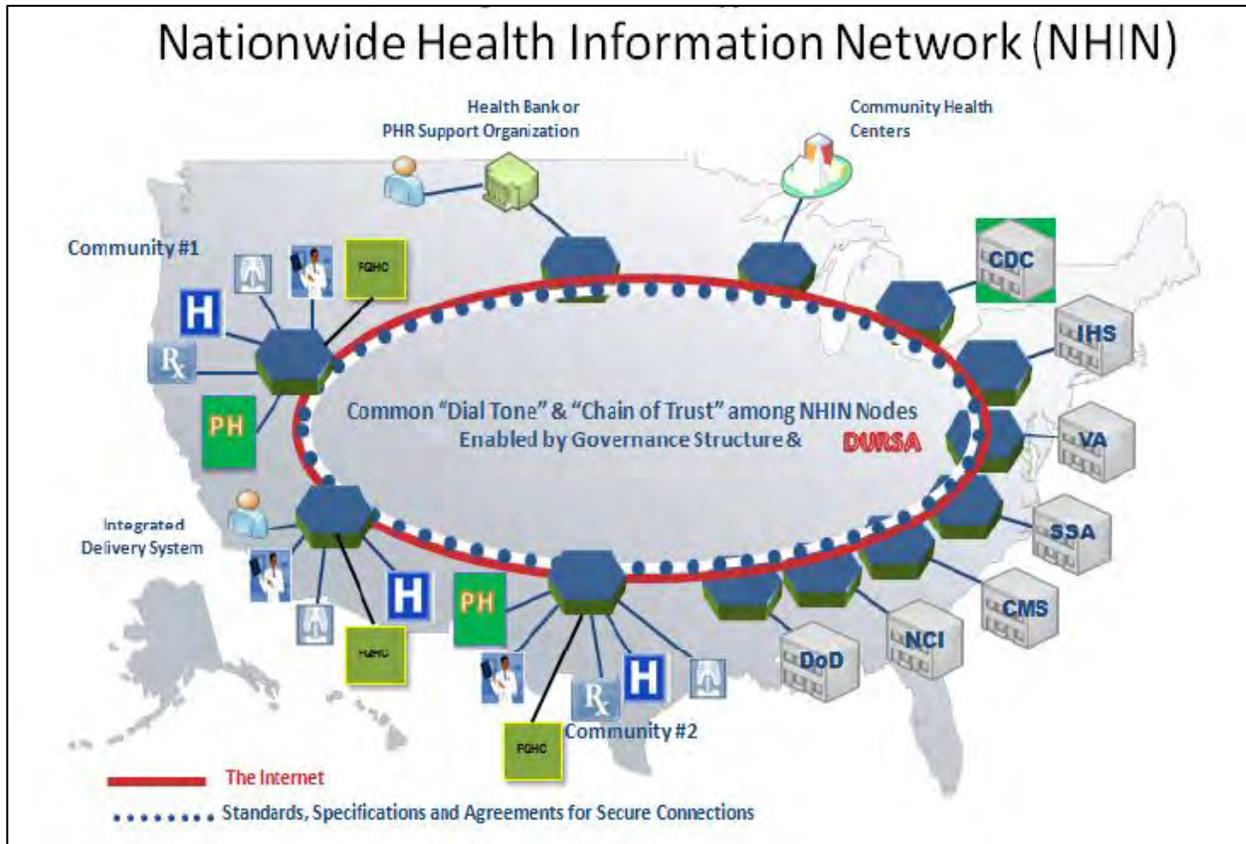
History of the Nationwide Health Information Network

In the early 1990s Community Health Information Networks (CHINs) began appearing across the US. Approximately 70 pilot projects were created but all eventually failed and were terminated.⁶ Most were thought to fail due to lack of perceived value and sustainable business plan and immature technology. In spite of this early failure, it became apparent that not only would electronic health records need to be adopted, there would be a need for new local and regional health information organizations (HIOs) to exchange data and eventually connect to a national health information exchange.

In April 2004 President Bush signed Executive Order 13335 creating the Office of the National Coordinator for Health Information Technology (ONC) and at the same time calling for interoperable electronic health records within the next decade.⁷ How that would be accomplished was not stated nor was it known at the time of the executive order. In November 2004 ONC sent out a *Request for Information* (RFI) asking for input on how the Nationwide Health Information Network (NHIN) should be established. In particular, they wanted to know how the NHIN should be governed, financed, operated and maintained.

Based on input obtained through the RFI, the ONC's 2005 report concluded that the NHIN should "*be a decentralized architecture built using the internet linked by uniform communications and a software framework of open standards and policies*" and a *network-of-networks*.⁸ That meant that there would not be a single centralized data repository of patient health information. Creation of the NHIN would require hundreds of HIOs to be interoperable with thousands of individual healthcare entities. (Figure 5.1) It is important to note that the NHIN is not a separate network; instead, it is a set of standards, services and policies that direct how the secure exchange of health information over the Internet will occur.

Figure 5.1: NHIN Model (Courtesy ONC)



NHIN Prototype Architecture

In 2005 ONC provided \$18.6 million in funding towards the NHIN Prototype Architecture initiative. The purpose of this initiative was to demonstrate that a *network-of-networks* approach without reliance on a centralized network could successfully exchange information between regional HIOs. The ultimate goal was to create a Health Internet comprised of services which facilitate the secure exchange of health information. Contracts were awarded to four contractors (Accenture, Computer Sciences Corporation, IBM and Northrop Grumman) to develop the prototype architectures.

The contractors had to support three *use cases*: (1) EHR-lab use, (2) consumer empowerment and

(3) biosurveillance. Additionally, ONC required each contractor to demonstrate the ability to interface with heterogeneous technologies including electronic health records, personal health records, health information organizations (HIOs), and specialized organizations that deal with secondary use of data like public health and research. Interfacing with these diverse users and technologies was intended to demonstrate viability of uniform standards, services and requirements.⁹

The prototype architecture initiatives, which were demonstrated in early 2007, highlighted the issues of security, data standards and technology. Specifics of the four different NHIN architectures can be found in an extensive monograph

published by Gartner in May 2007.¹⁰ According to the report, the contractors validated the following basic NHIN principles:

- A *network-of-networks* approach without a centralized database or services was possible.
- Common standards governing the way exchanges interact with each other are critical.
- The same infrastructure should support both consumers and healthcare providers.
- Consumer controls over the management of information sharing can be implemented.
- An evolutionary approach, rather than a massive replacement or modification of existing health information systems, is desired.

NHIN Trial Implementation

In June 2007 as a follow-up to the successful NHIN Prototype Architecture initiative, the Department of Health and Human Services released a request for proposal (RFP) to participate in phase 2 known as *Trial Implementation*. Contracts totaling \$22.5 million were awarded to nine operational HIOs in October 2007 as part of the NHIN Cooperative: CareSpark, Delaware Health Information Network, Indiana University (Regenstrief Institute), Long Beach Network for Health, Lovelace Clinic Foundation, MedVirginia, New York eHealth Collaborative, North Carolina HealthCare Information and Communication Alliance, Inc. and West Virginia Health Information Network. In addition, the CDC awarded contracts to study the use of HIOs to support public health information exchange and biosurveillance.¹¹ In February 2008 ONC announced that 20 federal agencies would connect to the NHIN, as the tenth partner. The Department of Defense and Veterans Administration jointly represent the largest NHIN participants, in terms of patient populations. The other government agencies involved are the Social Security Administration, National Cancer Institute, and the Indian Health Service. This was followed in April 2008 with six additional ONC grants awarded to HealthLINC (Bloomington

Hospital), Cleveland Clinic, Community Health Information Collaborative, HealthBridge, Kaiser Permanente, and Wright State University.

Organizations participating in the trial implementation were referred to as Nationwide Health Information Exchanges or NHIEs. This overall effort utilized technology known as the NHIN-Connect Gateway (previously referred to as NHIN-C). The purpose of the Trial Implementation was to utilize these NHIEs to test a set of core health information exchange capabilities. The Core Capabilities that were tested by the NHIEs during the Trial Implementation were:

- Look-up, retrieval, and secure exchange of health information
- Application of patient preferences and permissions for sharing of data
- The use of NHIN for other business purposes as authorized by consumers

Eight use cases were developed that would be tested by the NHIEs. For each use case, an interoperability specification which included software services and data structures was developed by the Health Information Technology Standards Panel (HITSP), a public-private sector cooperative partnership. The eight use cases were:

- Authorized release of information to a third-party trusted entity such as the Social Security Administration or Veterans Affairs.
- Bio-surveillance involving the transmission of data to public health entities.
- Consumer control over personally controlled health record information related to registration and medication history.
- Incorporation of laboratory results into an EHR.
- Release of patient health information in response to medical emergencies.
- Transmission of clinical for quality analysis and reporting.

- Specifications for pseudonymization and re-identification.
- Medication management and reconciliation.

In late 2008, HHS hosted a national demonstration of phase 2 of the NHIN, wherein the aforementioned participants exchanged live health information (using test patient data). Specifically, participants tested the ability for a health entity to query a record, compile a patient summary record and send that information back to the person or entity that requested it. The standard used for interoperability by the NHIN was the HITSP C32 specification for Continuity of Care Documents (see chapter on data standards), that included patient demographic and medication information.¹²⁻¹³ In summary, the NHIN strategy through the end of 2008 was to establish cross-agency collaboration, identify and develop underlying standards, services and policies, develop gateway tools and participate in trial implementations.

NwHIN Exchange

Using the specifications and services developed during the NHIN Trial Implementation, several federal agencies and private sector organizations began exchanging health information in 2009. These current efforts are known as the Nationwide Health Information Network (NwHIN) Exchange. The Social Security Administration (SSA), which requests 15 to 20 million medical records each year as part of disability determinations, was selected as the first federal agency to use the NHIN standards and policies to connect to a non-federal entity. In 2009, SSA requested patient information for disability determinations from MedVirginia HIO. The successful exchange with MedVirginia HIO has reduced SSA's time to retrieve disability verification information from an average of 84 days to 46 days. It was announced in February 2010 that the SSA had released \$17.4 million to expand their ability to exchange disability-related patient information electronically with 15 additional HIOs.¹⁴ Recognizing that the majority of veterans and active duty service members receive medical care outside their respective

systems, the VA and DoD are also involved in the NwHIN Exchange.

Participants in the NwHIN Exchange had to submit an application, sign a data use and reciprocal support agreement (DURSA), complete validation testing and be accepted by a coordinating committee. Non-federal entities can participate only through a federally sponsored contract, grant or cooperative agreement. It was anticipated that hospitals, integrated delivery networks, HIOs, state HIOs, Beacon Communities and others would become NwHIN Exchange participants in the future.

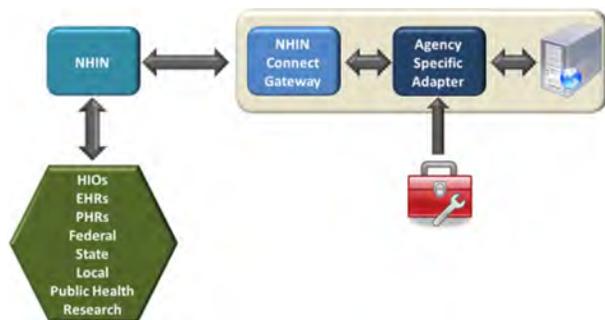
eHealth Exchange and HealthWay

In 2012 the NwHIN Exchange was renamed the eHealth Exchange. Additionally, in 2012 a new entity HealthWay was created to help direct the future of the NwHIN Exchange, discussed in the prior paragraph.. HealthWay is a non-profit public-private organization that promotes open source, open standards based exchange of health information. As of September 2013, there were 40 members, including 4 federal agencies, multiple HIOs and healthcare organizations. They plan to have CCHIT test the standards for HIO to HIO exchange of information.¹⁵

Aurion Project (NHIN CONNECT)

The Federal Health Architecture (FHA), which is part of the ONC as well as a collaborative eGovernment Initiative under the Office of Management and Budget (OMB), released the code for an open source NHIN gateway into the public domain in March 2009. Known as CONNECT, the intent of this release was to incentivize and promote adoption of the NHIN by releasing a basic reference implementation of NHIN standard services. With this tool, federal agencies and private sector organizations can use the same gateway to access the NHIN as opposed to each entity developing their own. CONNECT utilizes service oriented architecture (SOA) on a Java-based platform (Figure 5.2). (SOA is discussed further in the chapter on architectures of information systems).

Figure 5.2: Federal Gateway Overview (Adapted from Federal Health Architecture)¹⁷



CONNECT is free to download and can be used to: set up a health information exchange within an organization; tie a health information exchange into a regional network of health information exchanges or tie a health information exchange into the eHealth Exchange. CONNECT ensures that health information exchanges utilizing CONNECT software are compatible with other exchanges across the country.

Version 2.4 CONNECT was released in April 2010 and is smaller, requiring less memory and faster. Later in 2010 they offered additional web services as part of CONNECT to support core services such as secure messaging and patient look-ups. These enhancements allow developers to create new healthcare applications to augment HIE (analogous to iPhone apps). CONNECT releases new versions and updates periodically, with the latest version 4.2, released in August 2013. FHA CONNECT consists of three elements:

- NHIN Gateway implements the core services such as locating patients at other health organizations within the NHIN and requesting and receiving documents associated with the patient. It also includes authenticating network participants, formulating and evaluating authorizations for the release of medical information and honoring consumer preferences for sharing their information
- Enterprise Service Component (ESC) provides enterprise components including a Master Patient Index (MPI), Document Registry and

Repository, Authorization Policy Engine, Consumer Preferences Manager, HIPAA-compliant Audit Log and others. This element also includes a software development kit (SDK) for developing adapters to plug in existing systems such as electronic health records to support exchange of health information across the NHIN

- The Universal Client Framework enables agencies to develop end-user applications using the enterprise service components in the ESC¹⁶

Direct Project

The original concept for the NHIN responded to the mobile nature of our society by recognizing the need of healthcare clinicians to have timely access to patient information across multiple organizations and locations. As initially envisioned, this interoperable exchange of patient data between distant and unaffiliated providers would occur through a *network-of-networks* consisting of HIOs and government agencies. By leveraging existing HIO's and the standards with which they were built, it was believed that these tested and reliable core services would speed the development of the NHIN. The real world implementation of the NHIN, however, has been delayed by issues ranging from technical (deciding on how much of the standard to support), to procedural (agreeing upon vocabularies for proper semantic interoperability), to political (reconciling patient privacy and consent laws between locales).

In response to the complexities of building the *network-of-networks* that have come to light, the NHIN concept was adjusted by the HIT policy committee's NHIN Working Group to provide more simplistic HIE capabilities via a secure email analogue. This modified version was renamed NHIN Direct (also referred to by some as NHIN Lite). The newer model provides a simplified set of standards, policies and services that support the secure exchange of patient data, but in a more lightweight manner. Focusing on the "email use case" allowed for a simpler, scalable, more direct exchange to support achieving Stage 2 Meaningful Use criteria. Direct and Connect expose different

use cases towards supporting nationwide adoption of secure HIE, representing a relationship similar to the one between email and the Internet.

Launched in March 2010, NHIN Direct focused on the deployment of functionality using the lowest cost of entry from a technical and operational perspective. The purpose of NHIN Direct is to supplement traditional fax and mail methods of exchanging health information between known and trusted recipients with a faster, more secure, internet-based method. In other words, Direct helps provider A transmit to provider B patient summaries, reconciliation of medications and lab and x-ray results. Use cases include connecting clinician-clinician, clinician-patient, clinician-health organization, and health organization-health organization exchange. An example of Direct is a primary care physician sending a specialist a clinical summary on a patient that is being referred for care.

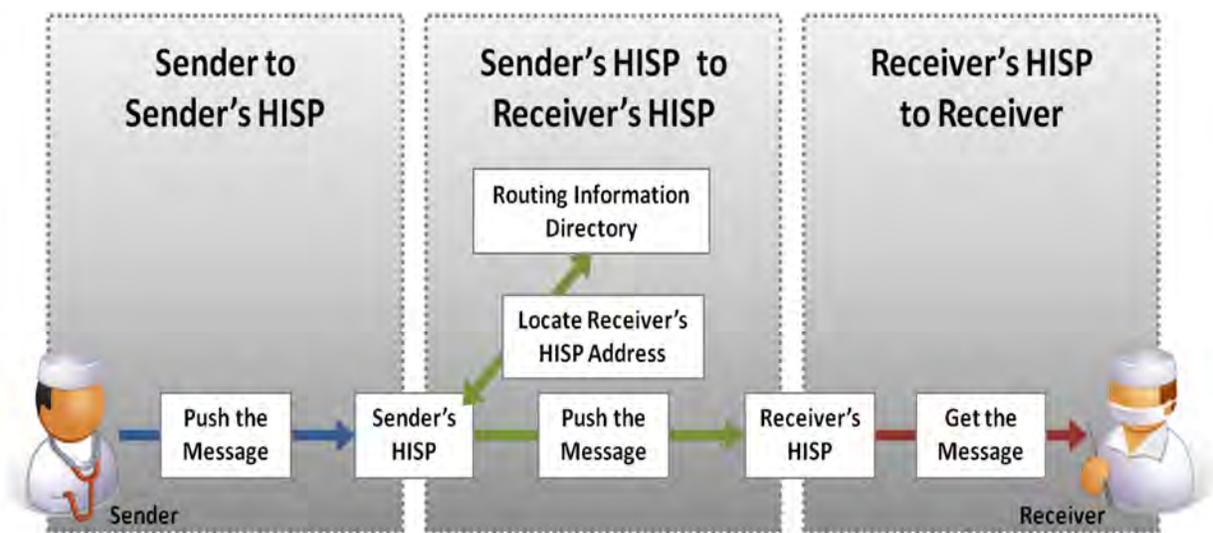
The system is based on secure messaging that is managed by a health information service provider (HISP). HISPs can be a healthcare entity, an HIO or an IT organization. The role of the HISP, in Direct, is to provide user authentication, message encryption and maintenance of system security

for sending and receiving organizations or clinicians (see Figure 5.3). By contracting with an HISP, health entities avoid the need for multiple DURSA or contracts with every provider with whom they exchange data. HISPs must enter into these agreements in order for trusted exchange to be possible. This poses a challenge to widespread adoption; with one potential solution of

Bundling trust anchors, trust agreements and certification programs under the DirectTrust network and the Electronic Healthcare Network Accreditation Commission (EHNAC).

The Direct Project relies on *push* technology, which refers to sending (pushing) data to a provider. Pushed messages can include attachments, such as referral summary documents. This push process is much simpler than *pull* technology where a health information exchange database is queried (pulled) for matches to the patient and then relevant document results are *pulled*. The HISP can maintain a provider directory, similar to an email address book or contacts list, containing relevant provider demographics including the direct email address that is used to authenticate both the sender and receiver. This process is less complicated than

Figure 5.3: HISP Schema (Courtesy Direct Project)



creating and maintaining master patient indices and record locator services that underlie pull technology.

Open source software has been developed to allow for a Direct Project compliant EHR to receive these secure messages and initiate new messages to other Direct Project participants. Direct Project providers must obtain a Direct Address and a security certificate from a HISP. An example of such a secure Direct Address would be b.wells@direct.aclinic.org. Direct messages can be received and sent by clinicians regardless of whether they have an EHR. However, most EHR vendors are now working towards Direct support as part of their efforts to achieve stage 2 meaningful use certification. These efforts permit messages to appear in the system's email inbox and output such as Continuity of Care documents (CCDs) can be generated and transmitted seamlessly and securely from one EHR to another.

Microsoft HealthVault, a participant in the Direct Project initiative, promotes that it is able to receive a continuity of care document (CCD) via direct secure messaging and parse it into its separate components in the personal health record. Another use case for this is provided by requirements for certification written by ONC for stage 2 which dictates that Certified EHR Technology (CEHRT) be capable of parsing and consuming medication, problems and allergy information from a document adhering to the Consolidated Clinical Document Architecture (CCDA) specification. By the same token, patients can initiate a secure direct message from a patient portal, such as HealthVault back to their physician or hospital.

One of the largest HISPs is SureScripts an electronic prescription network provider. In 2013 they reported having 19 state health information networks, and a variety of other large healthcare entities as part of their Direct network, known as SureScripts health information network.¹⁸

Direct protocols are part of stage 2 meaningful use standards. Specifically, SMTP/SMME, SMTP+XDM or SOAP + XDR can be supported by CEHRT. Much work remains to be done before the Direct Project reaches national scale.

Currently, a number of pilots are underway in the United States.¹⁹⁻²¹ One of the largest pilots is occurring as part of the Western States Consortium where sharing of health information is occurring across state lines with its 15 state HIOs.²²

Blue Button Project

Blue button (see figure 5.4) literally means the presence of a blue button in an electronic application such that a patient can download their healthcare data. Various organizations such as the Department of Veterans Affairs, Medicare and large payer organizations have taken the lead to make this available. Initially, data was primarily based on administrative claims data and available as an ASCII or PDF formatted file.²³ With increased adoption of electronic health records and meaningful use requirements structured clinical documents can be generated and shared.

Figure 5.4
Blue Button
icon



Blue buttons could be part of every patient portal or personal health record that is integrated with a personal health record (PHR) providing patients with easily identified ready access to their record in a portable format. ONC has promoted the idea that more should be done with this user-friendly initiative and therefore developed the Blue Button Plus project. Blue Button + represents the ability to have these records in a human readable and machine readable format and the ability to send or share them. The end user has the choice whether to print or share them electronically. This also helps eligible professionals meet meaningful use stage 2 requirements (view, download and transmit) as Blue Button Plus will leverage consolidated CDAs (see chapter on data standards) and the Direct Project. They also recommend the evolving new data standard HL7 FHIR (see chapter on data standards) that will facilitate interoperability with mobile devices and RESTful APIs. There is a Blue Button Implementation Guide available in 2013 created for data

holders, providers and third party developers. This was developed by the ONC's Standards and Interoperability Framework initiative.²⁴

HIE Timeline

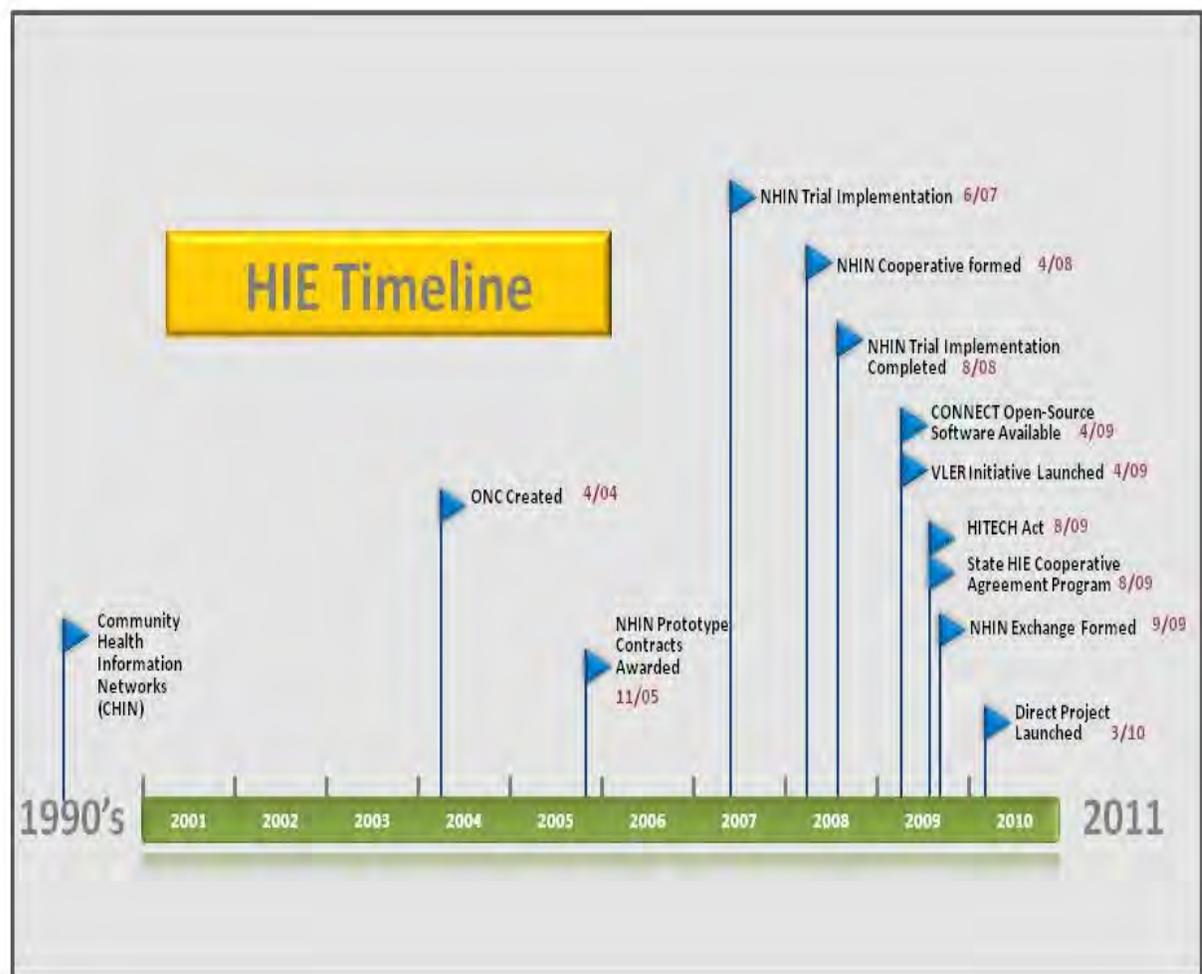
The timing of the development of the NHIN and its various components is depicted in Figure 5-5.

HITECH Act Impact on HIE

The 2009 HITECH Act signaled a major federal commitment to expansion of health information technology. Although the HITECH Act focused on incentivizing the expansion of EHRs, it also encouraged the growth of health information

exchange through the authorization and funding of the State HIE Cooperative Agreement Program, discussed in a later section. This program closed the state and regional HIE gap by awarding \$548 million to 56 state agencies.²⁵ HIE is further supported by incorporating HIE into Meaningful Use stage 2 objectives necessary for EHR reimbursement. The bar was set lower in terms of information sharing in stage 1 because most physicians and hospitals lacked the technology to share.²⁶ Table 5.2 enumerates the stage 2 objectives that have definite and potential HIE implications.

Figure 5.5: NHIN and HIE Timeline



**Table 5.2 HIE and Stage 2 Meaningful Use Objectives
(EP = eligible physician, EH = eligible hospital)**

Stage 2 Objective	Group	HIE Implications
Patient Access: Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP	EP	This could be achieved through either a patient portal integrated with the EHR or through a HIO
Patient Access: Provide patients the ability to view online, download, and transmit information about a hospital admission	EH	This would be achieved through either a patient portal/EHR or through a HIO
Clinical Summaries: Provide clinical summaries for patients for each office visit.	EH	This could be achieved through either a patient portal integrated with the EHR or through a HIO
Transitions of Care: The EP or EH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary of care record for each transition of care or referral	EH, EP	This can be achieved using directed exchange
Immunization registries: Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	EP	This could be done via HL7 messages from EHRs or through a HIO
Cancer registries: Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice	EP	This could be done via HL7 messages from EHRs or through a HIO
Specialized registries: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice	EP	This could be done via HL7 messages from EHRs or through a HIO
Lab-test reporting: Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	EH	This could be done via HL7 messages from EHRs or through a HIO
Syndromic surveillance: Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	EH	This could be done via HL7 messages from EHRs or through a HIO
Advanced directives: Record whether a patient 65 years or older has an advance directive		Strong HIE implications because patients travel and easy access to the AD is imperative
Imaging results: Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology		Most HIOs will store the result and possibly be able to direct to a web based PACS

Health Information Organizations

The late 1990s saw the rise of health information organizations (HIOs) in the United States, largely created with federal startup funds. There was, however, no national game plan as to how to create or maintain them. The National Coordinator for Health Information Technology in 2006 made the following suggestions as to how HIOs might proceed:

- Leverage the Internet as the foundation and think web-based
- Build upon existing successes; take advantage of any existing infrastructure
- Have a realistic implementation plan; build incrementally or by phases or modules
- Develop strong physician involvement; involve medical schools and medical societies
- Obtain hospital leadership commitment; much of the information to be shared comes from hospital IT systems
- Do not exclude any stakeholders; HIOs should consist of multiple types of healthcare organizations
- Seek inclusion of local public health officials; the goal is to also develop a public health information network or PHIN
- Obtain support from the business community; vendors who have networking experience will be valuable partners
- Establish a neutral managing partner; a commission or network authority²⁷

According to a 2011 national survey there were 85 operational HIOs (actually exchanging clinical information) out of 255 reported HIE entities.²⁸ It is not known, however, how many HIOs have started and failed. For example, the Santa Barbara County Care Data Exchange was a highly visible HIO that folded in 2007 due to legal, technological and financial issues.²⁹ An excellent monograph describes the lessons learned from

this project.³⁰ The Pennsylvania RHIO also closed in 2007 due to lack of short and long term financial support.³¹

Most HIOs begin with a collaborative planning process that involves multiple stake holders in the healthcare community. Participation from a broad spectrum of health care entities is necessary for long term sustainability. Potential participants include: insurers (payers), physicians, hospitals, medical societies, medical schools, health informatics programs, state and local government, employers, consumers, pharmacies and pharmacy networks, ambulatory care providers, business leaders, selected vendors and public health departments.

Social capital or an atmosphere of trust is a prerequisite for HIO success. This is particularly true in highly competitive health care regions, where health systems, physician groups, other providers, and payers distrust the motives of the other parties. HIOs are usually complex organizations in which the governing members must reach consensus on governance structure, privacy and security issues, as well as business, technical and legal aspects of HIE. The building of social capital and trust is necessary for sustainability of the HIO.

Multiple functions need to be addressed by a HIO:

- **Financing:** what will be the sources for short term startup money and on-going revenue? What is the long term business plan? What is the pricing structure?
- **Regulations:** what data, privacy and security standards will be used?
- **Information technology:** who will create and maintain the actual network? Who will do the training? Will the HIO use a centralized or de-centralized data repository?
- **Clinical process improvements:** what processes will be selected to improve? Will the analysis use claims data or provider patient data? Who will monitor and report the progress?
- **Incentives:** what incentives exist for disparate entities to join?

- Public relations (PR): how will information on the benefits of the HIO be spread to healthcare organizations, physicians and the public?
- Consumer participation: how will the HIO reach out to stakeholders and patients for input?

The planning phase generally takes several years and generally relies on federal and/or state grant support. Upon completion of the planning phase, the HIO is ready to focus on building the technical infrastructure. The web-based infrastructure can be built by local IT expertise or an HIE-specific vendor. HIOs start with simple processes such as clinical messaging (test results retrieval) before tackling more complicated functionality.

Several types of data exchange models exist and determine how data is shared and stored. The following are general categories:

- Federated: decentralized approach where data is stored locally on a server at each network node (hospital, pharmacy or lab). Data therefore has to be shared among the users of the HIO with an import/export scheme
- Centralized: the HIO operates a central data repository that all entities must access
- Hybrid: a combination of some aspects of federated and centralized model
- Further details concerning clinical data exchange models as well as HIOs using these models, are discussed in the article by Just and Durkin.³²

Table 5.3 outlines some of the pros and cons of the federated and centralized models.

Although HIOs utilize a variety of web-based infrastructures they tend to utilize the following similar shared services:

- Master patient index (MPI) is a database containing all of the registered patients within the HIO. The MPI assigns a unique patient identifier and uses algorithms to locate the correct patient and any existing records by sorting through a myriad of demographic

identifiers. Duplicate records, or poor matching algorithms, can still be a problem for most functioning HIOs.

Table 5.3: Pros and Cons of RHIO models (Adapted from Scalese³³)

	Centralized	Federated
Pros	Simplicity Data appearance is uniform Faster access to data Easier to create	Greater privacy Good examples exist Buy-in may be easier if data is local
Cons	Higher hardware costs Higher operating costs More difficult with very large HIOs	Data display might not be uniform Data retrieval delays from others Potential for node downtime

- Record locator service (RLS) directs the inquirer to the physical location of the patient’s records based on the patient matching by the MPI. These results can in turn allow for retrieval of the documents to which they relate. One such implementation would be a document registry which serves as an index for content housed in a repository.
- Provider directory lists all of the potential data suppliers and users pertinent across the HIO. It is likely to include credentials, address, phone numbers, email addresses and hospital affiliation.
- Data warehouses such as document repositories provide the storage of patient data accessible via HIE.

The expectation is that HIOs will save money once they are operational. It is presumed that the network will decrease office labor costs (e.g. costs associated with faxing, etc.), improve medical care and reduce duplication of tests, treatments, and medications. Many people feel that insurers are likely to benefit more from HIE than clinicians. It is clear that one of the potential benefits of health information exchange is more cost-effective electronic claims submission. As reported by the Utah Health Information Network, a paper claim

costs \$8, compared with an electronic claim cost of \$1 plus the \$0.20 charge by the HIO; therefore a savings of \$6.80.³⁴

Health Information Organizations may be operated by governmental agencies, private entities or a private-public hybrid organization. They can be for-profit or not-for-profit, however the vast majority are not-for-profit. Operating capital for HIOs in most cases comes from fees charged to participating hospitals, physician offices, labs and imaging centers. Some HIOs charge clinicians a subscription fee (e.g. a flat fee per physician per month), others charge a transaction fee, while others charge nothing. Several HIOs are very transparent in regards to their charges and this reference includes a charge matrix for users.³⁵ HIOs can address the entire medical arena or simply a sector such as Medicaid patients. HIOs can cover a city, region, an entire state, multiple states or an entire country. Because HIE can be a marketing strategy, important in meeting Meaningful Use as well as new healthcare delivery models such as accountable care organizations (ACOs), integrated delivery networks (IDNs) may be adopting HIE faster than traditional HIOs are being created. Importantly, IDNs can rapidly offer HIE to their networks without the long and difficult process of creating governance and trust between disparate and competitive healthcare organizations.

There are at least four current HIE business models:

- Not for profit HIOs are usually 501(c) 3 tax-exempt organizations that focus on the patient and community and are funded by federal or state funds and rely on tax advantages. An example would be HealthBridge.
- Public utility HIOs are usually created and maintained by state or federal funding. An example is the Delaware Health Information Network.

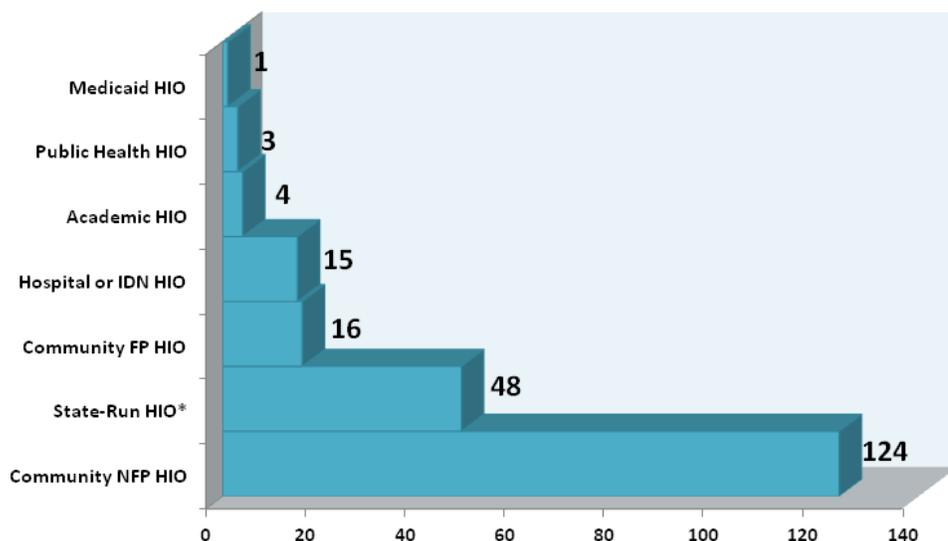
- Physician and payer collaborative HIOs are created within a defined geographic area and can be either for-profit or not-for-profit. An example is the Inland Northwest Health Services HIE
- For-profit HIOs focus on the financial benefits of exchanging data. An example is the Strategic Health Intelligence HIE.

Furthermore, HIOs can be categorized based on ownership (see Figure 5.6)

HIOs are relatively new so many regions have little experience with the concept and further education is necessary for clinicians and healthcare administrators to convince them to participate in the regional HIO. Studies so far have shown that clinicians and patients are not very knowledgeable about HIOs but support the concept of sharing medical information securely.³⁶⁻³⁷

There are open source tools available for evolving HIOs. One such example is the California HealthCare Foundation which donated server software for the master patient index and records locator services. These tools are available through Open Health Tools (OHT), an international consortium dedicated to open projects across the healthcare information technology domain. There are open source offerings that cover a wide range of services and toolkits covering the gap from the core services to the edge system nodes in an exchange. This technology assists the EHR vendors attending the yearly Connectathon (interoperability testing event) held at the annual HIMSS conference.³⁸⁻³⁹

Furthermore, Misys Open Source Solution uses an open source platform for HIE, in spite of the fact that they are a commercial entity.⁴⁰ An interesting open source HIE tool (Mirth) is discussed in the info box.⁴¹

Figure 5.6: Types of HIOs (Courtesy eHealth Initiative 2011 Survey)

Mirth



Mirth is known as the *Swiss Army Knife* of interoperability. As an open source application it supports all major health data standards and incorporates NwHIN Connect. Mirth Meaningful Use Extender (Mux) can operate as a simple HIE to connect area hospitals and medical offices with access via the internet and connectivity to the NwHIN. This platform is less expensive than most HIE platforms because it is open source and there is no charge for the software license, however installation, maintenance and support charges pertain. Other exchange products and services are posted on their web site. In 2013 they were purchased by the EHR vendor NextGen. ⁴¹

According to the 2011 eHealth Initiative survey, which is the authoritative source of information on HIO activity, of 255 HIOs that completed the survey, 24 were termed sustainable: that is, operational, not dependent on federal funding in the past year and at least broke even through operational revenue alone. This compares with 18 sustainable HIOs the year before. Approximately half of operational HIOs charge providers a subscription fee, but multiple revenue models exist. The most common sources of HIO revenue, in order of significance, are: membership fees, federal funds, state appropriations or grants, fees for HIE services and assessment fees.

Many HIOs are not ready for Meaningful Use but many satisfy at least one MU objective such as the exchange of lab results, care summaries, emergency department (ED) episodes or pharmacy summaries. A majority plan to incorporate the Direct Project into their offerings with the most common use case being transitions of care. Eighteen HIOs had behavioral health clinicians contribute data, which is a new trend.

The 2011 eHealth Initiative survey found that HIOs are more likely to adhere to an opt-out policy than to a policy where consumers must actively give permission to the exchange of their health records. Depending on the consent model adopted by the HIO, patient choice can be made by provider, by data type (lab, radiology, etc.),

encounter type, by sending organization, by data field or by sensitive data (mental health, etc.).²⁸

George Washington University reporting to ONC in March 2010 identified the following consent choices:

- No consent: no provision for patient to opt out
- Opt out: patient’s data is automatically included but they can revoke permission
- Opt out with exceptions: only select patient data is included (for example, the patient can exclude certain demographic information or sensitive information such as HIV status); patient can withdraw permission to share this limited data set
- Opt in: no patient data is included without permission; patient permits sharing of all or none of information

- Opt in with restriction: patient gives permission to share information but limits which information is included⁴²

eHealth Initiative found multiple challenges facing HIOs. Among the challenges identified in the 2011 survey were: developing a sustainable business plan, defining value for providers and consumers, addressing government mandates (e.g. Meaningful Use), addressing technological issues such as integration, governance issues, addressing privacy and security, engaging potential users and accurately linking patient data.

The three most common sources of shared information were hospitals, primary care physicians and community/public health clinics.²⁸

Some of the more common HIE functions are listed in Table 5.4.

Table 5.4: Health information exchange functionality (Courtesy eHealthinitiative)

Functionality	Functionality
Results delivery	Quality reporting
Connectivity with EHRs	Results distribution
Clinical documentation	Electronic health record (EHR) hosting
Alerts to clinicians	Assist data loads into EHRs
Electronic prescribing	EHR interfaces
Health summaries	Drug-drug alerts
Electronic referral processing	Drug-allergy alerts
Consultation/referrals	Drug-food allergy alerts
Credentialing	Billing

Health Information Organization Examples

The following are local, regional or statewide HIOs that are innovative and successful and can serve as examples to follow.

Utah Health Information Network

- Created in 1993, it has been one of the most financially successful non-profit statewide HIOs in existence.
- 90% of Utah physicians and the state government are connected

Services include:

- Clinical HIE for physician sharing of patient data
- CHIE Direct so patient information can be pushed
- Utrasend they provide administrative (billing and eligibility) services
- UHINt2.6 is a baseline tool that allows the user to create electronic claims or upload electronic claims from a practice management system to the UHIN network
- Users can connect to multiple clearinghouses to access payers outside of Utah with one connection.
- Their web site is highly educational and includes their standards and specifications⁴³

Nebraska Health Information Initiative (NeHII)

- Statewide roll out began July 2009 and they are now part of the Statewide HIE Cooperative Agreement Program
- Offers a dynamic virtual health record (VHR) for users when they log on that resembles a CCD document
- Also offers a certified EMR-Lite for clinicians who desire an EMR as part of the HIE. Does not include practice management software

- Has a hybrid-federated data storage architecture
- They have experienced a low opt-out rate of about 2%
- 92% of requests are completed in two seconds or less
- E-prescribing available as part of HIE, as well as Direct secure messaging
- Approximately 1,400 physicians are members
- Weekly usage stats are posted on the web site
- Fees are transparent; \$52 per month per clinician for all services⁴⁴

Maine Statewide Health Information Exchange

- One of the largest statewide HIOs
- The network known as HealthInfoNet was launched August 2009 and is now also a Regional Extension Center
- Has ability to create a virtual EHR based on collated data
- Goal is to link all healthcare entities in the state by 2015⁴⁵

Indiana Health Information Exchange (IHIE)

Multiple partners helped create this RHIO in 1999, including the Regenstrief Institute that is part of the Indiana University School of Medicine. In 2011, 80 hospitals, long term care and other facilities and 18,000 physicians from within Indiana and adjacent states participated. They opted to use a centralized approach to storing data in one location. They also wanted to be an example for the rest of the country, employ more workers and create more data for better research. The network includes state and local public health departments and homeless shelters. They link to two other HIOs (HealthBridge and Michiana). IHIE is now part of the Central Indiana Beacon Community, the VLER initiative and a Medicare Health Care Quality demonstration project. IHIE

is working with a statewide HIE Cooperative Agreement Program to link the state's five HIOs to accomplish statewide HIE. IHIE's disease management program known as QualityHealth First™ supplies monthly reports, alerts and reminders to clinicians, at no charge and is the centerpiece of the Beacon Community program. Their HIO offers the following functions:

- Clinical abstracts
- Physician profiling data and professional services
- Results review: radiology results, discharge summaries, operative notes, pathology reports, medication records and EKG reports
- Clinical quality reports
- Research
- Electronic laboratory reports for public health: childhood immunization information and tumor registry
- Syndromic surveillance (looking for syndromes like flu like illnesses to track epidemics or bioterrorism)
- Adverse Drug Event (ADE) detection
- ACO services
- Web based image sharing
- They plan to launch medication reconciliation, diabetes and cholesterol management and breast cancer and colorectal cancer screening⁴⁶⁻⁴⁹

HealthBridge

On the following page is a case study of HealthBridge a successful not for profit HIO that is able to provide a multitude of services, compared to many nascent HIOs. Similarly, they have expanded their services to three states or *franchised HIE*. Given their size and maturity, they are also able to point out financial advantages of HIE which is under-reported. Their analysis points out that the manual delivery of lab results costs about \$0.75/message compared to \$0.12/message for the exchange.

They also point out that lab results can be pushed from the HIE directly into their EHR, thus preventing the need for an expensive interface to be built for each lab and hospital. Data is also codified with LOINC, making the data more valuable for quality reporting and analytics.⁵⁰

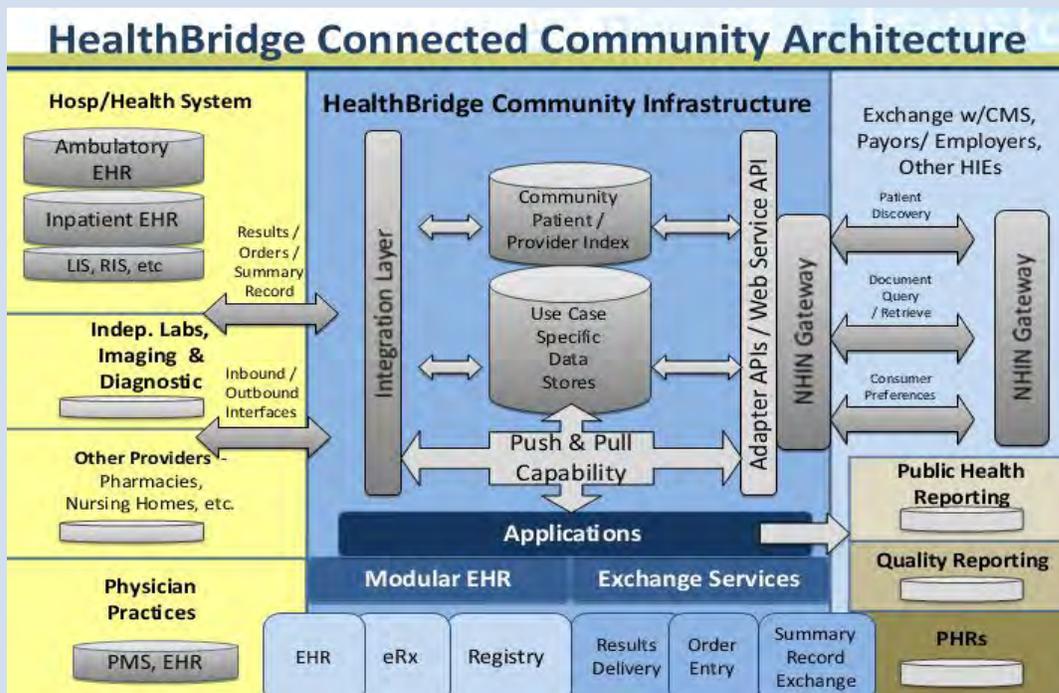
Claims-based HIOs

Availity Health Information Network. This is the first multi-payer based health information exchange. This network uses claims data for patients insured by Blue Cross/Blue Shield of Florida and Minnesota, Health Care Service Corporation, WellPoint, and Humana with customers in all 50 states. They claim to integrate with EHRs, practice management systems and hospital information systems and most services are available for free. Users can access this site for eligibility/benefit questions, claims clearinghouse, treatment authorizations, referral status, payment collections and to review medications, diagnoses, treatments and lab orders. They claim 600 million transactions per year and offer the following features:

- Availity Care Profile® includes:
 - Availity A Continuity of Care Record (CCR) that shows services rendered, lab and x-rays ordered, diagnoses, procedures performed, hospitalizations and immunizations
 - CarePrescribe®, an e-prescribing service
 - An optional patient portal (RelayHealth)
- Availity CareCost®, a cost estimator for patients
- Availity RealMed® revenue cycle management
- Availity CareCollect®, a payment processing service for upfront payments
- Availity CareRead® is a magnetic swipe card with all of the member's ID information⁵¹

Case Study: HealthBridge

HealthBridge is a not-for-profit HIO serving the greater Cincinnati, Ohio, as well as parts of Kentucky and Indiana that was founded in 1997. It has been quite successful financially with income not based on federal grants, but rather on monthly subscription fees. HealthBridge provides information exchange for 50 hospitals and 7500+ physicians. They provide access to imaging, fetal heart monitoring and hospital-based EHRs. They were an early NwHIN trial participant and in 2010 they were selected to be a regional HIT extension center and a Beacon Community. Their early technology partner was Axolotl who offered EMR Lite to integrate with their HIE. They have selected Mirth Meaningful Use Exchange (Mirth MUx) as their interoperability platform. HealthBridge exchanges 3 million messages per month and they have been able to demonstrate an annual return of 5-8% over the past 8 years. Forty nine percent of connections to the HIE are with the EMR Lite option, 38% with other EHRs, 2% print content and 1% faxes. Physicians are not charged with this model for core services. Figure below demonstrates the architecture used to create the community infrastructure by HealthBridge. They are a HISP and participate in the Direct Project. They also offer workflow redesign and disease registries, data analytics, HIE consulting, quality reporting, public health reporting, syndromic surveillance, claims checks and eligibility verification.⁵⁰



It is uncertain whether claims-based HIOs will catch on and whether new services will be added. Payers stand to gain a lot from electronic data collection and analysis. It should also be noted that the following limitations are associated with this model:

- Model only covers insured patients in the network
- If a patient does not file a claim for a service (pays out of pocket), there will be no record
- A patient can opt-out of sharing data on the HIO
- Patient's employer can opt-out from sharing claims
- Data older than 24 months cannot be retrieved
- Because it is claims-based, there is a lag time between when the test was taken and when the results are posted

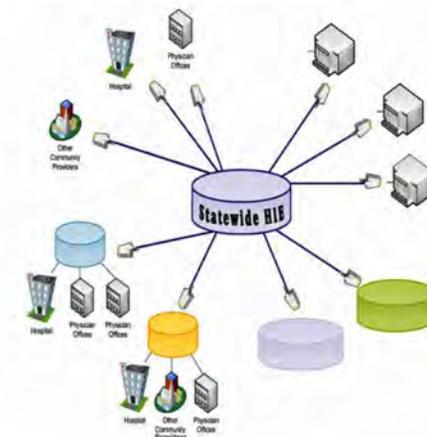
Statewide Health Information Exchange Cooperative Agreement Program (SHIECAP)

In March 2010, fifty-six states, eligible territories, and qualified State Designated Entities (SDE) were funded to build capacity for exchanging health information within and across state lines. This program was created under the HITECH Act to expand HIE/HIO efforts at the state-level while also supporting nationwide interoperability and Meaningful Use. In some states, existing RHIOs expanded to become statewide entities/SDEs. Figure 5.7 shows the schema of how SHIECAP is intended to contribute to the overall HIE.

ONC mandated that State HIE programs ensure that providers will have access to at least one option to satisfy Meaningful Use requirements. Towards that end, State HIEs and SDEs must address the following priority HIE capabilities:

- E-Prescribing
- Receipt of structured lab results

Figure 5.7: SHIECAP schema (Courtesy ONC State HIE Program⁵²)



- Sharing of patient care summaries across unaffiliated organizations
- To receive continued funding, States and SDEs must submit a Strategic and Operational Plans for approval. Each plan must address six key areas:
 - Initiate a transparent process for input from multiple stakeholders
 - Monitor and track Meaningful Use HIE capabilities (e.g. the percent of pharmacies accepting e-prescribing requests)
 - Ensure that the State or SDE framework for privacy and security is consistent with national standards as set by Health and Human Services
 - Address gaps in HIE capabilities to achieve Meaningful Use (example of potential gaps include Medicaid services, rural providers and, small pharmacies)
 - Ensure consistency with national policies and standards including NHIN
 - Align HIE strategies with Medicaid and Public Health⁵²⁻⁵³

Direct Project standards are also commonly adopted by SHIECAP participants. To date, states have adopted one of three approaches to statewide HIE: state-led so the state receives the ONC funds; state designated entity (SDE) receives

funds; SDE-like entity shares governance from the state but receives no federal money. The University of Chicago reported on the status of 27 state programs in early 2012 and noted that the problems encountered were similar to those experienced by existing HIOs.⁵⁴

The efforts of Florida to meet these ONC mandates are described in the following info box.

Current Status of US Health Information Exchange

It is difficult to know how many individual and state-wide HIOs are in existence and at what stage of maturity and data exchange capabilities. One helpful resource has been the annual national survey sponsored by eHealth Initiative. They have measured HIO maturity based on a stage 1-7 taxonomy, with state 7 representing “sustainable and fully operational HIO”.....they offer “advanced analytics, quality reporting, clinical decision support, PACS reporting....”. The following are highlights from the 2013 survey:

- 199 organizations *volunteered* to take the survey. It is unknown how many didn't respond and why.
- Interoperability was a major problem due to the necessity to connect to multiple systems and the fact that creating interfaces with e.g. EHRs was difficult and expensive. They desired standardized integrated products and pricing from vendors
- More than half of respondents support accountable care organizations (ACO) and patient centered medical home (PCMH) models
- Federal funding is still needed for many HIOs, particularly advanced HIOs. Most of these are state-designated entities. Only 52 claimed they received enough revenue from users to cover operating costs.
- Patient engagement was limited: 37 HIOs allow patients to view their data, 24 support patient scheduling and 17 permit patients to submit data.

- HIOs continue to face challenges of sustainability, funding and privacy issues but also face competition from other HIOs, ACOs and HIE vendors. Sharing often does not occur outside the network.
- Ninety organizations used the push model (Direct Project).⁵⁶

A 2013 report on *hospital-based* HIE showed that it grew substantially since 2008. Roughly, 60% of hospitals shared electronic health data with physicians and other hospitals outside their organization.⁵⁷ However, another 2013 article reported that only 30% of hospitals and 10% of practices participated with a HIO. Test results were the most frequently shared data (82%), followed by discharge summaries (66%) and outpatient clinical summaries (61%). They also reported that fewer than 25% were financially sustainable and most viewed viability as a major issue. Only 10% of reported HIOs could meet all six stage 1 meaningful use criteria for HIE.⁵⁸ In the report to Congress by ONC in June 2013 they stated that 39 states had the ability to exchange



Florida Health Information Exchange

The Florida HIE is being managed by the contractor Harris Corp. Its goal is to coordinate the exchange of health information between patients, clinicians, Regional Extension Centers, hospitals, medical offices, HIOs, integrated delivery networks, independent practice associations, long term care facilities, department of health, state immunization registry, federally qualified health centers, labs and electronic prescribing. As of mid-2011 they offered Direct Project connectivity and patient CCD look up services. The backbone for the exchange is based on Mirth® technology, discussed elsewhere in this chapter. Three existing HIOs in Florida are the first participants. Direct messaging connects with Georgia and Alabama. Outreach funding is available for rural and financially disadvantaged organizations.⁵⁵

health data via the push technology, whereas, 25 states had pull technology for HIE.⁵⁹

Health Information Exchange Concerns

There are multiple concerns surrounding the creation and sustainment of a health information organization. The following are just few of the reported concerns:

- Each HIO has a different business model. Is there enough data to know which model is preferred?
- It is unclear how HIOs will be funded long term. Will funding come from insurers? Clinicians? Employers? Consumers? Federal or state government?
- Approximately \$550 million from the HITECH ACT went towards statewide HIE. Have enough been learned at this point to decrease the failure rate?
- Will universal standards be adopted or will different standards for different HIOs prevail?
- Poor cities, states and regions tend to be at a disadvantage. What should be done with geographical gaps in HIOs and what regions should they cover? Should they be based on geography, insurance coverage or prior history?
- Will nationwide exchange of health information be possible with a low number of sustainable HIOs fail and incomplete adoption of EHRs?
- What are the incentives for competing hospitals and competing physicians in the average city or region to collaborate and share information?⁶⁰
- Will HIOs have to comply with FISMA regulations?
- Will the newest HIPAA regulations (or state personal health information-related laws) become impediments to HIO implementation and operation?
- Opt-in and opt-out patient consent models vary by locality, region, and state. Will one model become standard?
- How to solve the patient matching and identity problem?
- Is there a strong reason to accredit HIOs?
- How will patient privacy and security rules under Meaningful Use come into play in the HIO domain?
- Very little research has been done to identify which physician specialties are the most frequent requestors of patient data from HIOs. Similarly, little is known about which clinical situations benefit the most from data exchange. This suggests that providers may not value HIE. In the future, will clinicians be comfortable making care decisions based on discrete data elements imported from an external record source?
- Will timely access to patient documentation be realized in the face of technical and procedural hurdles?
- Will physician adoption of the Direct Project standards, in order to meet Meaningful Use paradoxically decrease adoption of the more formal pull model?
- How can payers be more consistently involved in support of HIOs? Will providers trust an HIO that is sponsored by or involves payers?
- When will there be more quantitative and qualitative studies to document value and return on investment?
- Will Accountable Care Organizations (ACOs) increase or decrease HIO use?
- Is the current HIO model too complex for success, compared to other models of HIE?

Health Information Organization Resources

It can be argued that creating the technology architecture is the easy part in the life of a HIO. Far more time must be spent planning the

governance and financing. It is therefore critical that localities do their homework to research the lessons learned from others who have successfully built a HIO. The following are valuable resources:

- Privacy and Security Solutions for Interoperable Health Information Exchange. Report for the AHRQ, December 2006⁶¹
- Guide to Establishing a Regional Health Information Organization. Publication by the Healthcare Information and Management Systems Society. 144 page step-by-step resource. Cost \$78 for non-members.⁶²
- Care Connectivity Consortium was founded in 2011 to enable sharing of EHR records between 5 major healthcare organizations: Geisenger, Group Health, Intermountain Health, Kaiser Permanente and Mayo Clinic. They coordinate their efforts with HealtheWay and use the 2010 eHealth Exchange standards.⁶³
- S&I Framework was created by the ONC's Office of Standards & Interoperability as a forum for information exchange regarding HIE. Comprehensive guidance for implementing NwHIN 1.0 Portfolio to meet meaningful use objectives. The site contains the transport and security measures, the vocabulary and code sets and content structure related to HIE.⁶⁴
- Rural Health Information Exchange Toolkit (2013) was released by ONC to add rural HIE. The toolkit has guidance regarding how to form or join a HIO, readiness assessment, a return on investment calculator, Direct Project guidance, a policy matrix and privacy/security requirements.⁶⁵
- Governance Framework for Trusted Electronic Health Information Exchange. ONC mono-graph that discusses organizational, trust, business and technical principles. 2013.⁶⁶
- HIE Interoperability Training Courses (2013). ONC has developed training modules for eligible physicians or hospitals in support of health information exchange that is part of stage 2 meaningful use. Specifically, they will focus on the standards related to transitions of care, lab exchange, patient engagement and public health. The training consists of five web-based courses that are self-paced.⁶⁷
- Direct Project: Implementation Guidelines to Assure Security and Interoperability. May 2013. This is a guide released by ONC that provides policies and practices for HISPs and other Direct participants.⁶⁸
- HIMSS Guide to Participating in a Regional Health Information Organization. 2009. Monograph provides helpful background history about the multiple facets of HIOs.⁶⁹
- Common Framework: Resources for Implementing Private and Secure Health Information Exchange is published by Connecting for Health that is part of the Markle Foundation. The Framework consists of multiple documents that help organizations exchange information in a secure private manner, with shared policies and technical standards. Using their protocols a tri-state prototype HIO was created. The Common Framework with nine policy guides and seven technical guides is available free for download on their site.⁷⁰
- Characteristics associated with Regional Health Information Organization viability. Authors analyzed data from a large 2008 survey of HIOs. Two factors for success stood out: simplicity in terms of not trying to do too much and early financial commitment from a wide variety of participants.⁷¹
- Electronic Personal Health Information Exchange. February 2010. Report to Congressional Committees. GAO report on healthcare entities' reported disclosure practices and effects on quality of care.⁷²
- Statewide Health Information Exchange. Best Practice Insights from the Field. Bates M, Kheterpal V. March 2010. White Paper. Provides 10 best practices and case studies for those who plan to build a statewide HIE/HIO.⁷³

- Secrets of HIE Success Revealed, Lessons from the Leaders. National eHealth Collaborative. July 2011.⁷⁴

Recommended Reading

The following articles summarize newer trends and knowledge related to health information exchange:

- *Effects Of Health Information Exchange Adoption On Ambulatory Testing Rates.* The authors looked at the effects of HIE on lab and radiology testing and allowable charges in Mesa County, Colorado 2005-2010. They found a reduction in lab testing but not cost and no change in ordering or cost of radiology tests by primary care physicians and specialists after HIE adoption.⁷⁵
- *Bridging The Chasm: Effect Of Health Information Exchange On Volume Of Laboratory Testing.* This paper looked retrospectively at testing associated with consultations before and after HIE was adopted in 2000. They found that there was a significant decrease in the number of lab tests ordered after HIE adoption, when recent tests were available from another institution.⁷⁶
- *Does Health Information Exchange Reduce Unnecessary Neuroimaging and Improve Quality of Headache Care in the Emergency Department?* Researchers looked at patient's records associated with multiple emergency room visits for headache to determine if the implementation of HIE translated into fewer ordered neuroimages and higher quality medical care. The regional HIE connected 15 major adult hospitals and two clinic systems. HIE was associated with fewer diagnostic images and increased compliance with clinical practice guidelines but not a reduction in overall cost. In spite of guidelines, more than two-thirds of repeat ER visits for headache were associated with CT imaging.⁷⁷

Future Trends

While the success of HIOs continues to be uncertain even with extensive HITECH ACT

funding, several trends are appearing from the more mature and successful HIOs. First, many are attempting to achieve Meaningful Use by providing HIE to include quality reporting and other advanced functionalities. Second, clinical messaging is being combined with administrative and financial data to give users more of a dashboard experience, where multiple data sources are aggregated to expose seemingly disparate functions on one web page. It seems likely that eventually seamless integration of EHRs, practice management systems and claims management as core HIO services will occur. This would offer a single platform to conduct all clinical and financial business and the ability to generate a wide range of reports. Third, more efforts to use data secondarily for research and as a means of financially supporting HIOs can be expected. Fourth, data analytics will likely evolve if the need is perceived and the value proven. Fifth, HIE has no natural or national boundaries. Examples of the international scope are Global Dolphin, a project to exchange medical information between countries⁷⁸ and epSOS, a European-based interoperability project (see info box below). Sixth, more mergers of HIE vendors and new vendors appearing can be anticipated if accountable care organizations and Meaningful Use continue mandated sharing of health information.⁷⁹⁻⁸¹ Seventh, more interoperability can be expected in the future between electronic health records, home telemedicine monitors and any other devices that generate medical data that should be collated and analyzed into one location for clinician review.

Lastly, new innovations can be expected to appear. One HIO decided in 2013 to make access to the exchange available for those clinicians who did not own an EHR. They offer secure access through Direct Project messaging, such that a non-EHR user can request records from the exchange in the C32 CCD XML format pushed to him/her as a PDF attachment. Because they are members of the state-wide Florida HIO, they can request records from other locales as well.⁸² Allscripts created a new patient portal in 2013 that connects to office and hospital EHRs and the HIO so that data can be pushed and pulled from all locations for the entire family. This portal is certified as a modular EHR

for meaningful use and records can be accessed from any computer, smartphone or tablet. In addition, they provide a link within their EHR that alerts clinicians when there is new information on a patient located on the HIO.⁸³

ONC and CMS have more work ahead to make HIE successful in the US. In August 2013 they

published *Principles and Strategy for Accelerating Health Information Exchange (HIE)* that was partly based on an earlier Request for Information (RFI) to gain input from vendors, clinicians and consumers. It is clear that new strategies are necessary to solve the issue of sustainability.⁸⁴

European eHealth Project



Founded in 2008, epSOS is the European electronic health interoperability project. Its primary purpose is to improve health care of European citizens while travelling abroad through the cross-border exchange of health data. At present 23 European countries participate.

A one-year pilot study is underway. During this pilot, 10 participating epSOS countries are testing the cross-border transmission of patient summary data sets and e-prescriptions. A second phase of testing will address integration of 112 emergency services (similar to the US 911 phone system), integration of the European Health Insurance Card, and patient access to data.

As a pilot project, epSOS is concentrating its efforts on the technical aspects of cross-border interoperability. It is simultaneously addressing the legal, organizational and semantic issues involved with exchanging data between participating nations.⁸⁵

Key Points

- Health information exchange is critical for achieving Meaningful Use of electronic health records
- In order to create a Nationwide Health Information Network (NwHIN) multiple data standards will need to be reconciled and adopted
- Creating the architecture for a Health Information Organization (HIO) is not difficult; developing the long term business plan is
- Important interoperable demonstrations of the NHIN Exchange model have taken place with multiple participating civilian and federal partners
- Direct is a very new fast-track approach to accomplishing Meaningful Use

Conclusion

Sharing of health-related data is a critical element of healthcare reform and Meaningful Use. Health information exchange among disparate partners is becoming more common in the United States due to evolving HIOs and the eHealth Exchange. Federal programs support the creation of

exchanges as well as the services, standards and policies that make HIE possible. HIOs are proliferating, largely due to government support but they are often impeded by a lack of a sustainable business model, as well as privacy and security issues. The federal government

has privatized the Nationwide Health Information Network in an effort to accelerate standards creation and adoption by private sector stakeholders. With the new monies from HITECH ACT for EHRs and HIOs and the new direction of Direct messaging, the immediate future should be very interesting. At the same time, insurance companies and claims

clearinghouses are creating new models based on claims data. Similarly, integrated delivery networks are offering health information exchange as a marketing strategy and so they can participate in new healthcare reform delivery models. It is too early to know what a HIO of the future will look like but it seems clear that more features and better integration can be expected.

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Chapter 6

Data Standards and Medical Coding

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Learning Objectives

After reading this chapter the reader should be able to:

- Enumerate the reasons data standards are necessary for interoperability
- Understand the importance of clinical summaries such as Continuity of Care Documents (CCDs) or Continuity of Care Records (CCRs)
- Discuss various data standards used for medical coding and billing
- Compare and contrast standards used for electronic health records and Meaningful Use

Introduction

According to the Institute of Medicine's 2003 report *Patient Safety: Achieving a New Standard for Care* one of the key components of a national health information infrastructure will be "data standards to make that information understandable to all users."¹

In order for electronic health records (EHRs), health information organizations (HIOs) and the Nationwide Health Information Network (now known as eHealth Exchange) to succeed there needs to be a standard language; otherwise one has a *Tower of Babel*. Standards are used every day but are often taken for granted. All languages are based on a semantic language standard known as grammar. The plumbing and electrical industries depend on standards that

are the same in every state. The railroad industry had to decide many years ago what gauge railroad track they would use to connect railroads throughout the United States.

Interoperability relies on syntax and semantics. Syntax is a concept that is related to the structure of the communication, e.g. HL7 discussed later in the chapter. Semantics is a concept that denotes meaning of the communication e.g. SNOMED also discussed later in the chapter. Data standards can come in many flavors. Standards that focus on communication between multiple systems are referred to as transport standards. The rules that dictate the format of information as it is packaged for transport are known as content standards. Individual segments within a content package are governed by a vocabulary.

All of these standards are developed after careful study of real world use cases.²

There are actually several terms that should be defined and discussed as part of understanding medical data standards.

Language is a system of communication; in the field of medicine it involves words that are used almost solely in the field

Vocabulary, Terminology and Nomenclature. Vocabulary means the terms used within a certain domain. Terminology means the terms used for a specific purpose, such as Common Procedural Terminology (CPT) discussed later in the chapter. Nomenclature refers to a defined system of naming such as Systematized Nomenclature of Medicine (SNOMED). Some would use these terms as synonyms, however.

Classification is a grouping of terms with similar meanings such as the International Classification of Diseases (ICD)

Taxonomy is the science of classification. This term is most often used to show a “parent-child” relationship and a common example is the Taxonomy of Medication Errors.

Codes are a representation of words that permit processing by a computer. Codes are usually applied to vocabularies and classifications. Terms such as diabetes are associated with codes such as ICD-9 250. EHRs have encoding software that assists with coding.

Ontologies are knowledge models about a domain. They include the concepts, attributes and relationships that exist; in this case a healthcare domain. An example could be the artificial intelligence in medicine (AIM) domain.³⁻⁴

While there have been considerable advancements towards universal standards, it does not exist yet. The progress has been slow in part due to the fact that participation in standards determining organizations (SDOs) is voluntary. Data standards have taken on new significance as a result of Meaningful Use objectives and the need for data sharing. The Office of the National Coordinator has listed the

pertinent data standards required as Reference Grids for stages 1 and 2 on their web site.⁵

The next sections will discuss the major data standards and how the standards facilitate the transmission and sharing of data. Not all data standards have been included in the following sections and many standards are still a “work in progress.”

Content Standards

Extensible Markup Language (XML)

XML is a data packaging standard. It has served as a structural component for domain specific languages for health information exchange. In order for disparate health entities to share messages and retrieve results, a common data packaging standard is necessary

- XML is a set of predefined rules to structure data so it can be universally interpreted and understood
- XML consists of elements and attributes
- Elements are tags that can envelop data and can be organized into a hierarchy. There are no predefined tags
- Attributes help describe the element
- XML messages have headings and message bodies packaging information by wrapping it in layers of “tags.” Software must be written to send, receive or display these structures

Below is a simple example where car-lot is the root element and car is a child element. Each car sibling uses attributes to further define the physical model being represented.⁶

```
<car-lot>
  <car make="Ford" model="Mustang">
    <year>1956</year>
    <id type="vin">9216604</id >
  </car>
  <car make="Honda" model="Civic">
```

```
<year>1988</year>
<id type="vin">9335676</id>
</car>
</car-lot>
```

Health Level Seven (HL7)

- A not-for-profit standards development organization (SDO) with chapters in 55 countries.
- After April 2013 many HL7 standards were considered open source and therefore available for free download.
- Health Level Seven’s domain is clinical and administrative data transmission and perhaps is the most prolific set of healthcare standards. In this section messaging, application and document standards only will be highlighted
- "Level Seven" refers to the seventh level of the International Organization for Standardization (ISO) model for Open System Interconnection. This serves to communicate that HL7 messaging lives in the application layer of the stack, with subordinate layers serving as items in the overall toolkit.
- HL7 provides a set or family of standards for interactions between healthcare data services.
- HL7 is a data standard for communication or messaging between:
 - Patient administrative systems (PAS)
 - Electronic practice management systems
 - Lab information systems (interfaces)
 - Dietary
 - Pharmacy (clinical decision support)
 - Billing
 - Electronic health records (EHRs)
- Figure 6.1 provides an example of a HL7 message.

- The first line is the message header (MSH)
- Each HL7 segment starts on a new line and has a segment ID, such as EVN
- Each segment can have fields, and they may have components
- Vertical bars (pipes) separate fields and carets separate components

Figure 6.1: HL7 Message

```
MSH|^~\&EPIC|EPICADT|SMS|SMSADT|199912271408|CHARRIS|ADT^A04|1817457|
EVN|A04|199912271408|||CHARRIS
PID||0493575^^^2^ID 1|454721||DOE^JOHN^^^^|DOE^JOHN^^^^|19480203|M
NK1||CONROY^MARI^^^^|SPO||216|731-4359|EC|||||||||||||||||
PV1||0|168~219~C~PHA^^^^^^^^^^^^|||1277^ALLEN FADZL^BONNIE^^^^||||||
```

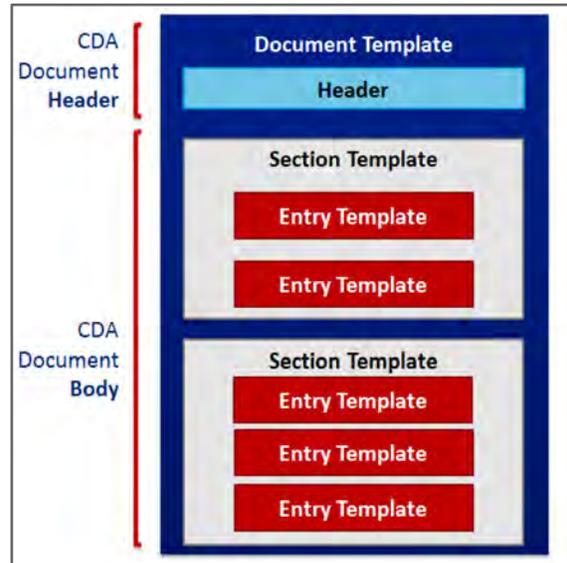
- The most current version of the HL7 standard is 3.0 but version 2.x is still widely in use by all HIT vendors.
- HL7 version 2.x separates messages into processable chunks known as segments which contain fields which contain components.
- HL7 version 2.x segments are sewn together into messages of a given type (e.g. Admit, Discharge and Transfer [ADT] or Pharmacy Administration [RAS]).
- HL7 version 2.x messaging is typically performed over minimal lower layer protocol (MLLP).
- HL7 version 3.0 includes The Reference Information Model (RIM). HL7 v3.0 is a content standard that makes documents human readable (using a web browser) and machine processable through the use of XML.⁷
- Clinical Context Object Workgroup (CCOW) is a standard that allows clinical applications to share information at the point of care. This means interoperability among disparate IT vendors and single sign on capability.

The Consolidated Clinical Document Architecture (Consolidated CDA)

- In 2007 HL7 recommended the use of the Continuity of Care Document (CCD) standard. The CCD is the marriage of the Continuity of Care Record (CCR) (developed by ASTM International) and the clinical document architecture CDA (developed by the HL7 organization). The CCD has the advantage over CCR of being able to accept free text and being capable of vocabulary specific semantic interoperability. It contains the most common information about patients in a summary XML format that can be shared by most computer applications and web browsers. It can be printed (pdf) or shared as html. The CCD is generally used as a patient summary
- In 2008 CCHIT required EHRs to generate and format CCD documents using the C32 specification for patient demographic information, medication history and allergies.
- For stage 1 meaningful use, EHRs could use either CCR or CCD. For stage 2 the standard is the consolidated CDA, meaning that there is only one standard and one implementation guide. The C-CDA will be essential for care coordination and patient engagement objectives of stage 2 meaningful use
- CDAs are used in EHRs, personal health records, discharge summaries and progress notes. CDA delineates the structure and semantics of clinical documents, consisting of a header and body. The Consolidated CDA implementation guide employs the concept of "templates." Templates are declared at the document, section, and entry level of CDA documents. There is a CDA implementation guide that takes advantage of CCD templates for a variety of purposes; for example, CDA for History and Physical Notes, CDA for Consultation Notes, CDA for Operative Notes, etc. Templates capture specific uses and can represent professional society recommendations, national clinical practice guidelines, and standardized data sets. C-CDAs can contain structured and unstructured data and are coded in XML.

Figure 6.2 displays CDA Template organization. More detail about C-CDAs can be found in these references.⁸⁻⁹

Figure 6.2: CDA Template Organization⁸



- The info box describes the Health Story Project and templated CDA for including narrative notes into EHRs.

Health Story Project



In spite of increasing adoption of EHRs, most patient notes are free text and are therefore not discrete data. C-CDA is a start in the right direction to comply with Meaningful Use.

This HL7/program known as the Health Story Project will match CCD coding patterns and conventions, called “templated CDA.” This strategy will help support the transfer of care summaries into an EHR from dictated notes, using CDA templates. In early 2013 the Health Story Project became part of HIMSS.¹⁰

- A generated C-CDA will have the fields displayed as human readable in table 6.1. Examples of C-CDAs in the machine

readable (XML) format exist in the Blue Button Plus Project. This initiative grew out of the Blue Button project championed by the Department of Veteran’s Affairs and Medicare. This would permit patients to download administrative claims data from large payer organizations and clinical data from patient portals integrated with electronic health records. Multiple data standards are necessary to make this initiative interoperable and consistent with stage 2 meaningful use goals. This initiative is discussed in detail in the chapter on health information exchange.¹¹

Digital Imaging and Communications in Medicine (DICOM)

- DICOM was formed by the National Electrical Manufacturers Association (NEMA) and the American College of Radiology (ACR). They first met in 1983 which suggests early on they recognized the potential benefits of the storage, sharing, and transmission of digital images.
- As more radiological tests became available digitally, by different vendors, there was a need for a common data standard. Similarly, as more EHRs had picture archiving and communication systems (PACS) functionality, DICOM became the standard for images in EHRs.
- While DICOM is a standard, vendors have modified it to suit their proprietary application resulting in lack of true interoperability. Vendor neutral DICOM viewers are needed.
- DICOM supports a networked environment using TCP/IP protocol (basic internet protocol).
- DICOM is also applicable to an offline environment.¹²
- “I Do Imaging” is a web site that promotes open source DICOM viewers, DICOM converters and PACS clients.¹³

Table 6.1: Consolidated CDA Data Set

Section	Description
Header	Patient demographics
Allergies, Adverse reactions and alerts	Status and severity
Encounters	Surgeries, visits, etc.
Immunizations	Immunizations
Medications	Those prescribed by physician
Care Plan	Planned testing and therapy
Discharge Medications	Part of hospital discharge summary
Reason for referral	Written reason
Problem List	Documented diagnoses
Procedures	History of procedures
Functional and Cognitive status	List of impairments
Results	Laboratory results
Social History	Habits such as smoking, drinking
Vital Signs	Height, weight, blood pressure, etc.
Discharge Instructions	Written Instructions

Terminology Standards

Logical Observations: Identifiers, Names and Codes (LOINC)

- This is a standard for the electronic exchange of lab results transmitted to

hospitals, clinics and payers. HL7 is a *content* standard, whereas LOINC is a *vocabulary* or *terminology* standard.

- The LOINC database has more than 72,000 terms (as of 2013) used for lab results. This is necessary as multiple labs have multiple unique codes that would otherwise not be interoperable.
- LOINC is divided into lab, clinical and HIPAA portions.
- The lab results portion of LOINC includes chemistry, hematology, serology, microbiology and toxicology.
- The clinical portion of LOINC includes vital signs, EKGs, echocardiograms, gastrointestinal endoscopy, hemodynamic data and others.
- The HIPAA portion is used for insurance claims.
- As an example:
 - The LOINC code for serum sodium is 2951-2; there would be another code for urine sodium.
 - The formal LOINC name for this test is: SODIUM:SCNC:PT:SER/PLAS:QN (component:property:timing:specimen:scale)
- LOINC is accepted widely in the US (including federal agencies) and internationally. Large commercial labs such as Quest and LabCorp have already mapped their internal codes to LOINC. The main web site has a search engine to find LOINC codes.
- Other standards such as DICOM, SNOMED and MEDCIN have cross references (mapping) to LOINC.
- RELMA is a mapping assistant to assist mapping of local test codes to LOINC codes.
- LOINC is maintained by the Regenstrief Institute at the Indiana School of Medicine.¹⁴ LOINC and RELMA are available free of charge to download from <http://loinc.org/>.

More detail on LOINC is available in an article by McDonald.¹⁵

RxNorm

- RxNorm is the recommended standard for medication vocabulary for clinical drugs and drug delivery devices, developed by the National Library of Medicine (NLM).
- Each commercial drug vocabulary company e.g. First Data Bank provides medication concept identifiers to the NLM which are then mapped to the concepts in the RxNorm vocabulary.
- Rxnorm supports interoperability among organizations that deal with clinical drugs.
- RxNorm is the standard for e-prescribing and will support Meaningful Use.
- RxNorm encapsulates other drug coding systems, such as National Drug Code (NDC).
- The standard only covers US drugs at this point.
- The standard includes three drug elements: the active ingredient, the strength and the dose
- An example of RxNorm: 311642 (Methylcellulose 10 MG/ML Ophthalmic Solution).¹⁶

Systematized Nomenclature of Medicine: Clinical Terminology (SNOMED-CT)

- SNOMED is the clinical terminology or medical vocabulary commonly used in software applications, including EHRs.
- SNOMED covers diseases, findings, procedures, drugs, etc.; a more convenient way to index and retrieve medical information.
- The vocabulary provides more clinical detail than ICD-9 and felt to be more appropriate for EHRs.
- SNOMED is also known as the International Health Terminology.
- This standard was developed by the American College of Pathologists. In 2007 ownership was transferred to the International Health Terminology Standards Development Organization www.ihtsdo.org.

- SNOMED will be used by the FDA and the Department of Health and Human Services.
- SNOMED will be required for stage 2 meaningful use to record family history, smoking history, transitions of care, hospital lab submission of reportable cases to public health agencies and submission of cancer cases to cancer registries.
- This standard currently includes about 1,000,000 clinical descriptions.
- Terms are divided into 19 hierarchical categories.
- The standard provides more detail by being able to state condition A is due to condition B.
- SNOMED concepts have *descriptions* and *concept* IDs (number codes). Example: open fracture of radius (concept ID 20354001 and description ID 34227016).
- SNOMED CT also defines two types of relationships:
 - “Is a” connects concepts within the same hierarchy. Example: asthma “is a” lung disease.
 - “Attribute” connects concepts in different hierarchies. Example: asthma is associated with inflammation.
- SNOMED links (maps) to LOINC and the International Classification of Diseases (ICD) codes.
- SNOMED is currently used in over 40 countries.
- There is some confusion concerning the standards SNOMED and ICD; the latter is used primarily for research, quality improvement and reimbursement and the former for communication of clinical conditions.¹⁷⁻¹⁹
- A study at the Mayo Clinic showed that SNOMED-CT was able to accurately

describe 92% of the most common patient problems²⁰

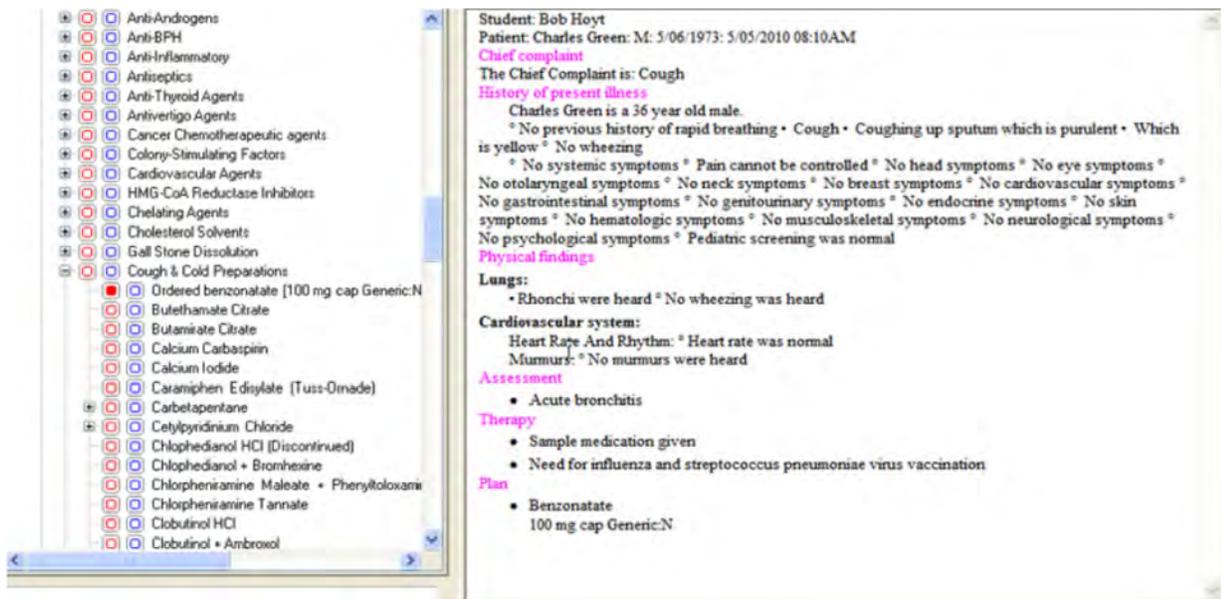
- SNOMED-CT Example: Tuberculosis
 - **DE-14800**
 -
 -
 - . . . Tuberculosis
 - . . Bacterial infections
 - . E = Infectious or parasitic diseases
 - D = disease or diagnosis

MEDCIN®

MEDCIN® was developed by Medicomp in the 1980s as a proprietary medical vocabulary. In 1997 it was released as a national standard. MEDCIN® cross-references to many of the other standards already discussed. The nomenclature consists of about 270,000 clinical concepts organized into categories: symptoms, history, physical exam, tests, diagnosis and therapy. Each finding is associated with a numerical code, up to seven digits, so the results are structured or codified. Unlike SNOMED, MEDCIN® findings can link to symptoms, exam, therapy and testing. The knowledge base also includes 600,000 synonyms, allowing look-ups under different terms. MEDCIN® is used by several EHR systems, to include the Department of Defense’s AHLTA.

The disadvantages of this system are the fact that there is a substantial learning curve to be able to search for all of the necessary MEDCIN® terms in order to create a completely structured note. Second, the note that is created tends to be poorly fluent and not like dictation (Figure 6.3). For that reason, Medicomp developed CliniTalk™ which is a voice to text option that means that a clinician can dictate and the end is structured data.²¹

Figure 6.3: MEDCIN® Encounter



Transport Standards

EHR-Lab Interoperability and Connectivity Standards (ELINCS)

- ELINCS was created in 2005 as a lab interface for ambulatory EHRs and a further “constraint” or refinement of HL7 standards.
- Traditionally, lab results are mailed or faxed to a clinician’s office and manually inputted into an EHR. ELINCS would permit standardized messaging between a laboratory and a clinician’s ambulatory EHR.
- Standard includes:
 - Standardized format and content for messages
 - Standardized model for transport of messages
 - Standardized vocabulary (LOINC)
- The Certification Commission for Healthcare Information Technology (CCHIT) has proposed that ELINCS be part of EHR certification.
- HL7 plans to adopt and maintain the ELINCS standard.

- California Healthcare Foundation sponsored this data standard.²²

IEEE 11073

- Data standards are needed for information to be sent from a medical device to an EHR or hospital information system.
- This is a fundamental standard for medical device connectivity and data exchange but is not widely used.
- HL7 version 2.x is used for data transfer but only supplies the syntax and not the semantics.
- Other initiatives are being developed to solve this interoperability problem:
 - Integrating the Healthcare Enterprise-Patient Care Device (IHE-PCD) Workgroup has developed use case profiles to support integration, alerts and implantable devices.
 - Medical Device Plug and Play Interoperability Program’s Integrated Clinical Environment will develop a solution like IHE-PCD that will be based on IEEE 11073.

- IEC 80001 is standard under development to address devices in a networked environment.
- Continua Health Alliance focuses on home healthcare devices.²³

National Council for Prescription Drug Programs (NCPDP)

- NCPDP is a pharmacy related SDO for exchange of prescription related information.
- Script (v10.10) is for communication between physician and pharmacist.
- Other standards: batch standard, billing standard, formulary and benefit standard, prescription file transfer standard and universal claim form standard²⁴

Accredited Standards Committee (ASC) X12

- A standard for electronic data interchange (EDI) or the computer-computer exchange of business data
- Standard is used in healthcare, transportation, insurance and finance industries.²⁵

Medical Coding and Reimbursement

Medical or clinical coding is the process of assigning alphanumeric characters to standardize the descriptions of the reasons for encounters between patients and healthcare providers and the descriptions of all services and procedures performed, including supplies. In the United States, coding is the language of reimbursement methodologies and therefore key to providers being reimbursed for the total amount of money to which they are legally and ethically entitled for all services rendered. Coding also provides rich data for disease registries, research, epidemiological studies, quality improvement and performance improvement.

A professional coder is an allied health professional, in that correct coding requires

extensive knowledge of the medical sciences in order to abstract key clinical information from medical records, determine which information impacts the current episode of care, and translate that information into appropriate diagnostic and procedural codes and then sequence those codes appropriately. Once a record is coded, the codes are entered into systems that create clinical data bases but also generate electronic claims for submission to third party payers to obtain reimbursement.

Hospital coding professionals typically work in a health information services department. The hospital billing is done in a financial services or business department of the hospital. Hospitals are reimbursed for the use of the facility and all of its resources. It is called the technical component of health care services. Since hospitals rely heavily on correct coding not only for reimbursement but the accuracy of indexes and registries, a hospital coding specialist must be an expert at quickly analyzing medical record documentation and making decisions about what to code and in what sequence. There are coding rules, regulations, conventions and guidelines but there is still some gray area where a coder must use good judgement. The coding is a little different for a hospital inpatient service than it is for a hospital outpatient service because inpatient hospitalizations are reimbursed using an inpatient prospective payment system based on Diagnosis Related Groups (DRGs). On the other hand, outpatient hospital services and procedures are reimbursed using an outpatient prospective payment system based on Ambulatory Patient Classifications (APCs) which are procedure-driven.

Coding for practitioners can vary depending on the size and specialty of a practice or clinic but often a physician uses a “superbill” which is a list of the most common codes used in that practice and then a billing or reimbursement specialist inputs those codes into a practice management system and follows the codes through the billing processes until each patient encounter is closed (either paid in full or some amount written off). Other practices have coding professionals who code from medical records but they may also be

a combination coder/biller which means they also process the claims.

Coding has become quite complex over the past decade and as such, certification is becoming more important to get a job as a coding and/or billing specialist.

The American Health Information Management Association (AHIMA) has the following certification exams that relate to coding professionals:

- Certified Coder Associate (CCA) which is a general certification geared toward coding at entry level for any healthcare provider.
- Certified Coder Specialist (CCS) which is geared toward hospital inpatient and outpatient coding at expert level. To sit for this exam one must have completed a comprehensive coding certificate or program that includes medical terminology, anatomy & physiology, pathophysiology and pharmacology as well as coding courses with reimbursement methodologies. This criterion is waived for someone who has at least 3 years of varied hospital coding experience.
- Certified Coder Specialist (CCS-P) which is geared toward coding for physicians and other clinicians such as advanced nurse practitioners at the expert level. The same eligibility criteria apply as above.
- Registered Health Information Administrators and Registered Health Information Technicians (RHIA, RHIT) also have coding and reimbursement knowledge as part of the competencies tested. These exams require graduation from a Commission on Accreditation of Health Informatics and Information Management (CAHIIM)-accredited school. The RHIA requires a bachelor's degree in Health Information Administration or Management and the RHIT requires an associate degree in Health Information Technology or Management.²⁶

The American Academy of Professional Coders (AAPC) has the following coder categories:

- Certified Professional Coder (CPC) which is similar to the CCS-P above.
- Certified Professional Coder-Hospital Based (CPC-H) which is similar to the CCS described above.²⁷

All services, procedures and operations carried out must have the medical necessity documented.

This coded data comes from the following coding and classification systems used today in the United States.

International Classification of Diseases (ICD)

The World Health Organization (WHO) publishes the ICD classification system to collect data worldwide on the causes of morbidity and mortality. ICD is updated annually but limitations on expansion of certain categories of disease have traditionally required a major revision of ICD approximately every ten years. In the U.S., ICD is clinically modified because it is also used for reimbursement. WHO published ICD-9 in 1978 and the United States adopted its clinically modified (CM) version (ICD-9-CM) in 1979. However, WHO published ICD-10 in 1990. The US has been using ICD-10 to code causes of death on death certificates since 1999 but is the last industrialized country in the world to adopt ICD-10 for morbidity.

ICD-9-CM (Volumes 1, 2 & 3)

Part of the clinical modification of ICD-9 by the US involved adding a 3rd volume to report inpatient hospital procedure codes for use by the facility in submitting claims for reimbursement of the hospital's technical component for procedures performed on hospital inpatients. The delay in adopting ICD-10-CM is largely due to the massive system changes that permeate every disease registry, electronic health record, practice management system, third-party payer processing systems, and database containing coded healthcare information. The maximum field length has to change from five characters to 7 and all data dictionaries (and transport standards) must be changed to accommodate

the new system. Although hierarchy between ICD-9-CM and ICD-10-CM is similar, the code structure is different and the number of codes in 2013 is nearly 69,000 versus approximately 14,000 in ICD-9-CM. Additionally, the US had to develop a replacement for Volume 3 of ICD-9-CM so hospital systems could report procedures on inpatients.

ICD-10-CM/PCS (GEMS for continuity of tracking)

In early 2012, the Department of Health and Human Services published a final rule

establishing ICD-10-CM as a new national coding standard with an implementation date by all providers of October 1, 2014. Hospitals and payers will concurrently implement the ICD *procedural coding system*, ICD-10-PCS. ICD-10-CM provides extensive expansion and significantly more specification than ICD-9-CM. There are 21 Chapters versus 17 in ICD-9. Figure 6.4 compares ICD-9-CM code format with ICD-10-CM. Table 6.2 further outlines some of the major differences between ICD-9 CM and ICD-10 CM.

Figure 6.4: ICD-10-CM versus ICD-9-CM

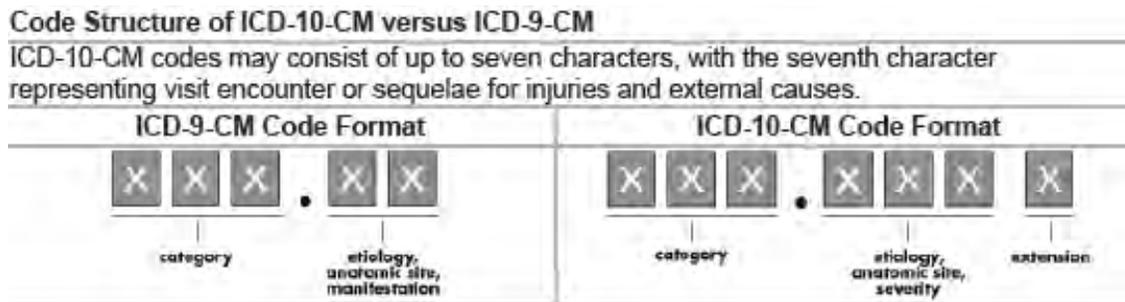


Table 6.2: ICD-9, ICD-10 comparison

ICD-9 CM	ICD-10 CM
3-4 numbers in length	3-7 alpha-numeric characters in length
About 14,000 codes	About 69,000
First digit may be alpha (E or V) or numeric; digits 2-5 are numeric	Digit 1 is alpha; digits 2 and 3 are numeric; digits 4-7 are alpha or numeric
Limited space for new codes	Flexible for adding new codes
Lacks detail	Very specific
Lacks laterality (right, left)	Has laterality

The following example explains the ICD-10 Code structure:

S52 Fracture of forearm (category)

S52.5 Fracture of lower end of radius (body system)

S52.52 Torus fracture of lower end of radius (anatomical site)

S52.521 Torus fracture of lower end of right radius (side)

S52.521A Torus fracture of lower end of right radius, initial encounter for closed fracture (extension)

ICD-10-PCS is a completely different hierarchical structure than volume 3 of ICD-9. PCS codes contain 7 alphanumeric characters and are actually built based on tables rather than on a tabular listing. PCS provides completeness, expandability and standardized terminology in addition to being multi-axial. It uses digits 0-9 and letters A-H, J-N, P-Z. The first character is a section (e.g. medical surgical). In the medical-surgical section: the second is the body system, the third is the root operation (standardized definitions), the fourth is the body part, the fifth is the approach, the sixth is the device and the 7th is a qualifier. The following is an example of an ICD-10-PCS code: 047K3DZ (dilation of right femoral artery with intraluminal device, percutaneous approach).

General equivalency mappings (GEMS) have been developed to convert multiple databases from ICD-9 to ICD-10 to accommodate a variety of research applications that rely on trend data. GEMS is not, however, a crosswalk since the mappings are often 1 to many or many to 1 and not 1 to 1. Therefore, a coder cannot find the appropriate ICD-9-CM code and rely on GEMS to convert it to the most appropriate ICD-10-CM code.²⁸⁻³⁰

Current Procedural Terminology (CPT) Coding System

CPT is a proprietary procedural coding system published and maintained by the American Medical Association. It was originally used strictly for reimbursement of services, procedures and operations but now contains quality measure tracking codes in addition to the procedure codes. A CPT code cannot be submitted for reimbursement without an ICD-CM code to justify the medical necessity of the procedure or the level of service performed. All

clinicians use CPT codes to obtain reimbursement for their work regardless of where the work is performed (e.g. consultation or surgery on a hospital inpatient, a procedure or service to a nursing home patient, medical office services and procedures etc.). Hospitals also use CPT codes to get reimbursed for utilization of hospital resources for all outpatient hospital-based services (e.g. ambulatory surgery center, emergency department, imaging, laboratory services, etc.).

CPT was originally published by the AMA in 1966 and is revised annually. It is divided into the following main sections:

Evaluation & Management (E&M) Codes (Code range 99201-99499). In order to bill for a patient visit, ICD and CPT codes are selected to best represent the visit. It is up to the clinician to provide documentation to prove the level of the visit. The visit or consultation can occur in any healthcare setting. CMS and other third party payers audit these services to combat the fraud and abuse that has historically been rampant. Abuse is the unintentional assignment of a higher level of code than is warranted and has resulted in annual changes to the rules governing the national correct coding initiative.

As an example, if a clinician chooses to select CPT code 99204 for a new patient visit in a physician's office, they must document that the problems are of moderate to high severity, the physician spends about 45 minutes face-to-face and the E&M requires these key components: comprehensive history and physical exam and medical decision making of moderate complexity. This implies that an excellent history and physical exam are documented and the problems discussed were moderately complex.

Many EHRs have E&M calculators to help assist the clinician in determining the level of service. This is made easier if templates are used because clicking on history and physical exam elements can calculate an E&M code in the background

Figure 6.5 shows a typical E&M calculator that is part of an EHR. Note: this is an established

patient, the E&M level is in the upper left, the diagnosis and ICD-9 code (462) are in the upper right. Multiple fields are available to input the complexity of the visit so the E&M code can be manually or automatically calculated.

- Anesthesia (Code Range 00100-01999)
- Surgery (Code Range 10021-69990)
- Radiology (Code Range 70010-79999)
- Pathology and Laboratory (Code Range 80047-89398)
- Medicine (Code Range 90281-99607)
- Category II Codes for supplemental tracking and performance measurement)
- Category III Codes for temporary tracking of emerging technology, services and procedures³¹⁻³²

- Level I is CPT and purchased by CMS from AMA annually.
- Level II codes are used to obtain reimbursement for any procedure, service, supply, injectable or IV drip medication/nutrition, durable home medical equipment, orthotics, prosthetics etc.

The intent is to not have any Level II codes that are identical to any CPT codes. However, Medicare will require hospitals and physicians to use Level II codes to provide more detail or to specify whether or not a test (e.g. colonoscopy) is screening or diagnostic. For example, CPT has supply codes and codes that identify various immunizations but Level II codes contain more specific details such as the route of administration, dosage and drug name so physicians use Level II codes to submit claims for these services to Medicare.

Most HCPC Level II codes are billed by medical suppliers and hospitals (for supplies used during surgeries such as stents).

More information is available from CMS.³³

Healthcare Common Procedure Coding System (HCPCS)

HCPCS are codes used by CMS and contain two Levels:

Figure 6.5: EHR E&M Calculator (Courtesy Network Systems)

Future Trends

We can expect more data standards as time goes by and further refinement of all existing standards. Subcommittees of ONC are working hard to harmonize data standards to facilitate health information exchange. Decisions will have to be made about what standards will be mandatory for electronic health records. For example, SNOMED CT will be the primary medical vocabulary of choice for electronic health records for stage 2 meaningful use.

As an example of developing new content standards it should be noted that Fast Health

Interoperable Resources (FHIR-pronounced FIRE), a new generation framework created by HL7, will combine the best features of HL7's Version 2, and CDA standards and will be suited for a myriad of use cases. FHIR should be available for trial use by the end of 2013.³⁴ Another example of an evolving and exciting standard is RESTful Health Exchange (RHEX), an open-source, open standard based on RESTful services for health information exchange.³⁵ Lastly, Open ID Connect is a new standard that will help all types of Clients (web-based, mobile, etc.) connect to end users via an authentication server.³⁶

Key Points

- Data standards play a major role in accomplishing interoperability
- Slow movement towards industry wide standards, such as the Continuity of Care Document
- Meaningful Use is a strong driver of data standards development
- Medical Coding standards and rules drive reimbursement for all healthcare providers. Therefore, medical coding and billing professionals will continue to be in high demand as experienced coders retire and the the U.S. moves toward adoption of ICD-10 coding on October 1, 2014

Conclusion

Data standards are critical for interoperability between disparate technologies and organizations. Without agreed upon standards for content and terminology, true semantic interoperability is next to impossible. Multiple standards developing organizations have harmonized and updated for application in the field of medicine. Standards are important to proposed standards that are being tested,

exchange clinical data, as well as, administrative and financial data. Standards are essential for exchange of information between electronic health records, health information organizations and the eHealth Exchange. Data standards are on the radar screen as a result of need to meet Meaningful Use and work by groups such as the Health Information Technology Standards Committee.

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Chapter 7

Architectures of Information Systems

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Learning Objectives

After reading this chapter the reader should be able to:

- Understand the internet and World Wide Web
- Discuss why web services are used by HIOs
- List of the components of service oriented architecture
- Understand the importance of networks in the field of medicine
- Compare and contrast wired and wireless local area networks (LANs)
- Describe the newest wireless broadband networks and their significance

Introduction

The average reader of this book, be they a budding student or seasoned clinician, should understand basic architectures and technologies that are commonly part of health information technology. This chapter will focus on three areas: the Internet, web services and networks.

The Internet and World Wide Web

Computers must network in order to exchange data. Computer networks scale from those in a home or office (Local Area Networks or LANs) to massive interconnected networks (an internet). The Internet is the largest and arguably most important of these large scale international

networks. The Internet is a global network-of-networks using the Telecommunications Protocol/Internet Protocol stack (TCP/IP) as their communications standard. The TCP/IP stack allows for layering of different standards and technologies based on the participants in an exchange and the payload being exchanged. The Internet began as an early (late 1960s) government project which created a network known as Advanced Research Projects Agency Network (ARPANET) capable of tying together universities and research organizations securely. The World Wide Web (WWW) operates on top of the Internet and was created by Tim Berners-Lee in 1989. The WWW introduced the web browser, a software program that allows for connection to web servers over the internet using Hypertext Transfer Protocol (HTTP). The

browser is able to request, retrieve, translate, and render the content from a remote server on the computer screen for users to view. Web pages are written using Hypertext Markup Language (HTML), an implementation of a markup language, or method for defining formatting of text in a document, which has become synonymous with the web. Here is a simple example of html:

```
<html>
  <body>
    <h1>My First Heading</h1>
    <p>My first paragraph.</p>
  </body>
</html>
```

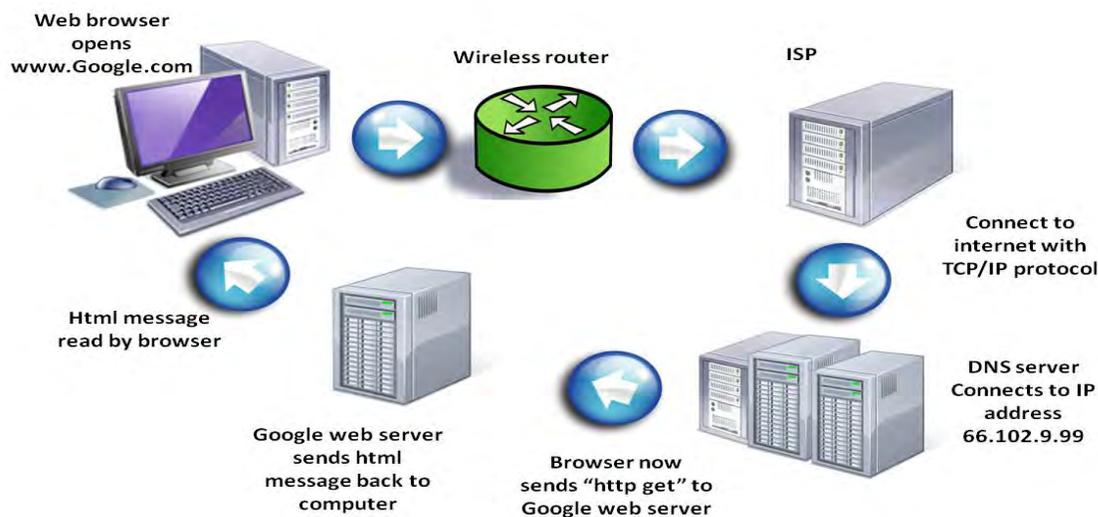
Achieving interoperability on the Internet depends on global use of standards. Standards exist for the exchange of data, such as HTTP; the format of data, such as HTML, and the transport of data, such as TCP/IP.

In a TCP/IP network, each device (host) must have an Internet Protocol (IP) address. IP addresses can be distributed amongst different tiers of lower layer networks, or “sub-networks.” In order for addressing to function properly in the presence of a sub-network, the machine must both have an IP address and a routing prefix or “subnet mask” (example: IP address of 192.168.10.1 and subnet mask of 255.254.254.0)

in order for it to be considered properly addressable by other network nodes. Two versions of IP addressing exists today, IP version 4 (IPv4) which has been around for more than 40 years is reaching depletion of its address space. IP version 6 (IPv6) is being used to phase out IPv4 before the complete depletion of assignable addresses brings the growth of the Internet to a complete halt. (To determine one’s own IP address using a Windows computer, type “ipconfig” in the command line).

Computers are great at thinking in numbers, as that is all they are doing at the lowest level, however communicating an address in IPv4 or IPv6 to another human is not an easy or issue free process. To circumvent this, a standard was created known as the Domain Name System (DNS). DNS solves the human address issue by allowing for easier to recognize and remember common language based addresses to be assigned and mapped to regions of the IP address space. This process which is managed by DNS servers, allows for one to tell someone to visit a website (www.uwf.edu) instead of using its IPv4 or IPv6 address (143.88.3.180). Figure 7.1 demonstrates how this works. Devices can connect to the internet using a dial-up modem, broadband modem or gateway, Wi-Fi, satellite, and 3/4G cellular data connections.

Figure 7.1: How the internet works to locate web content



It is useful to think of the Internet as comprised of two main components, protocols and hardware. The common types of hardware needed are cabling, client computers, servers, hubs, switches, firewalls, gateways, and routers. The client computer is an end point using a network service provided by a server. Each machine addressable on a network is known as a node. Computers connect to the internet through an Internet Service Provider (ISP) such as Bell South or AT&T. For example, if one uses a web browser (e.g. Chrome, Safari, Opera, Internet Explorer, Firefox) to connect to a web site there are many systems involved in servicing that request. An electronic request for an IP address is sent via the network link provided by the one's ISP to a DNS server. The DNS server then matches the requested domain name and responds with an IP address. The browser is now capable of sending an HTTP GET request (again routed through one's ISP provided link) to the IP address returned from the DNS request. The result of this set of transactions is an HTTP response with an HTML payload from the server. The browser can now render and display the document defined by the HTML response on the user's screen.

In order for this to occur the message must be sent using small packets of information. Packets can arrive via different routes, useful when there is web congestion, and are reassembled back at one's computer. All traffic sent using TCP/IP (such as phone calls over the internet (VoIP) and email) are sent using packets. A router is a node which directs the packets on the internet. The role of ordering these packets and making sure that they make it to their intended recipient in the proper structure is one of the jobs of TCP/IP.

The Uniform Resource Locator (URL) is a specified address to a specific resource. A URL (sometimes also referred to as the Uniform Resource Identifier or URI) can, for example, specify a document provided on the WWW by a web server (e.g. <http://www.google.com>). The first part of the URL is the protocol identifier, indicating which protocol will be necessary to retrieve the resource. The remainder, known as the resource name, specifies the address of the

system to retrieve from as well as the full path to the content to retrieve. The protocol identifier and the resource name are separated by a colon and two forward slashes. As an example, <http://uwf.edu/uwfmain/about> describes HTTP as the protocol, "uwf.edu" as the server to which the HTTP request will be made, and "/uwfmain/about" as the path to the resource being requested.^{1,2} The most common domains end in .com, .edu, .org, .net, .mil, .gov and .int.

Web Services

Prior to the advent of the internet, disparate businesses and health care entities were not able to easily exchange data; instead data resided on a local PC or server and controlled communication links (such as via modem) were required to transport that data to another system. *Web services* are task specific applications which are deployed in a platform independent manner via a series of transactions to and from other web-aware applications/services over a network (such as the Internet). Web services can reduce the cost of converting data with external partners, by allowing for a modular component of a larger system to be invoked with little up front effort.

Web services can be broken down into two categories. Representational State Transfer (or RESTful) services are lightweight services which use existing internet infrastructure and World Wide Web (WWW) concepts as their backbone. Simple Object Access Protocol (SOAP) web services utilize a potentially complex series of eXtensible Markup Language (XML)-based ontologies to describe and invoke services over a network. There are obvious pros and cons to each concept, but most often the tradeoff between ease of implementation versus technical depth of field is the main point of comparison struck between the two.

RESTful Services

REST, as a concept, is an aggregate description of the functional model of how HTTP allows for the deployment of the WWW over the internet. It can be utilized to provide non-WWW content

delivery over any application protocol, not solely trapped in the realm of the HyperText Transfer Protocol (HTTP). It is important to realize that REST is an architecture, not a standard. As such, there are endless possibilities as to how REST can be applied to act as a service bus. Even though REST itself is not a standard, many standards are utilized when it is used for service interaction. Communication with a RESTful service is a relatively quick process and can utilize any existing content standard for packaging its messaging. Most commonly, a RESTful service will use XML or JavaScript Object Notation (JSON) for this content delivery. RESTful web services require three basic aspects:

URI (Uniform Resource Identifier). URI is a set of characters defining a specific object, resource, or location. One of the more common uses for a URI is in providing a Uniform Resource Locator (URL) for an object on the WWW. In a RESTful service, a URI can describe the service being invoked or a component within said service.

Operation Type (GET, DELETE, POST, PUT). These HTTP methods can be extended past their WWW function to provide four different points of access to a RESTful service. If a URI identifies an object, the HTTP operation type defines an accessor method to that object (e.g. GET a list, POST an update, PUT a new record, DELETE a purged record).

MIME Type (Multipurpose Internet Mail Extensions). MIME is a means of communicating the content type used within a message transferred over the internet. Typically, in a RESTful service, this would be XML or JSON, but it could be any other type.

Web Services using SOAP

SOAP is a protocol standard for interacting with web services. These services require a set of standards for content and a service oriented architecture (SOA) stack, a collection of services. The most common standards used in web services transactions are HTTP, as the internet protocol, with XML as the delivery language (covered in the data standards chapter). SOAP

web services require three basic platform elements:

- **SOAP (Simple Object Access Protocol):** a communication protocol between applications. It is a XML-based platform neutral format for the invocation and response of web services functions over a network. It re-uses the HTTP for transporting data as messages.
- **WSDL (Web Services Description Language):** a XML document used to describe and locate web services. A WSDL can inform a calling application as to the functionality available from a given service, as well as the structure and types of function arguments and responses.
- **UDDI (Universal Description, Discovery and Integration):** a directory for storing information about web services, described by WSDL. UDDI utilizes the SOAP protocol for providing access to WSDL documents necessary for interacting with services indexed by its directory.

So how does this work? SOAP acts as the means of communicating, UDDI provides the service registry (like the yellow pages) and WSDL describes the services and the requirements for their interaction. One can begin the process acting as a service requester seeking a web service to provide a specific function. The application would search a service directory for a function that meets one's needs using a structured language. There is a service requester seeking a web service. One searches using a search engine that uses a structured language. Once the service provider is located, a SOAP message can be sent back and forth between the service requester and service provider. In reality, a service provider can also be a service consumer so it is helpful to view web services like the *bus* in a PC, where one plugs in a variety of circuit boards.

HIOs often require a Master Patient Index (MPI) service to locate and confirm patients and a Record Locator Service (RLS) to identify documentation on those patients. For connecting multiple HIOs one may also require gateways (a network point that acts as an

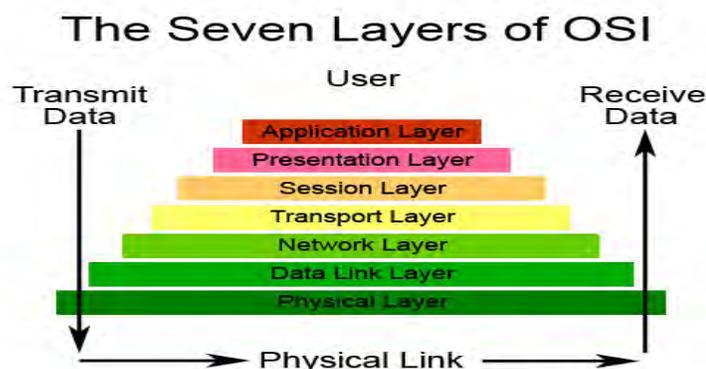
entrance to another network) and adapters (software that connects to applications).³⁻⁵ A valuable recent article, “Improving Performance of Healthcare Systems with Service Oriented Architecture,” describes how SOA is the logical backbone for HIOs and electronic health records.⁶ Another resource for understanding SOA and healthcare was published in March 2009 by the California HealthCare Foundation, *Lessons from Amazon.com for Health Care and Social Service Agencies*.⁷

The OSI Model

The Open Systems Interconnection (OSI) created a conceptual model in 1984 to help with understanding network architectures. This model divides computer-to-computer communication into seven layers known as the OSI Stack. (See figure 7.2). The Stack’s seven layers are divided into upper and lower layers as follows:

- Upper layers
 - 7. Application. This is the layer where applications access network services. Examples, software for database access, email and file transfer and the Internet protocols FTP, HTTP and SMTP.
 - 6. Presentation. This layer translates (formats) the data for the application layer for the network. Examples, data encryption and compression.
- Lower layers
 - 5. Session. This layer establishes, maintains and terminates “sessions” between computers.
 - 4. Transport. This layers deals with error recognition and recovery. It handles message size issues and can reduce large messages into smaller data packets. The receiving transport layer can send receipt acknowledgments. The Internet protocol related to this is TCP.
 - 3. Network. This layer is involved with message control, switching and routing. Translates logical addresses into physical addresses.
 - 2. Data link. This layer packages data from the physical layer into frames (special packets) and is responsible for error free from transfer from one computer (node) to another.
 - 1. Physical. This layer deals with the unstructured raw data stream from the other layers. Specifically, it encodes data and decides whether the bits will be sent via a digital or analog mode and decides if the bits will be transmitted as electrical or optical signals. This layer is involved with communication with devices. Examples: USB, Bluetooth and RS-232.

Figure 7.2 OSI Model (Courtesy University of Washington)



Networks

A network is a group of computers that are linked together in order to share information. Although a majority of medical data resides in silos, there is a distinct need to share data between offices, hospitals, insurers, health information organizations, etc. A network can share patient information as well as provide internet access for multiple users. Networks can be small, connecting just several computers in a clinician's office or very large, connecting computers in an entire organization in multiple locations.

There are several ways to access the internet: dial-up modem, wireless fidelity (WiFi), a Digital Subscription Line (DSL), 3G/4G

telecommunication, cable modem or T1 lines. The most common type of DSL is Asymmetric DSL (ADSL) which means that the upload speed is slower than the download speeds, because residential users utilize the download function more than the upload function this allows a segmenting of available bandwidth to give the illusion of greater availability. Symmetric DSL is also available and features similar upload and download speeds. Cable modem networks can either be fully coaxial up to a fiber channel node further upstream or can begin with fiber optic transmission to the building, with coaxial cable run internally. Table 7.1 displays data transfer speeds based on the different technologies. Multiple factors influence these speeds, so that theoretical maximum as well as more typical speed ranges are listed.

Table 7.1: Data transfer rates

Transmission method	Theoretical max speed	Typical speed range
Dial-up modem	56 Kbps	56 Kbps
DSL	6 Mbps	1.5-8Mbps downlink/128 Kbps uplink
Cable modem	30 Mbps	3-15 Mbps downlink/1-3 Mbps uplink
Wired Ethernet (Cat 5)	1000 Mbps	100 Mbps
Fiber optic cable	100 Gbps	2.5-40 Gbps
T-1 line	1.5 Mbps	1-1.5 Mbps
Wireless 802.11g	54 Mbps	1-20 Mbps
Wireless 802.11n	300 Mbps	40-115 Mbps
WiMax	70 Mbps	54-70 Mbps
LTE	60 Mbps	8-12 Mbps
Bluetooth	24 Mbps	1-24 Mbps
3G	2.4 Mbps	144-384 kbps
4G	100 Mbps	10-70 Mbps
Satellite	10 Mbps	10 Mbps

Information Transmission via the Internet

Given the omnipresent nature of the internet and faster broadband speeds, the internet is the network of choice for transmission of voice, data and images. It is important to understand the basics of transmission using packets of information. The Internet Protocol (IP) is a standard that segments data, voice and video into packets with unique destination addresses. Routers read the address of the packet and forward it towards its destination. Transmission performance is affected by the following:

- Bandwidth is the size of the pipe to transmit packets (a formatted data unit carried by a packet mode computer network). Networks should have bandwidth excess to operate optimally
- Packet loss is an issue because packets may rarely fail to reach their destination. The IP Transmission Control Protocol (TCP) makes sure a packet reaches its destination or re-sends it. The User Datagram Protocol (UDP) does not guarantee delivery and is used with, for example, live streaming video. In this case the user would not want the transmission held up for one packet
- End-to-end delay is the latency or delay in receiving a packet. With fiber optics the latency is minimal because the transmission occurs at the speed of light

Jitter is the random variation in packet delay and reflects internet spikes in activity

Packets travel through the very public internet. An encryption technique such as the Federal Information Processing Standard (FIPS) encodes the content of each packet so that it can't be read while being transmitted on the internet. Encryption, however, adds some delay and increase in bandwidth requirements.⁸

Network Types

Networks are named based on connection method, as well as configuration or size. As an example, a network can be connected by fiber optic cable, Ethernet or wireless. Networks can also be described by different configurations or

topologies. They can be connected to a common backbone or bus, in a star configuration using a central hub or a ring configuration. In this chapter networks will be described by size or scale.

Personal Area Networks (PANs). A PAN is a close proximity network designed to link phones computers, PDAs, etc. The most common technology to create a wireless personal area network or WPAN is Bluetooth. Bluetooth technology has been around since 1995 and is designed to wirelessly connect an assortment of devices at a maximum distance of about 300 feet with the most recent Bluetooth devices (version 4.0). It does have the advantages of not requiring much power and connecting automatically. It operates in the 2.4 MHz frequency range. Clearly, the most common application of Bluetooth today is as a wireless headset to connect to a mobile phone, however human interface devices (such as keyboards, mice and fitness apps) are tipping the scales on Bluetooth usage. Many new computers are Bluetooth enabled and if not, a Bluetooth USB adapter known as a dongle can be used or a Bluetooth wireless card. This technology can connect multiple devices simultaneously and does not require "line of sight" to connect. In an office Bluetooth can be used to wirelessly connect computers to keyboards, mice, printers, PDAs and smartphones. This will avoid the tangle of multiple wires. Bluetooth can connect in one direction (half duplex) or in two directions (full duplex). Security must be enabled due to the fact that even though the transmission range is short, hackers have taken advantage of this common frequency. In addition, faster Bluetooth 4.0 devices are available with speeds in the 24 Mbps range that piggyback on the 802.11 standard.⁸ The second Bluetooth standard is Bluetooth Smart or Low Energy 4.0 that requires less power and is less expensive. The frequency is the same but the data bit rate is slower and the range is less (about 50 meters). A common use would be for fitness devices that sync with smartphones. Devices with this standard may transmit for months or years on coin-type battery.⁹ WPANs can also use other standards: Infrared to connect

devices using the IrDA standard, ZigBee networks, Wireless USB and a body area network (BAN). A wireless body area network (WBAN) is also known as a body sensor network which is gaining importance in healthcare with new body sensors being developed continuously.¹⁰ Another wireless sensor network protocol known as ANT™ is available for ultra-low power applications. The proprietary network operates on the 2.4 GHz ISM band. This protocol has wide applicability with wellness, fitness and home monitoring wireless sensors. A variety of chip sets, developer's tools and ANT USB dongles are discussed on the web site.¹¹

Local Area Networks (LANs). Generally refers to linked computers in an office, hospital, home or close proximity situation. A typical network consists of nodes (computers, printers, etc.), a connecting technology (wired or wireless) and specialized equipment such as hubs, routers and switches. LANs can be wired or wireless.

1. **Wired networks.** To connect several computers in a home or office scenario, a hub or a network switch is needed. Routers direct messages between networks and the internet; whereas, switches connect computers to one another and prevent delay. Unlike Hubs that share bandwidth, switches operate at full bandwidth. Switches are like traffic cops that direct simultaneous messages in the right direction. They are generally not necessary unless multiple computers are running on the same network. To handle larger enterprise demands Gigabit Ethernet LANs are available that are based on copper or fiber optics. Cat5e or Cat6 cables are necessary. Greater bandwidth is necessary for many hospital systems that now have multiple IT systems, an electronic medical record and picture archiving and communication systems (PACS). A typical wired LAN is demonstrated in Figure 7.3. To connect to the internet through an Internet Service Provider (ISP) one has several options:

Figure 7.3: Typical wired local area network (Courtesy Department of Transportation)



- Phone lines can connect a computer to the internet by using a dial-up modem. The downside is that the connection is relatively slow. Digital subscription lines (DSL) also use standard phone lines that have additional capacity (bandwidth) and are much faster network connection than dial up. DSL also has the advantage over modems of being able to access the internet and use the telephone at the same time. Home or office networks can use phone lines to connect computers, etc. Newer technologies include frequency-division multiplexing (FDM) to separate data from voice signals. This type of network is inexpensive and easy to install. Speeds of 128 Mbps can be expected even when the phone is in use. Up to 50 computers can be connected in this manner and hubs and routers are not necessary. Each computer must have a home phone line network alliance (PNA) card and noise filters are occasionally necessary. The downside is largely the fact that not all home rooms or exam rooms have phone jacks.
- Power lines are another option using standard power outlets to create a network. A newer product (PowerPacket®) is inexpensive to install and claims data transfer speeds of 14 Mbps. All that is needed is a power outlet in each room
- Ethernet is a network protocol and most networks are connected by fiber or twisted-

pair/copper wire connections. Ethernet networks are faster, less expensive and more secure than wireless networks. The most common Ethernet cable is category 5 (Cat 5) unshielded twisted pair (UTP).⁸

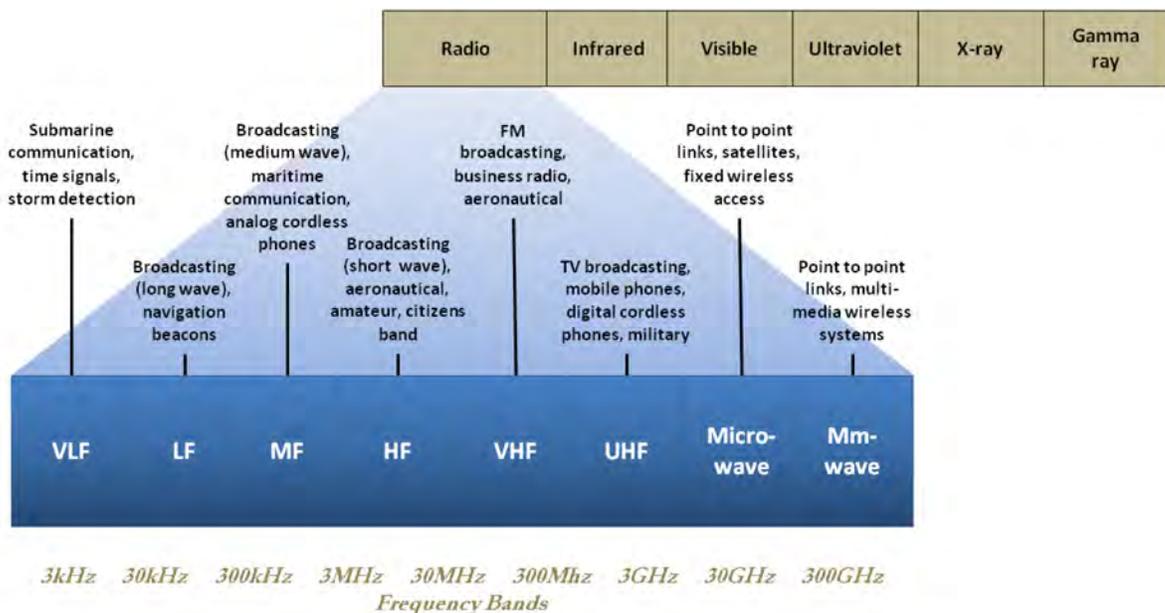
2. Wireless (WiFi) networks (WLANs).

Wireless networks are based on the Institute of Electrical and Electronics Engineers (IEEE) 802.11 standard and operate in the 900 MHz, 2.4 GHz and 5 GHz frequencies. These frequencies are “unlicensed” by the FCC and are therefore available to the public. Figure 7.4 shows the radio frequency portion of the electromagnetic spectrum where wireless networks function.

Wireless networks have become much cheaper and easier to install so many offices and hospitals have opted to go wireless. This allows laptop/tablet PCs and smartphones in exam and patient rooms to be connected to the local network or internet without the limitations of hardwiring but it does require a wireless router and access points. If an office already has a wired Ethernet network then a wireless access

point needs to be added to the network router. A wireless router or access point being used as the hub of communications between systems makes the wireless network be in a state known as infrastructure mode. An ad hoc or peer-to-peer mode means that a computer connects wirelessly directly to another computer and through a routing device. In general, wireless is slower than cable and can be more expensive, but does not require hubs or switches. The standards for wireless continue to evolve. Most people have used early 802.11 networks that operated on the 2.4 GHz frequency at peak speeds of 54 Mbps with a range of about 100 meters. Keep in mind that this frequency is vulnerable to interference from microwaves, some cordless phones and Bluetooth. 802.11ac is the newest standard (December 2012) that can operate at speeds up to 900 Mbps with a frequency of 5 GHz and multiple bandwidths of 20, 40, 80 and 120 MHz. This is accomplished with multiple input/multiple output (MIMO) or multiple input/multiple output (MIMO) or multiple antennas that send and receive data much faster and at greater distances. Actual data transfer

Figure 7.4: Radio frequency spectrums (Courtesy Commission for Communications Regulation)



speeds may be slower than the theoretical max speeds for several reasons. Most modern laptop computers have wireless technology factory installed so a wireless card is no longer necessary.

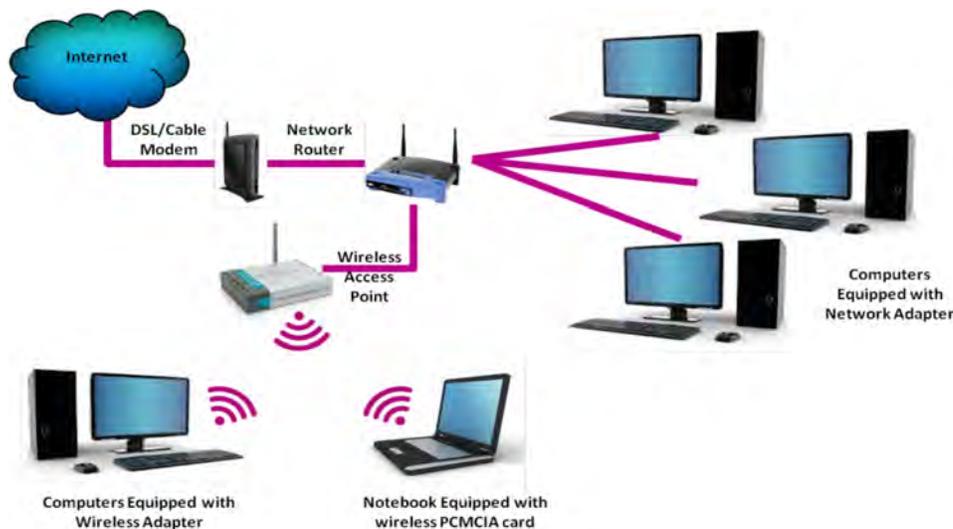
In Figure 7.5 a simple WLAN is demonstrated, with access to the internet over a cable modem and the possibility of both Ethernet and wireless connectivity to different client computers demonstrated.

A wireless router will connect the computers, server and printers and has a range of about 90 to 120 feet. For a larger office or hospital multiple access points will be necessary. The network router is usually connected to the internet by an Ethernet cable to DSL or a cable modem. Security must be established using an encryption scheme such as WiFi Protected Access II (WPA2) encryption. Other best-practices for securing a wireless network are the use of a firewall and a unique media access control (MAC) address filtering. Each device on a network has a unique address (MAC) and routers can have security lists which only allow known devices or MACs into the network.

An emerging trend for hospitals is to use Voice over IP on a wireless network, referred to as VoWLAN. Hospitals can use existing wireless networks to contact nurses, physicians and employees with any wireless enabled device. Devices such as the Nortel VoWLAN phone or Vocera are frequently used. The chief advantage of this approach is saving local and long distance phone call charges. Using this technology, a patient could directly contact a nurse making rounds so a nurse is not forced to be located near a central nurse-call system. While in the hospital this system could replace landlines, pagers, cell phones and 2-way radios. The downside is that a strong signal is necessary for this system and is more important than that needed with just data.

Another wireless option is wireless mesh networks that rely on a single transmitter to connect to the internet. Additional transmitters transmit signals to each other over a wide area and only require a power source. Municipalities, airports, etc. are using this type of technology to cover larger defined areas.¹²⁻¹⁴

Figure 7.5: Wireless Local Area Network (WLAN) (Courtesy Home-Network-Help.com)



Wide Area Networks (WANs). Cross city, state or national borders. The internet could be considered a WAN and is often used to connect LANs together.

Global Area Networks (GANs). GANs are networks that connect other networks and have an unlimited geographic area. The problem with broadband technology is that it is expensive and the problem with WiFi is that it may result in spotty coverage. These shortcomings created an initiative known as Worldwide Interoperability for Microwave Access (WiMax), using the

IEEE 802.16 standard. This 4G network is about 10 times faster than 3G and has greater capacity which is equally important. The network is also known as a global area network (GAN) with operating speeds in the 54-70 Mbps range. The goal is to be faster than standard WiFi and reach greater distances, such that it might replace broadband services and permit widespread wireless access to the internet by PCs or phones. A user would be able to access the internet while traveling or from a fixed location. Ironically, the introduction of one 4G network (WiMax) was so slow that major carriers elected LTE, discussed in the next paragraph.

The second 4G wireless network rolled out in US cities is Long Term Evolution or LTE and offered by Verizon, AT&T, Sprint and T-Mobile. As of mid-2013 Verizon LTE covers 497 cities; AT&T LTE 237 cities; Sprint LTE 88 cities and T-Mobile 7 cities. Approximately 1/3 of Verizon and AT&T customers are using 4G LTE services.¹⁵ Operating in the 700 MHz range it has maximum download rates of 100 Mbps and upload rates of 50 Mbps.¹⁶

Both 4G wireless approaches transport voice, video and data digitally via Internet Protocol (IP) rather than through switches which will reduce delay and latency. 3G phones will not work on 4G networks.

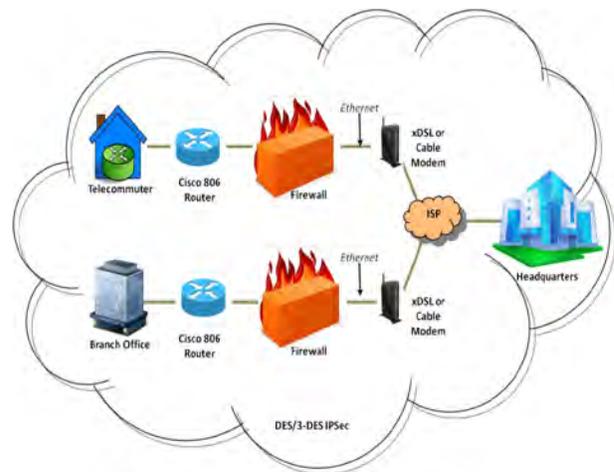
The Commerce Department will establish a lab to test 4G networks so that it can be used for a national public safety network. The lab will specifically test LTE networks because they are

supported by a larger number of cellular vendors (80% of cellular market). They plan for the public safety network to be established in the 700 MHz band.¹⁷

Virtual Private Virtual Networks (VPNs)

If a clinician desires access from home to the electronic health records, one option is a VPN. In this case the home computer is the client and is attached to the network at work by communicating with a VPN server associated with that network. Communicating with nodes over a VPN is akin to working from that network's physical location. The internet can serve as the means of connection with VPN working over both wired and wireless LANs. Authentication and overall security are key elements of setting up remote access to someone else's computer network. (Figure 7.6) "Tunneling protocols" encrypt data by the sender and decrypt it at the receiver's end via a secure tunnel. In addition, the sender's and receiver's network addresses can be encrypted. The end user can use the VPN option in computers using the Windows operating system. Type VPN into the search window and a set up wizard will create the network.¹⁸

Figure 7.6: Virtual private network diagram (Courtesy Cisco)



Future Trends

There is a tremendous amount of government and civilian data on the internet but it often is stored in formats such as pdf that are largely non-computable. The Semantic Web will find and interpret the data or create a common framework for data sharing. Data will need to be tagged with metadata tags (data that describes data) and known as “linked data.” The World Wide Web Consortium (W3C) has promoted the notion of Resource Description Framework (RDF) as the means to describe documents and images. Another specification will be Web Ontology Language. Better definitions will produce better search results. It will also allow for applications run on the internet to receive and understand data from another application. Sir Timothy Berners-Lee, considered to be the father of the WWW, now promotes the concept of linked data as part of the RDF. He points out that currently one must have application programming interfaces (APIs) and programs like Excel and PDF to interpret data. If the data was linked and encoded by RDF standards, the extra steps would not be necessary. Slowly, organizations such as BestBuy, eBay, BBC and Data.gov have begun participation in web 3.0.¹⁹⁻²⁰

Internet2 is a not-for-profit networking consortium of more than 200 universities, government agencies, researchers and business groups developing applications and a network for the future. The current network is known as *Abilene* and it operates at 10 gigabits per second (100 to 1,000 times faster than Internet1). They

have deployed 13,500 miles of dedicated fiber optics as the backbone of the system. They are in the process of upgrading to 8.8 Terabits of capacity and transmission speeds of 100 Gb/s (7,000 times faster than a T1 line). National LambdaRail (NLR) also connects universities (150+) across the nation through fiber optic networks. This unique network connects 28 American cities. Members benefit from using the faster internet to communicate and from the development of interesting middleware. Research is underway to develop programs to support digital video, authentication and security.²¹⁻²² The Iowa Health System has created a high speed network, known as HealthNet connect for medical sharing described in the info box.²³

The Institute of Electrical and Electronics Engineers (IEEE) released new standards (802.3ba) for 40 and 100 Gigabit Ethernet network in June 2010.²⁴ It is anticipated that this network will be used by researchers and others like the Department of Energy (ESnet) who need advanced speed. Verizon recently deployed a 100 Gigabit network in Europe as the first commercial network of its type. There is already talk about bundling 100 Gigabit pipes to create a Terabit Ethernet. WiFi will get faster in the 2013-2014 time frame with release of 802.11ac routers operating in the 60GHz spectrum. It is thought that transmissions will be roughly seven times faster than current technologies, but with the drawback of shorter transmission distances.²⁴



Ultra-Fast HIE

HealthNet connect was created by Iowa Health System it has become a fiber optic network of 96 Mid-West urban and rural hospital systems based on LambdaRail. The network will provide health information exchange to include large images, education, network services, cloud computing, clinical research and telemedicine. They are also offering BroadNet connect or ultra-fast fiber optic cable for non-healthcare businesses.²³

Key Points

- Most HIOs use web services and service oriented architecture to exchange health related information
- Clinicians who use client-server based electronic health records need to understand wired and wireless office networks
- Wireless networks have become more attractive due to faster speeds and lower prices
- Wireless broadband is here and will make Internet access faster and more widely available

Conclusion

Computer systems can use TCP/IP to allow for the transmission of data over multiple different protocols to provide content sharing across a network such as the internet.

Disparate services can be integrated by using web services as part of SOA. This platform provides the greatest degree of flexibility for many businesses, to include HIOs.

Hospitals' and clinicians' offices rely on a variety of networks to connect hardware, share data/

images and access the internet. In spite of initial cost, most elements of the various networks discussed continue to improve in terms of speed and cost. Many clinicians' offices will require a network expert to ensure proper installation and maintenance. Wireless technology (WiFi) has become commonplace in many medical offices and hospitals. When wireless broadband (LTE) becomes cost effective and widely available it may become the network mode of choice. Network security will continue to be an important issue regardless of mode.

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Chapter 8

Health Information Privacy and Security

BRENT HUTFLESS

Learning Objectives

After reading this chapter the reader should be able to:

- Describe privacy and security measures that are part of HIPAA, HITECH Act, and Meaningful Use and how they fit into the national health IT strategy
- Recognize the importance of data security and privacy as related to public perception, particularly in regards to data breach and loss
- Identify the benefits and pitfalls of local vs. Software-as-a-Service (SaaS) technical security solutions
- Enumerate the definitions of confidentiality, availability and integrity
- Discuss multiple ways to ensure authentication
- Compare and contrast digital signature and certificate based encryption
- Enumerate different types of security breaches and their causes
- Discuss security standards and the laws intended to protect health data

Introduction

The Health Insurance Portability & Accountability Act (HIPAA) passed in 1996 laid much of the groundwork for the privacy and security measures being adopted within healthcare today. The original intent was to direct how patient data was used and made available when patients switched physicians or insurers, and included two major rules covering privacy and security of that data. The American Recovery and Reinvestment Act of 2009 (ARRA), and the HITECH Act which accompanied it, both brought about changes designed to improve privacy and security measures required by modern technologies and closed loopholes within the original law. With a

verifiable need to protect health information well established, there is a need to cover the information security aspects. How is health data protected against exposure? How does an increasingly targeted industry turn the tide against the news stories, hackers, criminals, and identity thieves? More importantly, what mechanisms are medical professionals likely to witness firsthand in the battle to keep the attacks at bay?

This chapter introduces general concepts of information privacy and security, and explains the technologies and techniques used by security professionals, without the technical jargon. The major topics include HIPAA review, major cases

of privacy and security breaches, basic security concepts, authentication and identity fundamentals, descriptions of the risk scenarios which may lead to breach, and lastly, the compliance and legal standards being applied to medicine.

HIPAA Review

Before discussing the current state of privacy and security regulations and intent, a primer on HIPAA is needed to show what the original law provided.

HIPAA for the Consumer

Certain organizations, known as *covered entities*, are required to follow the HIPAA Privacy Rule:¹

- Health Plans
 - Health insurers
 - HMOs
 - Company health plans
 - Government programs such as Medicare and Medicaid
- Health Care Providers who conduct business electronically
 - Most doctors
 - Clinics
 - Hospitals
 - Psychologists
 - Chiropractors
 - Nursing homes
 - Pharmacies
 - Dentists
- Health care clearinghouses

A number of organizations *do not* have to follow HIPAA law despite using personal health information (PHI):¹

- Life insurers

- Employers
- Workers compensation carriers
- Many schools and school districts
- Many state agencies like child protective service agencies
- Many law enforcement agencies
- Many municipal offices

For those organizations that are required to abide by HIPAA, patient data and personal information must be protected according to the Security Rule. Protections apply to all personal health information (PHI), whether in hard copy records, electronic personal health information (ePHI) stored on computing systems, or even verbal discussions between medical professionals. Covered entities must put safeguards in place to ensure data is not compromised, and that it is only used for the intended purpose. The HIPAA rules are not designed to and should not impede the treatment of patients.² Covered entities must comply with certain consumer rights; specifically a patient may:¹

- Ask to see and get a copy of their health records
- Have corrections added to their health information
- Receive a notice that discusses how health information may be used and shared
- Provide permission on whether health information can be used or shared for certain purposes, such as for marketing
- Get reports on when and why health information was shared for certain purposes
- File a complaint with a provider, health insurer, and/or the U.S. Government if patient rights are being denied or health information is not being protected

HIPAA Privacy for Covered Entities

Covered entities have a significant responsibility

to protect the privacy and security of patient data and personal information. The U.S. Department of Health & Human Services (HHS) has an excellent website, www.hhs.gov/ocr/privacy/hipaa/under-standing/coveredentities/index.html designed to serve this population and inform entities about subjects ranging from patient consent, incidental disclosures, and contracts with business associates to the proper disposal of protected information. For detailed information regarding the HIPAA Privacy and Security rules, HHS, the Office of Civil Rights, and others provide formalized guidance. The following is a summary of highlights.

The Privacy Rule strictly limits how a covered entity and their business associates can use patient data, but there is a method that can be employed to use and release the data without restrictions. The Privacy Rule mandates that organizations de-identify the data by removing 18 identifiers, which reasonably precludes the resulting information from being attributed to a patient. The 18 identifiers include:³

- Names
 - All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
 - The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
 - The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
 - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
 - Telephone numbers
 - Facsimile numbers
 - Electronic mail addresses
 - Social security numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers, including license plate numbers
 - Device identifiers and serial numbers
 - Web universal resource locators (URLs)
 - Internet protocol (IP) address numbers
 - Biometric identifiers, including fingerprints and voiceprints
 - Full-face photographic images and any comparable images
 - Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- Covered Entity Permitted Uses and Disclosures of patient data according to the Privacy Rule:⁴
- To the individual
 - For treatment, payment or health care operations
 - Uses and disclosures with opportunity to agree or object
 - Facility directories
 - For notification and other purposes
 - Incidental use and disclosure
 - Public interest and benefit activities
 - Required by law
 - Public health activities

- Victims of abuse, neglect or domestic violence
- Health oversight activities
- Judicial and administrative proceedings
- Law enforcement purposes
- Decedents
- Cadaveric organ, eye, or tissue donation
- Research
- Serious threat to health or safety
- Essential government functions
- Workers' compensation
- Limited data set

Administrative requirements were established by the Privacy Rule to ensure that all covered entities, regardless of size or organization, met a minimum standard for protecting patient privacy and permitting patients to exercise their rights. The scope of the solutions for each of the requirements is left up to the individual organization, but the required categories are as follows:⁴

- Develop and implement written privacy policies and procedures
- Designate a privacy official
- Workforce training and management
- Mitigation strategy for privacy breaches
- Data safeguards - administrative, technical, and physical
- Designate a complaint official and procedure to file complaints
- Establish retaliation and waiver policies and restrictions
- Documentation and record retention - six years
- Fully-insured group health plan exception

HIPAA Security for Covered Entities

There are three safeguard categories that are required by the HIPAA Security Rule that serve as a foundation:⁵

Administrative Safeguards

- Security management processes to reduce risks and vulnerabilities
- Security personnel responsible for developing and implementing security policies
- Information access management - minimum access necessary to perform duty
- Workforce training and management
- Evaluation of security policies and procedures

Physical Safeguards

- Facility access and control limiting physical access to facilities
- Workstation and device security policies and procedures covering transfer, removal, disposal, and re-use of electronic media

Technical Safeguards

- Access control that restricts access to authorized personnel
- Audit controls for hardware, software, and transactions
- Integrity controls to ensure data is not altered or destroyed
- Transmission security to protect against unauthorized access to data transmitted on networks and via email

Data Storage and Defining Covered Entities

When HIPAA was passed in 1996, most healthcare organizations were still entrenched as paper-based systems. As technology evolved over the past decade, so too did the methods that healthcare entities used to share and store

medical information. Electronic billing, patient records and personal data storage was becoming a more common practice, but high profile cases of data loss were increasingly in the news, as occurred when the VA lost a laptop containing more than 26 million veteran records, and later lost another with an additional 38,000 records.⁶

As a result of these and similar breaches, the HIPAA security standard enacted in 2003 needed amending to clarify the requirements for storing and sharing ePHI. In late 2006, HHS released its HIPAA Security Guidance, which identified various forms of remote use, data storage and the requirements for handling and reporting ePHI by covered entities.⁷ While it was hoped that this guidance would lead to increased protections, loopholes would remain that would need to be addressed by the ARRA.

By 2009, HIPAA faced new challenges regarding the definition of covered entities. Major software companies had begun aligning new products to the burgeoning field of HIT with a variety of fee-based, open-source, and free solutions and services. Industry leaders Microsoft and Google both offered consumers no-cost, web-based personal health records that allowed users to share information with physicians, hospitals and pharmacies, and stored vast amounts of medical and personal data. Although this initially appeared to be a significant development, both companies asserted that HIPAA did not cover them.⁸ Neither giant has come to dominate the no-cost market, and Google Health has left the market as of January 2012.

Medical organizations and physicians have been bound by HIPAA regulations for more than a decade, but compliance with HIPAA has the potential to impact the financial bottom line beyond fines and penalties now that the new standards have been adopted. The Health IT Policy Committee's recommendations "that CMS withhold meaningful use payment for any entity until any confirmed HIPAA privacy or security violation has been resolved" have tied adherence to a financial obligation.⁹ Payment withholdings would be in addition to any potential fines and penalties attributed to the HIPAA privacy or

security violations. Those earlier recommendations were later reinforced throughout the Meaningful Use rule published in the Federal Register.¹⁰

HIPAA, HITECH elements of the ARRA of 2009, and Meaning Use standards all serve to protect privacy and implement security consistency, but these tools alone are not enough to protect the systems, networks and data shares necessary for a national healthcare system. To be able to protect patient data and share medical records securely, other measures must be put in place. Unfortunately, there are far too many examples of what can happen to patient data if not treated appropriately.

Basic Security Principles

The shift towards electronic health records, personal health records, health information exchanges, and web-based health applications creates a security challenge of incredible proportions. How does one secure the most private of personal information, health data, for just over 300 million people? More difficult still, how does an industry spotlighted in the media for failing to protect this data instill confidence with the public whose data is being collected and used? Some 2013 findings indicate that a little over 12% of participants had withheld information from a healthcare provider because of security concerns.¹¹ This lack of communication could have dire consequences on the provider/patient relationship and essentially the patient's health as a whole. But without better assurances and solutions by vendors, insurers and health care organizations, it may be difficult to win and keep the public trust. The resolution may rely on a set of security principles that are the foundation for current solutions in other industries, such as banking, retail industries or the airlines.

Definitions

According to the International Information Systems Security Certification Consortium (ISC²), among others, there are three pillars of

information security (confidentiality, availability, and integrity) that are fundamental to protecting information technology solutions such as health information technology (HIT).¹² Security measures are instituted collectively to meet one or more of these primary goals, with the end result being one where confidentiality, availability and integrity are all covered.

- *Confidentiality* refers to the prevention of data loss, and is the category most easily identified with HIPAA privacy and security within healthcare environments. Usernames, passwords, and encryption are common measures implemented to ensure confidentiality.
- *Availability* refers to system and network accessibility, and often focuses on power loss or network connectivity outages. Loss of availability may be attributed to natural or accidental disasters such as tornados, earthquakes, hurricanes or fire, but also refer to man-made scenarios, such as a Denial of Service (DoS) attack or a malicious infection which compromises a network and prevents system use. To counteract such issues, backup generators, continuity of operations planning and peripheral network security equipment are used to maintain availability.
- *Integrity* describes the trustworthiness and permanence of data, an assurance that the lab results or personal medical history of a patient is not modifiable by unauthorized entities or corrupted by a poorly designed process. Database best practices, data loss solutions, and data backup and archival tools are implemented to prevent data manipulation, corruption, or loss; thereby maintaining the integrity of patient data.

Security Tools and Solutions

Information security is in many ways analogous to physical security techniques employed at a residence or place of employment. Some solutions are used to deter and prevent access, such as locks on doors and windows, use of

shrubs, bright or motion-sensitive lighting, video cameras, guard shacks, fencing and gates. Similarly, business networks and information resources are protected by access control lists (ACL), firewalls, intrusion detection and intrusion prevention systems, authentication systems, and monitoring and auditing services designed to mimic their physical counterparts around the building or home. Instead of a key, one uses a username and password or token to gain access. The firewall acts as the barrier designed to keep out those who do not belong. Intrusion systems take the place of video surveillance; and similar to footage used for evidence in a crime, these systems can help forensics investigators track an intrusion back to its source. Monitored services imitate physical alarm systems, and forensics specialist track intruders who may unwittingly leave a trail of evidence, ultimately leading to real-world arrests and convictions. One real-world example of this is the case of Army PFC Bradley Manning, who leaked untold quantities of classified data to WikiLeaks founder Julian Assange, and then failed to cover the digital tracks which led investigators to the evidence used to try him.¹³ It is the correlation between the physical and the electronic that much of this chapter builds on.

Organizational Roles

Information security roles and responsibilities can vary widely from organization to organization depending on size, industry, compliance mandates and laws, technology initiatives, maturity, private or public status, and even profit model. Policy regarding information security practices is often set by chief information officers (CIOs), chief technology officers (CTOs), information technology (IT) directors or similar; often with input from chief medical informatics officers (CMIOs), HIPAA compliance officers, or the like. Depending on resources, the information technology teams may consist of network, system administration, security and data personnel, or could be the very same technical staff relied upon for all office or clinic IT needs. No matter the titles, this supporting staff is often tasked to defend key

systems, networks, and patient data from risk, and assist with any investigations resulting from a data breach.

HIPAA, Meaningful Use, and the HITECH Act

Many of the core concepts surrounding HIPAA were introduced at the beginning of the chapter, but HHS maintains an excellent 25 page summary of the HIPAA Privacy Rule in PDF format

(www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf) for quick reference. It is important to remember that the Privacy and Security Rules established through HIPAA were designed for the healthcare system and processes that were in place in the mid-1990s. This system is transforming to technology-driven solutions through the use of electronic medical records (EMRs), clinical decision support systems (CDSS) and other solutions broadly known as health information technology (HIT). Many of the changes are due to a convergence of driving forces: current and imminent government regulations, the need to cut rising insurance costs, calls for healthcare reform, improved technical capability, advanced software solutions, and a higher expectation from consumers to control and manage their own healthcare information.

Today, technology has the opportunity to revolutionize health care, changing hospitals and clinical environments from isolated and unconnected islands of patient treatment records and knowledge to an interconnected system of healthcare. Hospitals and practitioners are taking note of studies advocating the use of electronic health records (EHR) and related systems that have the capability to quickly retrieve patient data and records, saving time, preventing duplication of treatment efforts, reducing drug interactions and contraindication situations; generally improving patient care and reducing administrative costs associated with paper records.¹⁴ However, with new opportunities there often come new risks, and in the case of

medicine, an escalating chance to violate HIPAA privacy and security regulations. The number of companies and organizations that are offering data solutions for patients and providers is growing exponentially, increasing the challenge of finding a solution that meets the new reporting, use and billing requirements.

Challenges for the Nationwide Health Information Network

The ARRA provides financial incentives for EHR adoption and use, aiding hospitals, clinics and physicians in the push toward meeting the evolving requirements for electronic capture and tracking of patient data outlined in the Meaningful Use definitions.^{9,15} Numerous stories of data breaches and subsequent lawsuits highlight how a growing number of healthcare organizations are experiencing adoption challenges that impact patients as well as their reputation and bottom line. Perhaps because of this, some of the Stage 2 Meaningful Use criteria were changed.

Certifying Compliance

For many HIT vendors, much of the past few years have been spent ensuring that current product lines met the new compliance standards needed for Meaningful Use requirements, particularly with large financial incentives at stake for their respective customer base. Originally, only one body was permitted to certify partial and complete EHR products; the Certification Commission for Health Information Technology (CCHIT). The CCHIT was established to ensure that a product met US Department of Health and Human Services minimum specifications for compliance criterion. Due to the increased workload and number of applications, five additional organizations were granted approval in 2010 as certification bodies. Beyond CCHIT, the others include Surescripts LLC, ICSA Labs, SLI Global Solutions, InfoGard Laboratories, Inc., and Drummond Group, Inc.¹⁶ The most important issue regarding the certification list is the dramatic growth of certified complete EHR products. In June 2010, only 12 vendors were

capable of offering certified products; while the list in late 2013 includes 3652 ambulatory products by 1071 vendors.^{16,17}

The enhanced selection of certified EHR helps ambulatory and inpatient organizations find a good fit, and also offers some assurances that products meet appropriate standards, but this first round of certifications does not yet incorporate the tougher Stage 2 criteria slated to begin in 2014.

Authentication and Identity Management

Who are you? More importantly, can you prove who you say you are? These are the chief tenants of authentication, and are supported by photo identification, biometrics, smart card technologies, tokens, and the old standard; user name and password. Authenticating users, patients and staff is essential for providing system access, ensuring only those with need to know have access, protecting important data, and lending legal credence to actions and records.

Basic Authentication

The devices and methods people use to gain access to systems, data, and web solutions vary depending upon the sensitivity of the data, the capabilities of the systems, resource constraints - both technical and monetary, and the frequency of access. All of the methods discussed here rely on what is known as two or multi-factor authentication. The factors fall into three categories – something one knows, something one has, or something that one is.¹⁸ The most basic of these is the tried and true username and password combination still employed by a majority of users today, combining two things that a user knows. Another option is utilizing a grid card, smart card, USB token, one time password (OTP) token, or OTP service in combination with something a user knows, such as a passphrase or PIN. All of these rely on something one has; either a card, token, or in the event of the OTP

service, some mechanism to view a message that contains the one time use character string or passphrase to be used. By combining something a user has with something he or she knows, two-factor authentication occurs. Figure 8.1 contains a selection of these authentication tools, showing a grid card, smart card, OTP card and OTP smartphone service application.

Figure 8.1: Various Authentication Tools (Image Sources – Entrust.com)¹⁹



Single Sign On

Anyone who has used a computing device more than a few times quickly learns that most systems, whether physical workstations or web based solutions, require some method of authentication, typically in the form of a username and password. Before long, users find themselves with a growing list of usernames and passwords for any number of devices, email accounts, banking access, social networks, retail websites, and even a few dedicated to work resources.

What if there was a way to use one set of credentials, or one mechanism, to easily access many of the resources one uses every day, but with security that identical usernames and passwords cannot provide? This is the practice known as single sign on (SSO), and when implemented correctly, it allows users to access a variety of disparate systems using one set of stored credentials. SSO can be utilized for more than system and network access, enabling users to authenticate to the web and software as a service (SaaS) solutions as well. One common example of SSO is a service offered by Google to

partner organizations which use Google Apps, such as Gmail, Google Docs, and Calendar. The partner organizations, perhaps a small business or school, “control usernames, passwords and other information used to identify, authenticate and authorize users for web applications that Google hosts” through the SSO solution, offering seamless transitions between local resources and hosted applications.²⁰

Although the above example employs a username and password, other mechanisms such as smart cards, tokens and even biometrics are capable of offering SSO capability for a wide range of client, software, and web-based solutions. This permits the use of a single token or card used for workstation or network access to also connect with web-based application and other solution software without additional user logon.²¹

Smart Cards

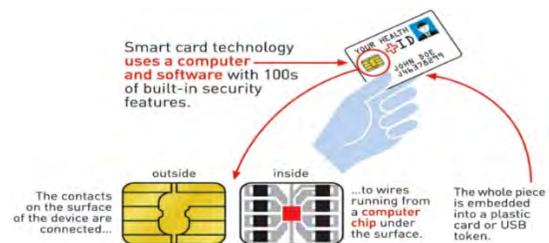
These portable card devices carry vital patient information and have a self-contained processor and memory. Typically smart cards are read by direct physical contact with the card reader or through remote radio frequency interface. Examples of the patient data that can be stored on the card are patient identity verification, complete patient demographics, allergies, medications, known medical issues, surgeries and procedures, additional patient information such as implanted devices, and insurance information.²² Some of the advantages are cost, ease of use, portability and durability, and ability to support multiple applications. Security features can include encrypted patient information as well as digital or biometric signatures and personal identification (PIN) numbers or passwords. Some of their drawbacks are a lack of standardization or integration, as well as cost of physician buy in, and new technology apprehension.²³ Smart Cards have the potential to be a valuable tool for patients, providers, and insurers alike if they prove to provide positive identification, deliver a secure and portable inclusive health record, and accelerate the entire patient experience from registration to treatment. Figure 8.2 demonstrates the smart card used in France for

healthcare transactions and figure 8.3 displays the computer chip that is embedded in the card.

Figure 8.2: Carte Vitale (Source: Gemalto)²⁴



Figure 8.3: Smart Card Technology (Source: Gemalto)²⁵

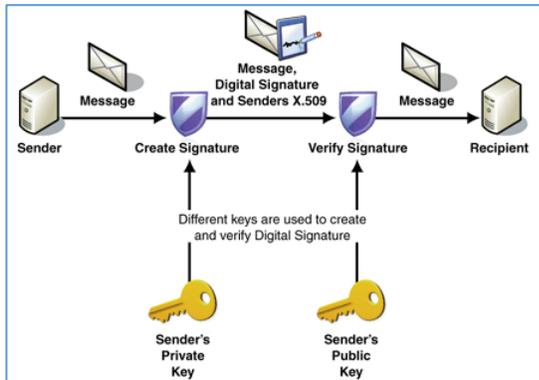


Digital Signature

Part of the problem that arises when shifting from hard copy medical record documentation to electronic format is signing new records. Beyond the obvious improvement in discerning the signatory compared to a handwritten signature, there needs to be some additional contrivance that provides some assurance that the digital signature is valid and that it was placed by the person it is attributed to. In the case of patient records, this digital signature also acts as the legal signature of the practitioner. As such it can serve as non-repudiation for electronic messaging and records access for audit purposes and in some cases meets compliance controls or measures for identity management. The strength of this technology is such that email correspondence containing an electronic signature is sufficient to prove that the originator and the signatory are one in the same. This is possible because the originator is the only one with the unique key required to produce the electronic signature.²⁶ The example shown in Figure 8.4 provides some insight into what occurs when a user send a digitally signed email,

a common form of official electronic correspondence.

Figure 8.4: Electronic Signature (Source - Microsoft X.509 Technical Supplement)²⁷

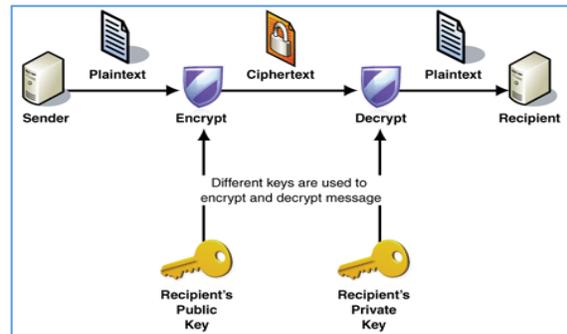


Certificate Based Encryption

An advanced form of digital certificate technology is certificate based encryption. Whereby a digital signature is used to provide assurances and non-repudiation from a given party, encryption is intended to completely obscure the contents of a message, preventing compromise of sensitive information in the event that a message is intercepted en route. Although the algorithms used for encrypting data are somewhat complex, the practical applications are easily understood. By having pre-shared public keys, individuals can send correspondence to each other taking comfort in the knowledge that the contents are protected from prying eyes. Figure 8.5 displays two employed keys, similar to the digitally signed message. In the case of encryption though, it is the recipient's public key that is used by the sender to encrypt the message, not the sender's. Since the recipient has the lone private key, only he or she will be able to decipher the message and view the contents.

Given the constraints placed upon organizations trying to meet HIPAA, Sarbanes-Oxley Security (SOX), or Payment Card Industry (PCI) compliance mandates, encryption provides a much-needed layer of security designed to protect the most sensitive of data. A practical

Figure 8.5: Public Key Encryption (Source - Microsoft X.509 Technical Supplement)²⁷



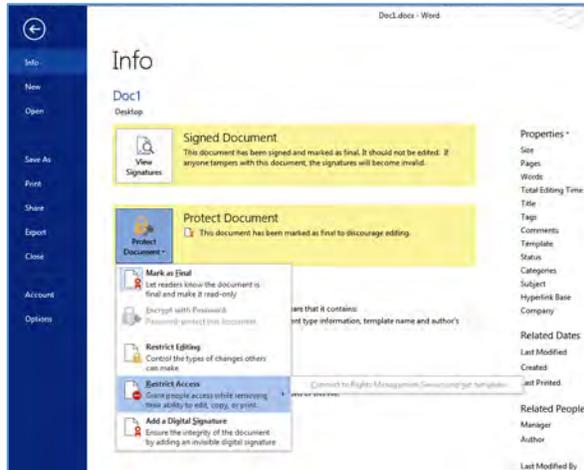
example where this could be employed is correspondence involving patient records. As an alternative to de-identification of a patient record, a record could be sent with all identifying data to a qualified recipient using the data encryption mechanism described above. This type of data protection mechanism is permitted for sensitive data in motion, as described in the Health Information Technology for Economic and Clinical Health (HITECH) Act²⁸ and is a component of secure messaging through the Direct Project as described in the chapter on health information exchange.

Digital & Information Rights Management

Beyond identifying the user and authenticating against systems and web solutions, users can also be controlled for roles, permissions, and access in fine detail. Digital Rights Management (DRM) and Information Rights Management (IRM) are related data access concepts that are gaining in adoption as compliance initiatives and risk management practices take hold in organizations across many industries. One common application of DRM and IRM functionality is with content management systems, such as Microsoft SharePoint or EMC Documentum product lines.²⁹ While it is essential to secure sensitive health data from unauthorized access, it is increasingly important to limit any unnecessary access to patient records. DRM and IRM allow organizations to limit user or system access to data only when it is needed, place time constraints upon said

access, limit how and where data can be viewed, modified and moved, as well as create records for auditing and forensics purposes. Figure 8.6 illustrates the permissions function within Microsoft Word.

Figure 8.6: Microsoft Word 2013 IRM (Source: Microsoft Office)



The DRM and IRM mechanisms employed on an organizational content management system (CMS), electronic health record (EHR) product data repositories and the like allow for setting granular rights permissions to the user level. Records of the activity can be used for compliance audits, but also serve as evidence in cases where unauthorized access is suspected, an example of which is a case in Florida where three non-medical hospital employees accessed medical records of accident victims and forwarded this information to a law referral service.³⁰ Though the three individuals were eventually caught, this activity could have been prevented if DRM and IRM controls had been in place.

Biometric Authentication

In addition to authentication mechanisms which rely on something the user has (e.g. grid card or USB token), there are now biometric authenticators based on physical user identifiers. Biometric authentication typically uses a fingerprint, retinal scan, or voice imprint, although iris, vein and even heart rhythm based ECG scans have been proposed as solutions in

recent years.³¹ When combined with passphrases or the tokens, cards, and OTP solutions discussed previously, a two or multi-factor authentication solution can be employed.

The key take-away from the examples of two-factor authentication is the difficulty these present to would-be attackers or data thieves, as it greatly increases the complexity required for user access over a simple username and password combination. Although usernames and passwords are not likely to fade away anytime soon, increased adoption of other more secure methods is almost certain, particularly in the face of increased data breaches, attacks, and even industry regulations.

Data Security in the Cloud and Traditional Client/Server Solutions

Recent changes in technology and product models have thrown an additional element into the mix for organizations to contend with; which type of solution to choose. The traditional practice management or electronic health record solution is based on software that runs on local network infrastructure and is delivered via a client terminal using terminal services or loaded on a workstation. Hospitals and practices maintain the system and equipment locally and work with vendors for troubleshooting, software change requests, and upgrades. The latest contender is software as a service (SaaS), used to deliver the solution via a Web browser. Oftentimes, SaaS solutions rely on another new technology, cloud computing, to store data and provide the back office computing power traditionally handled by servers and network storage devices. In this type of solution, the hospital contracts with a vendor to provide all of the services which are delivered to the end user. Each solution type has security risks and vulnerability for HIT workers to contend with; whether it is a stolen laptop, missing backup media, or a SaaS service compromise.

Deciding which solution is appropriate for an organization is decided by a number of factors

that require careful deliberation and planning. Products like the Application Security Questionnaire (ASQ) from HIMSS can assist organizations performing their own research and planning for HIT solutions. The ASQ is a vendor-neutral, seven page capabilities checklist that hospitals, practices or medical organizations can request that software or

services vendors complete for later comparative analysis of the various options being reviewed for selection.³² Table 8.1 was created to compare the SaaS/Cloud and Client/Server models, indicating some of the advantages and disadvantages of each.^{33, 34, 35, 36} While the list is not all-inclusive, it provides a primer on what criteria and potential risks need to be considered.

Table 8.1: Cloud versus client-server model

Feature or Attribute	SaaS/Cloud	Client/Server
Integration with current systems	Web-based solution used with browser reduces client integration issues, but may have interoperability issues with other solutions in use.	Client software may have integration issues based on client configuration and may have interoperability issues with other solutions as well.
Software updates or upgrades	Software upgrades and updates are typically seamless, as they occur within the cloud before being delivered to the browser on the client end.	Software upgrades and updates require testing, may require downtime, and can be problematic if some systems are not available during the update window.
Costs	Infrastructure costs tend to be less than client/server, and SaaS solutions are less hardware dependent, but costs for bandwidth availability and service contracts can offset some of the savings.	Infrastructure costs associated with servers, storage, the solution product and support, in addition to life cycle costs of hardware and software that the solutions depend on for new features.
Reliability	Reliability is dependent of the product vendor and the quality and availability of the Internet connection to the provider.	Reliability is dependent of the product vendor and the capability of IT staff.
Availability	24/7 availability dependent upon Internet service	24/7 availability
Scalability	Easily scalable, but highly reliant on amount of bandwidth and signal latency, which serves as the performance bottleneck.	Scalability depends on capability of servers, storage and network infrastructure. Has less network latency to affect performance.
Security	Security in a cloud is still major sticking point, as data is on shared infrastructure and relies on virtual security methods and techniques.	Organization owns equipment and controls network security. Security dependent upon staff and defense measures.
Customization	Customization may be costly or limited due to support requirements in day-to-day operational environment.	Customization may be costly, but organization controls the implementation once complete.
Ownership	No ownership of solution, data is not located on site. Data may be difficult to obtain after contract ends, vendor is absorbed or goes bankrupt.	Organization owns data. Software is still usable in the event the vendor goes bankrupt.
Infrastructure	Requires no changes to infrastructure to support, unless additional bandwidth requirements dictate.	Requires more hardware; application servers and network storage. COOP solutions for redundancy require more equipment still.
Support	Support is almost entirely dependent upon vendor and service level agreement.	Support is dependent upon local IT staff and vendor when needed.

Standards, Compliance and Law

Outside of avoiding the bad publicity and financial implications that attacks and data breaches pose, organizations often have additional incentives to maintain or increase their security posture, which often originates with laws and compliance mandates. HIPAA and subsequent laws have placed breach notification reporting requirements on covered entities and business units. Recent guidance places a 60 day requirement on breach reporting, but responsible organizations should be encouraged to visit the instructions pages hosted by HHS.³⁷ Failure to meet the requirements, acknowledge responsibility, and provide notification to HHS and news outlets for breaches affecting 500 or more individuals could result in severe fines and penalties.

HIPAA, the HITECH Act and Meaningful Use all play prominent roles in compliance initiatives for many healthcare organizations, but

depending on the size, complexity, and public or private standing of a company, other compliance initiatives and laws exist which have direct bearing on how data must be protected, reported, and even audited. Instead of covering these topics in depth, they are listed in Table 8.2 with simple descriptors. Each standard, regulation, best practice or governance is too complex to cover in detail here.

Security Breaches and Attacks

Overall healthcare data breaches are reported to be down when compared to other sectors such as financial and retail industries. However particular types of health data breaches are on the rise such as identity theft. This may not be surprising given the volume and scope of data coupled with increasing demand from patients, providers, and the government to digitize health record data. According to a report from the

Table 8.2: Security Standards and Law

Security Standard/Law	Brief Description
ISO 20000/27000	International IT Governance and IT Security standards
COBIT	IT Governance framework
ITIL	Information Technology Infrastructure Library , IT service management
NIST SP 800-53	National Institute of Standards and Technology, IT security controls
SOX	Sarbanes–Oxley Act; Public company accounting law
HIPAA	Health Insurance Portability and Accountability Act of 1996
Meaningful Use (HITECH Act)	Identifies the technical capabilities required for certified EHR technology, and bonus qualifiers for organizations which meet them
PCI-DSS	Payment Card Industry Data Security Standard
FISMA	Federal Information Security Management Act

Poneman Institute there was a 19% increase from 2012 to 2013 in medical identity theft. The Identity Theft Resource Center reports that in September 2013 there had been an increase from the previous year of 2.4 million to 2.7 million victims.^{38,39,40} An upward trend in healthcare breaches cannot continue without impacting further adoption and acceptance of electronic health records by the public and providers alike. The following sections describe some of the issues which lead to data compromise followed by an information box summarizing some of the security trends noted in 2013.

Physical Theft

Several years ago a laptop was stolen from a Veteran's Administration (VA) employee containing the records of millions of veterans. Although that laptop was later recovered, theft of devices and storage continue to result in data loss, and more specifically, patient data loss despite the advent of protection mechanisms which would render such information irretrievable to the thieves.⁴¹

Computing devices such as laptops, desktops, and even servers are stolen each year out of cars, homes, and places of business. Although servers are usually considered relatively safe due to their back office location out of public view, facilities still fall victim to break-ins where thieves take valuables such as servers without directly targeting those resources for their data.⁴² Unfortunately, in such cases the burglars make off with the entire databases, exposing patients and facilities alike to grave risks. Beyond computing devices, storage also presents risks to organizations when not encrypted and treated with an appropriate level of care. A multi-billion dollar lawsuit stemming from lost archive tapes stolen from an employee vehicle has the potential to financially ruin the company SAIC, that was managing the storage media for Tricare Management Activity.⁴³ Portable and removable storage media is, by its very nature, more susceptible to theft but its limited commercial application may have thus far prevented large breaches.

To put the impact of medical data theft into perspective readers should visit the HHS website that lists all of the reported data breaches affecting over 500 users from 2009-2013. The site lists the covered entity, the number of breach victims, the type of breach and the location of data (laptop, server, paper, etc.). The link is located at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachtool.html> and is available in a variety of formats. Of the 720 losses listed, no fewer than 268 involved a laptop computer or portable electronic device, indicating that portable computing devices are still used to store sensitive data despite industry recommendations to avoid such behavior.

Theft Countermeasures

Outside of recovering lost and stolen devices and performing forensic analysis to determine whether data has been accessed by unauthorized individuals, there are a number of measures that can be used to render data unusable to the thieves. Encryption standards such as FIPS 140-2 are being applied to storage mandates in order for organizations to adhere to HIPAA data protection criteria in the event of loss or theft.⁴⁴ Simply put, encryption renders the stored data irretrievable or otherwise indecipherable to those who attempt to access it without the proper decryption key. Some of these solutions exist at a hardware level, and the FIPS 140-2 validation that often accompanies it is applied to physical storage devices such as drives found in servers, workstations and portable computing devices, as well as hardened portable storage devices, such as thumb drives. Figure 8.7 shows a common encrypted personal storage device.

Figure 8.7: IronKey Encrypted Drive⁴⁵



Other software-based encryption techniques, such as hard disk encryption, can be applied to computing platforms after the fact to similarly protect these devices. When encryption is configured appropriately, an organization could theoretically leave their most sensitive data in a box outside of their doors with no worry of data compromise, although few would recommend this practice.

Physical or Logical Access

In the information security profession, there is a common expression that states that “if one can touch a system, one can own it.” In the health care environment, this is more difficult to accomplish for the outsider has to bypass the greater physical security mechanisms often in place. For the insider however, this is far easier to achieve. Insider threat for the purposes of this discussion can be defined as those employees or staff with physical or logical access to systems in an organization who seek to steal, damage, or compromise data. Whether it is a disgruntled employee seeking retribution, someone performing data collection for personal gain by identity theft, or an insider seeking data for competitive or corporate espionage purposes, organizations need to be aware of the potential risks from within. For hospitals this threat could extend to data corruption, similar to what happened at a Minnesota hospital after a logic bomb planted by an angry former employee disabled a core program.⁴⁶

There are a wide variety of data collection techniques that can be used by insiders, ranging from simple storage devices and key-loggers to technologies that seemingly spring from the latest spy movie, where malicious users create encrypted connections to destinations outside of organizational networks to pass the information. A new technique employs a feature common to most smartphones to capture keyboard keystrokes with 80 percent accuracy – the phone merely needs to sit on the same surface and does not employ the microphone.⁴⁷ In spite of this seemingly complex onslaught of technology designed to gather the most sensitive of data, most can be mitigated through identification

and remediation of vulnerable systems by IT and security staff within an organization. The key to preventing incidents often comes down to user awareness, training, policies designed to limit access, and layered security practices known as defense in depth.

Accidental or Negligent Disclosure

Large data breaches and disclosures make the news and fill the pages of Health and Human Services (HHS) notification website, but many of the routine disclosures are accidental or negligent in nature. Luckily, HHS added a threshold for harm that permits covered entities and business units to perform a risk assessment and determine whether an incidental exposure poses any risk to the affected patient.⁴⁸ This type of leak can occur through inadequate control of paper records, inadvertent release of sensitive information to unauthorized parties, through overheard conversations, or even poor housekeeping practices around copiers, fax machines, and recycling bins. Protected health information that is transmitted in non-secure means across networks, or through email messages without the proper levels of protection or adequate de-identification are also examples of electronic disclosure.

Intrusions and Attacks

Theft has accounted for a number of HIPAA-related data breaches, but a growing risk is data loss or exposure due to intrusions and attacks by groups such as Anonymous and LulzSec which seek to expose wide swathes of private data to public scrutiny.⁴⁹ These and other groups rely on a combination of intrusion vectors more commonly known as an advanced persistent threat (APT). APT is not an attack type in and of itself, but a methodology that employs as many mechanisms as possible to gain a foothold inside of an organization; attacking organizations on physical and wireless networks, attempting to compromise machines and user accounts through disguised email messages, corrupted PDF files and exploited webpages, social networking sites such as Facebook, and by using

social engineering through phone calls and brazen onsite attempts.⁵⁰ As could be expected, these attacks are significantly more difficult to defend against, but diligent staff and awareness can reduce the risks to organizations.

Medical Privacy and Security Stories in the News

Healthcare data breaches have gained traction in the news due to the large number of patients involved and the sensitive nature of health records.

- TRICARE (2011)* - The largest breach in history occurred in 2011 and reported to have affected between 4.9 and 5.1 million military active duty service members, retirees, and their families within the Tricare health system.⁵¹⁻⁵² The breach was in the form of unencrypted backup tapes stolen from the vehicle of an employee of Science Applications International Corp (SAIC), a Tricare contractor.⁵³ Data was expansive and covered those cared for in military facilities between 1992 and September 2011. Information that was contained on the tapes included names, addresses, birth dates, social security numbers, and personal health data. There was no financial data such as credit card or bank account information contained on the tapes; however with the level of personal information that was obtained financial ramifications have been reported by the affected patients.⁵⁴ Four people initially filed a single \$4.9 billion federal lawsuit against TRICARE and SAIC in 2011, but by the close of 2012 the suits grew to eight that were consolidated into one to be heard and handled by the U.S. District Court in Washington, D.C.⁵²
- Advocate Medical Group (2013)* – In July 2013, Advocate reported that patient health and identity data for 4 million patients was at risk due to theft. The data were contained on 4 unencrypted company computers stolen from their administrative building and contained names, addresses, birth dates and personal health data. While this is historically the second largest breach, what is most notable is that this is their second large breach (over 500 patients).⁵⁵ Less than a month after the announcement of this breach there were two class action lawsuits addressing Advocate’s “failure to take the necessary precautions required to safeguard patients’ protected health information” and claim that the computers were stolen from an “unmonitored” room with “little to no security”⁵⁶ and site negligence, invasion of privacy, consumer fraud, and intentional infliction of emotional distress.⁵⁷
- Affinity Health Plan, Inc. (2010)* – This breach occurred in 2009 but went unreported until 2010 and affected more than 300,000 patient records. While not the most significant in terms of novelty or number of records, the distinguishing feature of this breach is how the data was breached. Affinity had returned seven photocopy machines they had leased long term. Unfortunately, the copiers were then sold to media giant CBS News as part of an investigative report on data security risks. The units had not been wiped before return and confidential patient information remained on their storage hard drives. Three hundred pages of documents from one copier contained personally identifiable information and included sensitive medical test results, cancer diagnoses, and prescription drug information.⁵⁸ In August of 2013, the U.S. Department of Health and Human Services (HHS) announced a settlement agreement that included a fine of over \$1.2 million and a Corrective Action Plan (CAP) that required Affinity to use its best efforts to obtain all hard drives from previously leased machines and to take specific measures to safeguard their patient’s health information.⁵⁹ This story highlights the importance of understanding the comprehensive nature of patient health data storage and exploring non-traditional avenues through which breaches may occur.

These and other high profile breaches illustrate the importance of securing these records systems and the data they contain. Data security is vital for winning the public trust, the key component to long term success of an electronic health data management system.

Recommended Reading

- *Information Security Requirements In Patient-Centered Healthcare Support Systems* discusses the security risks involved in the patient centered medical home (PCMH) model which requires that all of a patient's providers share access to their PHI to collaborate on a unified treatment plan. While this method may enhance the quality of care, there are pitfalls in privacy and security that need to be addressed because of the number of providers that may share the PHI as well as their multiple policy-enforcement points and inconsistent security rules. Using domain analysis, observations, and interviews this article addresses six key requirements for existing systems to balance availability, integrity, and confidentiality: role-based access control, fine-grained access control, circle of trust, persistent control, dynamic control, and human-level policy awareness.⁶⁰
- *Privacy And Information Security Risks In A Technology Platform For Home-Based Chronic Disease Rehabilitation And Education* addresses the design and implementation of a secure home based service that provides a health diary and allows patient communication with peers and healthcare providers. The platform was tested with obstructive pulmonary disease and diabetes. Risk assessment for privacy and security were performed and out of 50 threats identified and analyzed the only one identified as an unacceptably high risk was third-party visitor's to the patient's home viewing PHI. The issue was addressed by adding a time-out mechanism when the patient had not interacted with the system. Developers were able to identify threats unique to in-home treatment and design a home-based service that delivered an essential level of privacy and security.⁶¹
- *Security Models And Requirements For Healthcare Application Clouds* determined that security and privacy issues such as malicious breaches or loss of service are preventing fast adoption of cloud computing. The creation of a healthcare cloud framework that includes business associate contracts, performance metrics, and compliance with all federal privacy and security regulations would reduce challenges to the security of cloud computing. Strategic planning on the part of a healthcare organization prior to selection and implementation are also necessary to ensure a successful cloud experience like budget, staff, organizational structure, and government regulations.⁶²
- *Information Security And Privacy In Healthcare: Current State Of Research* is a survey of information security and privacy research literature of various disciplines ranging from publications in health informatics to law and popular trade reports. Included is a general overview of privacy and security in healthcare, a summary of literature across multiple disciplines, and identification of areas for future research. They identify and categorized threat sources as: "imposter agents, unauthorized use of resources, unauthorized discloser of information, unauthorized alteration of resources, and unauthorized denial of service". Some current technologies of interest cited include concepts such as federated identity management. Future research areas named were relationships between information integrity problems and tort claims, prescriptive strategies for information access technologies, and employee security hygiene.⁶³

2013 Healthcare Security in Review



Ponemon Institute released their fourth report on patient privacy and security as it relates to medical identity theft. Data was obtained from 788 surveys with adult individuals who identified themselves or close family members as having been a victim of medical identity theft. The following are key findings:

- There were approximately 1.8 million medical-related identity thefts in 2013, a 19% increase from 2012 levels.
- Of victims surveyed, 50% took no action to prevent future medical identity theft.
- Fully 78% of participants indicated it is important to control personal medical record data while also admitting that they took no action to do so; 56% failed to verify whether their data was correct.
- Of those surveyed, 39% lost their medical insurance due to the medical identity theft
- A majority of victims had the crime perpetrated by someone they willingly shared their information with or had their identification stolen by family members; 30% admitted to letting family members borrow their personal identification to access medical treatment, healthcare products or pharmaceuticals.
- While only 36% of victims polled had out of pocket costs, these expenses averaged over \$18,600 per victim.
- Only 50% of participants understood that their medical identity theft posed a risk of permanent medical record data inaccuracies.

<http://lpa.idexperts.com/acton/attachment/6200/f-0033/1/-/-/-/-/file.pdf>

Future Trends

Multifactor authentication technologies will gain acceptance and offer acceptable performance to become more common in larger practices and hospitals. Patient privacy and security may drive this further, particularly if medical care and access is tied to benefit confirmation through more secure mechanism to limit medical identity theft.

It is predicted that by the end of 2015, there will be 2 billion owners of smart devices (smart phones and tablets) worldwide.⁶⁴ It was recently reported in a survey of bring your own device (BYOD) trends in healthcare that as many as 88.6% of respondents use smartphones for work related purposes but 41% of them did not use

any password protection.⁶⁵ With this increased use of smart devices in healthcare facilities there will need to be more polices addressing records, access, and security. Multiple factors lead to the necessity of such a policy including: rapidly evolving technology, the realization made by many organizations that BYOD tends to happen whether it is authorized or not, and the fact that addressing BYOD before there is breach or an incident should prove less costly in terms of time, energy, and money. There are a few groups that have created guidelines that can be helpful in striking a fine balance when creating a BYOD policy.⁶⁶ Any policy adopted should ensure compliance with laws and protect patient data while respecting the employee's rights as well.

Along with putting BYOD policies in place new technologies are emerging as valuable tools to control security of digital health care data more powerfully and efficiently. One such feature gaining in popularity is geo-fencing which uses global positioning to define virtual boundaries.⁶⁷ The geo-fence defines “safe areas” for devices to turn on and function and has the ability to allow access to health care data only in that specified area. If a device entrusted to store any secure data were to leave the pre-defined area for a specific amount of time it can also cause an alarm to sound, email hospital security its location, or even engage in a remote wipe.⁶⁸ Originally created to expand sales and marketing to mobile technology geo-fencing is in its early stages of use in securing data in the health care industry but shows promise as valuable security tool.

There have been significant changes in password cracking technology recently that may have a marked impact on many industries housing sensitive data, particularly health care. A new free password cracking tool permits the cracking

of passwords up to 55 characters in length, more than what the average user would ever consider using and far more than the previous limit of 15. In addition to a possible increase in costly patient health data breaches this could lead to health care organizations shifting to multi-factor technologies sooner rather than later.⁶⁹

Given the slow adoption of information security practices by the medical industry and current prevalence of data loss, data breaches are likely to remain in the forefront of healthcare security for the next few years. Unfortunately, there is still a great deal of work to be done securing the medical records and systems access for these new solutions. Data breaches affecting millions of patients by well-established providers is not a trend that can continue if the industry wants to instill patient confidence that practitioners can adequately protect the most sensitive of personal data. Based on Stage 2 Meaningful Use standards set to take place in 2014, efforts are under way to ensure that appropriate actions are in place to meet security and privacy requirements.⁷⁰

Key Points

- The security of Healthcare data is extremely important for successful current and future adoption of HIT
- ARRA and the HITECH Act are designed to supplement the administrative, physical and technical safeguards implemented by HIPAA
- Hundreds of HIT products now meet the 2011 certification requirements
- Data and records security will play a vital role in HIT success or failure
- Emerging technologies offer organizations a choice between traditional client-server or SaaS-Cloud product models
- Security measures will continue to improve and proliferate, but so will the efforts of criminals who seek illicit access to protected health data and identify theft

Conclusion

In conclusion, this chapter has sought to evaluate HIPAA and highlight its evolving impact on the future of HIT, the latest healthcare systems such as EHRs, and continue

its intent in securing privacy data. The government continues to form and enforce healthcare privacy and security standards through the passage of the HITECH Act, and the

adoption of Stage 1 and Stage 2 Meaningful Use standards. Although there will certainly be more questions and technical hurdles to face as EHRs gain prominence and medical data is collected on a national level, this section identified key topics of importance that should be considered for healthcare data privacy and security. An overview of health information security is offered with emphasis on authentication and other basic security concepts. Until appropriate security measures are adopted, embraced and enforced healthcare organizations will be faced with a variety of old and new breaches. The end result will be expensive due to law suits and fines and there will be an erosion of patient confidence in any new technology that stores protected patient information. It seems likely therefore that there will be new security laws and new penalties for those who fail to adopt and enforce the appropriate security of

healthcare data. It can be expected that more security-related objectives and measures in the administration of meaningful use stages 2 and the development of Stage 3 are developed.

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Chapter 9

Health Informatics Ethics

KEN MASTERS

Learning Objectives

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

- Describe the 20th century medical and computing background to health informatics ethics
- Identify the main sections of the IMIA Code of Ethics for Health Information Professionals
- Describe the complexities in the relationship between ethics, law, culture and society
- Describe different views of ethics in different countries
- Summarize the most pertinent principles in health informatics ethics
- Discuss the application of health informatics ethics to research into pertinent areas of health informatics
- Discuss appropriate health informatics behaviour by medical students

“It is immaterial for the experiment whether it is done with or against the will of the person concerned.” - Dr. Karl Brandt, Final Statement, Nuremberg Trials, 19 July 1947.¹

Introduction

As is obvious from the subject in this text book, health informatics combines themes from medical fields and from informatics fields. It is to be expected, then, that health informatics ethics will combine information from medical ethics and from informatics ethics. This section details the recent history of these two fields so that the reader can understand the context within which modern health informatics ethics is to be discussed. This chapter will first examine some of the historical context in which medical ethics should be understood.

The Road from Nuremberg

Nuremberg (alternate spelling *Nuernberg*, German spelling *Nürnberg*) is a town in Germany. Before and during World War II, Germany's National Socialist Party (Nazi Party) had controlled Germany, and had occupied much of Europe. During this time, at least 11 million people (mostly Jews, Poles, Romani (“Gypsies”), Eastern Europeans, and others regarded by the Nazis as “sub-humans” or “undesirables”²) were systematically murdered in what is now referred to as “The Holocaust.” Many of the victims were murdered in large camps called concentration camps.

At the end of World War II, a series of legal trials was held in Nuremberg and other cities to examine crimes against humanity that had been committed in Germany and German-occupied countries.³ To its shame, the German medical profession had cooperated with the Nazi Party on such a scale that medical and other health professionals were tried separately, and the abridged transcripts of these trials (referred to as the “Medical Case”) make up more than 1,300 pages of testimony and supporting documentation.^{1,4}

Crimes committed by medical professionals had included widespread euthanasia and sterilization of mentally and physically handicapped people (referred to as “useless eaters” (*unnützen Esser*) and lives “unworthy of life” (*lebensunwerten Lebens* or *Lebensunwerten*)),⁴⁻⁷ and also a large number of medical and biological experiments conducted on concentration camp inmates. Victims included men, women and children. Most died extremely painfully as a result of the experiments, and many of those who survived were later murdered by the camp authorities. Permission or consent for the medical experiments was almost never obtained from the

inmates. Where “permission” was obtained, it was usually only as an alternative to death, or with the promise of release. None of the surviving victims was ever released by their captors, nor were any death sentences commuted.⁴ Ironically, many of the experiments would have been illegal if they had been conducted on animals, as the Nazis had introduced strict laws governing the use of animals in medical experiments.¹

At the Nuremberg medical trial, a code of conduct, which later became known as “The Nuremberg Code,” was presented. The Nuremberg Code was in direct response to the medical crimes.¹ (See the NIH site at <http://ohsr.od.nih.gov/index.html> for the Code). The Code emphasised the need for experimental subjects’ voluntary consent to the experiment, regard for their safety (including mental suffering), balance of risks, and right to withdraw from the experiment if they wish. In addition, the Code noted that the responsibility for performing the experiment lay with the qualified medical experimenter, and this responsibility could not easily be transferred. (See Figures 9.1 and 9.2.)

Figure 9.1: Children’s Memorial, Mauthausen Concentration Camp



Figure 9.2: Dissection Room, Mauthausen Concentration Camp



As the prosecution at Nuremberg had noted, the medical professionals who had performed these procedures had violated a basic medical principle of “First, do no harm” (*primum non nocere*).⁴ Because the Code was in direct response to the Nazi medical experiments, it focuses on the rights of patients and experimental subjects; it is not a broader code dealing with general ethics of medical practitioners in other situations.

World Medical Associations’ (WMA) Declaration of Helsinki

After the publication of the Nuremberg Code, several countries reviewed their medical ethics (See Section 2 for some discussion of national influences). In 1964, the World Medical Association drew up the first version of the “Declaration of Helsinki” (DoH), which broadened the concerns of the Nuremberg Code, and was to be applicable across the globe. Since then, the DoH has been through several reviews, and the current version was adopted in Seoul in 2008.⁸

Although it is not the same as the Nuremberg Code, the DoH is similar to it, as it deals with the human subjects’ safety, consent, risks, and right of withdrawal. Amongst the significant additions (significant in the light of health informatics) is the right to “privacy, and confidentiality of personal information of research subjects” (Article 10 and 23) and the privacy regarding the use of identifiable human information (Article 25). These issues will be addressed later.

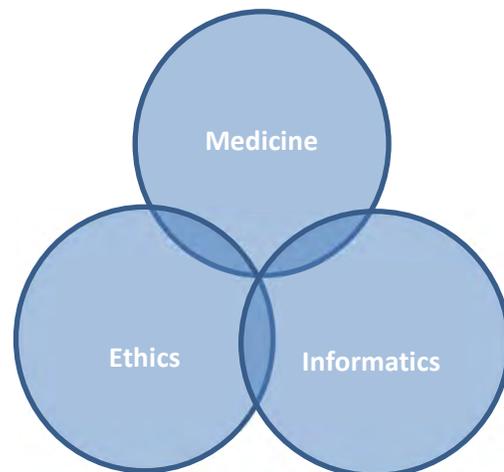
Informatics Ethics

Although one may argue that the history of informatics ethics begins with the ancient Greeks,⁹ it is only in the latter half of the 20th century that machine-based information and ethics were viewed together for the first time. At roughly the same time that the Nuremberg Code was being developed, Norbet Wiener first published his book *The Human Use of Human*

Beings in which he considered the social and ethical implications in the relationship between machines and humans.¹⁰ From the 1970s onwards, work by people like Kostrewski and Oppenheim¹¹ and Robert Hauptman¹² dealt with ethical questions in information research. In 1986, Mason introduced the PAPA acronym of Privacy, Accuracy, Property, and Accessibility as part of a “social contract among people in the information age” to “enhance the dignity of mankind.”¹³ In 1997, Severson¹⁴ introduced 4 principles of Information Ethics: (1) Respect for intellectual property; (2) Respect for privacy; (3) Fair representation; (4) Non-maleficence (or “doing no harm”).

As computers have developed further, codes of ethics for professional organisations have also evolved. Two examples are the Association for Computing Machinery’s *Code of Ethics and Professional Conduct*¹⁵ and the Canadian Information Processing Society’s *Code of Ethics and Professional Conduct*.¹⁶ These codes also refer directly to honouring the rights of the individual, respecting privacy and confidentiality, and doing no harm. (see Figure 9.3)

Figure 9.3: Health Informatics Ethics formed from Medicine, Ethics and Informatics



With similarities between the principles of ethics in medicine and ethics in informatics (especially in areas of respect for subjects, privacy, and doing no harm), it is to be expected that these would be issues contained in health informatics codes that were developed in the late 20th and early 21st century. Indeed, these principles are contained in the International Medical Informatics Association's (IMIA) Code of Ethics for Health Information Professionals.¹⁷

Although the code is aimed at health informatics personnel, it should be remembered that any medical person working with electronic data will also be a Health Informatics Professional (HIP) or a Clinical Informatics Professional (CIP).

The IMIA code is extensive, going much further than the Nuremberg Code and the Declaration of Helsinki, and has the following components (Table 9.1)

Table 9.1 IMIA Code

IMIA Code
Part I: Principles
A. Fundamental Ethics Principles: autonomy, equality and justice, beneficence, non-maleficence, impossibility (recognising that some things are impossible), and integrity.
B. General Principles of Information Ethics: information-privacy and disposition, openness, security, access, legitimate infringement, least intrusive alternative, and accountability.
Part II: Rules of Ethical Conduct
A. Subject-centred duties: these focus on electronic records, and are aimed at ensuring that subjects of electronic records are protected from abuse of their information.
B. Duties towards other Health Care Professionals (HCPs): these focus on proper support, keeping HCPs informed of relevant information, maintaining standards of data storage, and intellectual property.
C. Duties towards institutions/ employees: these include integrity, loyalty, ensuring the safety of the institution's data, evaluation of systems' security, alerting and informing the institution of problems in good time and working within their scope of competence.
D. Duties towards society: these include the proper collection, storage and safe-guarding of appropriate data, informing the public, and not participating in work that violates human rights.
E. Self-regarding duties: these include recognising one's own limitations, maintaining competency and avoiding conflict.
F. Duties towards the profession: these include not bringing the profession into disrepute, impartiality, and assisting and maintaining standards of professionalism amongst colleagues.

The IMIA Code is continually under review, and serves as a useful guide for all people who work in health informatics fields.

International Considerations: Ethics, Laws and Culture

The first part of this chapter describes the medical ethics' developments from World War II to the present day, and then the development of health informatics ethics. The impression is one of a great tragedy created by one country's lapse of medical ethics, internationally punished for breaking the widely-accepted ethical practices, resulting in a neat and linear path towards a set of near-perfect and internationally-accepted codes of ethics in the medical and health informatics fields.

While useful, this impression is a deceptive oversimplification, and the student of health informatics needs to be aware of greater complexities, especially with regards to national and international practices, and the relationship between ethics and the law. Part of the reason for the conflict is that ethics in general is strongly influenced by a country's laws and culture, but the relationship between ethics, law, culture and society is unclear, is not fixed internationally, and may be fluid even within a given country over time.

Different Views of Ethics

While there are many theories of ethics, for our purposes, there are three broad views regarding the relationship between ethics, law, culture and society:

- Ethics does not exist outside the law, and exists only for the good of a properly ordered and legal society. Therefore, a society's needs and the prevailing laws define ethical behaviour.
- Ethics is usually strongly informed by the law, society, and the prevailing culture, and are extensions of these. There are ethical requirements that are not necessarily required by law, but what is ethical can never conflict with what is legally required.
- Ethics exists entirely outside of the law, and is a matter of personal conscience. Because ethics grows from within social practices,

there is usually correspondence between ethics and the law; where there is conflict, the ethical viewpoint must always prevail.

Significance of Different Views

In the codes and activities outlined above, one can see the different views being expressed. When these views are translated into practises, the difficulties of implementing ethics become more apparent. Some examples are:

- Among some Western doctors, there was the feeling that the Nuremberg Code was useful for "barbarians," but unnecessary for civilised physicians.¹⁸
- Many of the principles in the Nuremberg code were not universally followed as standard procedures, even in prosecuting countries. The Nuremberg Code had not existed before World War II; rather, it emerged as a response to the atrocities witnessed. Part of the defence was that, at the time, there had been many international medical experiments performed on condemned prisoners (including conscientious objectors), who received no pardon or reduction in sentence, and it was also questionable whether all international medical experiment subjects (or their parents, in the case of minors) had given their permission.^{1,19} Some of the most important medical experiments (such as those by Edward Jenner) had been performed without any indication of consent.
- The medical experiments carried out by the Nazi doctors were almost always in compliance with the law and legal instructions from superiors, and were usually meticulously documented in reports.^{1,4} A strong argument for supporting the Nazi medical experiments was for the good of society, especially considering the saving of soldiers' lives during war.^{1,4} The counter-argument was that, even if a legal order were received, the physician should refuse to obey an order that he believes to be morally unjustified.¹

- Medical staff from Japan had also conducted many experiments on the Chinese population, and had used live prisoners in training procedures for their doctors.^{20,21}
- In more than 31 US States, until the late 1970s, Eugenics Boards routinely sterilised people for various reasons, including being poor, or “feeble-minded,” or young girls who had been raped. In North Carolina alone, an estimated 7,500 people were sterilised under this program.²²⁻²⁴
- Although not widespread, other countries, including the USA, had conducted medical experiments on humans who were not fully informed, and so, could not have given informed consent. Some had been conducted before the war, but many continued well after.

At the very time of the Nuremberg trials, the Tuskegee Syphilis Experiment was being conducted in the USA, and ended only in 1972 when it was reported in the press.²⁵⁻²⁷ (see Figure 9.4). Other experiments included the U.S. syphilis tests in Guatemala,²⁸ the Sonoma State Hospital experiments on disabled children,²⁹ and the radiation experiments on American citizens.³⁰ In all of these cases, the central tenets of the

Nuremberg Code had not been followed. (For further reading on this topic, see Anthony Clare’s *Medicine Betrayed*.³¹)

- There are many instances where a second person’s rights might override the confidentiality rights of a patient.³²
- Although the Declaration of Helsinki says that local laws must be respected (Article 10), it points out that “no national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.” This can be a meaningless contradiction
- A code of ethics is only a code of ethics. It carries no legal weight *at all*. If a person is found to be acting unethically, then their organisations and institutions may take actions such as revoking licenses, and refusing permission to practice, but that is the extent of their powers. A person must be guilty of committing a *crime* in order to be punished in a court of law. The codes of ethics referred to always place their ethics in the context of law (for example, the confidentiality requirement exists, unless otherwise demanded by law).^{15,16}

Figure 9.4: Doctor examining a Tuskegee Syphilis Experiment subject (Source: United States National Archives and Records Administration)



Codes of Individual Countries

The American Medical Informatics Association.

With the international differences in medical ethics, it is to be that expected there are also differences in health informatics ethics. Indeed there are, and several individual countries have their own health informatics codes. A complication is that much of the activity covered by health informatics may also be conducted in other fields, so different codes may exist for workers in those fields. This section highlights a few.

The American Medical Informatics Association (AMIA) has a code of ethics for its members.³³ It is significantly shorter than the IMIA code, but also looks the ethical relationship between doctor and patient (and the patients' family), colleagues, institutions and employers, and society in general. Regarding patients, there is an emphasis on confidentiality and security of information, and using all information for the intended purpose only. In the area of research, the code notes that "Basic human rights, especially as articulated and regulated in conducting research, must remain the highest ethical standard,"³³ although there is no specific mention of issues like informed consent and right of withdrawal from the experiment or trial.

The AMIA document is also cognizant of difficulties, however, and makes it clear that the code "is not intended to be prescriptive; it relies on the common sense of the membership."³³

United Kingdom.

In the United Kingdom, the UK Council for Health Informatics Professions (UKCHIP) has the *UKCHIP Code of Conduct*,³⁴ which "sets out the standards of behaviour required of health informatics professionals registered with the" UKCHIP. The code has four short sections, dealing with "Working to professional standards," "Respecting the rights and interests of others," "Protecting and acting in the interests

of patients and the public," and "Promoting the standards and standing of the profession." In addition, the UK's General Medical Council (GMC) has guidelines in its Good Medical Practice (<http://www.gmc-uk.org/guidance/index.asp>) which deals with patient consent and best practices in media recordings of patients (Sections 10-12; 36-42).

European Parliament Directives.

Similarly, there are several European Parliament Directives, such as (95/46/EC) of 1995³⁵ and others³⁶⁻³⁸ which are binding on member countries of the European Union, deal with the protection of data, and cover a wide range of issues from privacy to security. The most pertinent principles have been synthesised by de Lusignan *et al.*³⁹ into these:

1. Personal data shall be processed fairly and lawfully.
2. Personal data shall be obtained and processed for one or more specified and lawful purposes and not in any manner incompatible with those purposes.
3. Personal data shall be adequate, relevant and not excessive in comparison to the purpose that it was collected for.
4. Personal data shall be accurate and up to date where necessary.
5. Personal data should not be kept longer than is deemed necessary.
6. Personal data shall be processed in accordance with the rights of individuals as set out in the act.
7. Personal data shall have appropriate security measures in place.
8. Personal data shall not be transferred outside of the European Economic Area (EEA) unless adequate protections exist for the rights and freedoms of data subjects.

While this is a useful guide, the actual legally applicative directive is difficult for the lay person to understand, and appears extremely difficult to apply. For example, Article 8 of the 95/46/EC

directive states that “Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.” It is then followed by a series of exceptions where this does *not* apply, and is also followed by the statement that “Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.” This means that member states may make laws that override the main paragraph of the article.

There are also several international guides developed by different international medical associations that deal with use of specific health informatics activities, such as electronic health records and email communication between doctor and patient. These guides cover ethical issues such as data privacy and protection. Some examples are American Medical Association’s (AMA) *Guidelines for Physician-Patient Electronic Communications*⁴⁰ and the *Guide to Australian electronic communication in health care*.⁴¹

Finally, there are many ethics guides from other disciplines that impact upon ethics in health informatics.⁴²

Pertinent Ethical Principles

In this rather strange mixture of ethics, laws, and cultural influences, there are some principles that appear to be common. Given the complexities outlined above, it is useful for the student of health informatics to have a summary of the most pertinent ethical points, and that summary is supplied here. Principles such as the right to privacy, informed consent in research, and the non-transferability of ethical responsibilities (accountability) will be discussed. With the understanding that the importance of each of these will be viewed differently in different circumstances, these are useful guides from medical ethics and health

informatics ethics. In these descriptions, any reference to patients would refer to research subjects and to their families. In health informatics education, these will extend to students.

- Right to privacy. The patient has a right to privacy, which means that information that the HIP has obtained must not be shared with others unless there is reason to believe that it is in the best interests of the patient.
- Guard against excess: there should be safeguards against excessive personal data collection; only data specifically needed should be collected.
- Security of data. The right to privacy, and maintaining patient safety, also means that there is a responsibility on the researcher to keep the data as secure as possible, in order to prevent unauthorised access to it. As an extension of this, and incorporating ethical operations of the institutions in which the HIP works, if the HIP becomes aware of security problems, even those that are not under his/her direct control, the responsible persons must be informed. The emphasis on security, however, must not be so strong that it impedes the patient’s right to access that data.
- Integrity of data. This is also related to security, and the HIP has to ensure that data are kept current and accurate. In addition, data cannot be presented in such a way that it presents an untrue picture of reality, or is designed to mislead the reader.
- Informed consent: while the patient should be aware of what is to happen, that awareness can be complete only if the patient is informed. Similarly, the researcher may do only what has been consented to, and, if the researcher wishes to do anything else (e.g. use data for any other purpose), then new consent must be obtained. Crucial aspects of informed consent are: “(1) competence of the subject to consent..., (2) disclosure of information, (3) the subject’s understanding of the information being disclosed, (4) volition or

choice in the consent, and (5) authorization of the consent.”⁴³

- **Laws:** the HIP needs to be aware of the laws that apply. Where there is a conflict between the law and the professional ethics, the HIP will have to make difficult decisions. In addition to the discussion above, this issue is explored further a little later in this chapter.
- **Medical ethics.** Health informatics ethics is a sub-set of medical ethics. This means that all issues that apply to medical ethics in general, such as the physical and psychological safety of the patient, also apply to health informatics ethics.
- **Sharing data.** If it is necessary to share the data with anyone else (e.g. for further research, temporary or permanent storage, or data transmission), then the HIP must be sure that all the above principles are also being followed.
- **Wider responsibility:** HIPs have ethical responsibilities towards their employers and the wider community regarding protecting data and maintaining professional standards.
- **Implicit in all these are the principles of beneficence and non-maleficence.** This means that the ethics must be beneficial to the patient, and must be consciously aimed at preventing harm to the patient.
- **Non-transferability:** the responsibility and accountability for adhering to these rests with the HIP, and cannot simply be transferred.

Difficulties Applying Medical Ethics in the Digital World

The previous section of this chapter traced the recent history of health informatics ethics, and showed the various principles involved. At this stage, it is obvious that the issues are extremely complex. It is now the time to turn to some

practical examples to see how some of these principles can be applied.

Ethical Issues with Large Databases: Informed Consent and Confidentiality.

A difficult issue when conducting research on large databases, including hospital data bases of Electronic Health Records or Electronic Medical Records (EHRs or EMRs), is how to obtain informed consent for the use of patient data.

One way of obtaining informed consent for use in research is to obtain “broad informed consent”⁴⁴ at the time that the information is gathered. This is an idea borrowed from the study of large biological samples, and is regarded as the most practical and economically viable approach for researchers. A variation is to grant consent for the database to be used for specific types of research only.

Some databases may be small (such as from a clinic or hospital) while others may be large (a national database), and several countries are grappling with problems of informed consent for researchers while protecting patients from abuse.^{45,46} In one instance, Iceland created a national database with “presumed consent,” but allowed individuals to opt out of the program, thereby removing their information from the database. This solution is not always simple, and the legal relationship between presumed and informed consent, especially around issues of identifiable genetic material, continues today.^{46,47}

Any approach will be influenced by the national culture, so will differ from country to country, and may also differ depending on the nature and purpose of the database.⁴⁵ Because obtaining general or presumed consent could be open to abuse, it is extremely important that the researcher ensures that the research does not conflict with other areas of ethics, such as exposing the patients to stress or exposing any identifying information.^{44,48}

One should also guard against corporate ownership of such databases, as these organisations may work to different ethical guidelines, and there may be conflicts of interest

in the research and research outcomes. Where such ownership cannot be avoided, then researchers should not be unethically influenced in their work.⁴⁹

As addressed in the chapter on Privacy, Health Care Workers in the US need to be aware of the HIPAA Privacy Rule,⁵⁰ as this applies to all doctors who transmit any patient data electronically.

Research on electronic postings: privacy and disclosure. The Internet is full of information simply waiting to be analysed. One area that has received attention has been online environments in which users create postings in conversations. These might be in discussion lists (sometimes called “listservs”), forums, bulletin boards, and social media or social networking sites, such as Facebook and Twitter.

In many of these sites, medical information, sometimes very personal, is exchanged. Even in sites where personal information is not exchanged, the context may be a medically-oriented site. The prime ethical questions for the researcher researching these sites revolve around informed consent and the privacy of the information that is shared on these sites. In short, the question is this: are these electronic postings to be treated with the same level of confidence and anonymity that one would apply to patients in a self-help group?

Resolving the issue depends on whether the ‘human-subject’ model or the ‘textual’ model is applied. These are explained further below.

- The human subject model. Briefly, the human subject model is an extension of the medical view of patient information, and it views the electronic postings as reflective of real people, and so all the ethical rules regarding informed consent, privacy, and ensuring that there is no psychological or physical harm to participants must apply.^{51,52} This means that, before quoting from or referring to a site, the researcher must obtain informed consent.

- The textual object model. An opposing view is that a posting in a bulletin board is merely a piece of text, and is subject only to the laws and ethics that govern any piece of text. These might include rules regarding plagiarism and copyright, but do not involve anything to do with a human patient. The text has been placed into a publicly-accessible area (the Internet) and any expectation of privacy and confidentiality is unwarranted. As Walther argues, this is much like a conversation in a park, and that “people do not expect to be recorded or observed although they understand that the potential to do so exists.”⁵³

If the person has not posted personally identifiable information, then there is even less concern regarding privacy; after all, the only problem that might exist is that the person can be identified. For example, in the USA, a “Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information.”⁵⁴

If people are concerned about identity, however, they can create pseudonyms and usernames that make it difficult to identify them. One may argue that, if they have not taken such precautions, then they are willing to have themselves publicly identified.

Finally, the textual object model is supported by much 20-century literary theory^{55,56} which clearly separates any discussion of text from the discussion of the author or even the author’s intention.^{57,58}

Problems with the textual object model.

There are several problems with applying the textual model to medical research, and some of these are:

- The arguments are frequently based on traditions from other fields (e.g. sociology,

or literary theory). When working in a medically-related field (specifically, health informatics), so one should give greater credence to ethical rules in that field of study.

- Although a specific posting may not contain information that can identify a person, when many of these postings are combined, it may be easy to form a picture that can be used to identify the person. There is a strong tradition in medicine that, even when objects are researched, they are not specifically identified.
- Based on the many examples above, laws should not be taken as a standard of ethics. At best, they may set a *minimum*, from which the ethical HIP works.

The difficulties and disadvantages of applying the human subject model to electronic postings.

Having said this, the researcher must be aware that there are difficulties with applying the human subject model when performing research on electronic postings. This sub-section identifies some of these, and suggests solutions.

- Establishing informed consent can be difficult, if not impossible. With a group of several thousand, where people join and leave continually, how does one establish informed consent?
- One approach is to attempt to determine whether these are necessary. This depends largely upon the rules of registration and public access to the list.^{54,59-61} If the list is very tightly controlled, where members have to be a member of a particular organisation, are have to supply corroborating evidence of their identity, then the researcher is advised to obtain full informed consent. If, however, the list is large, registration requires only an arbitrary user name and password (and, perhaps an email address), and the site is searched and indexed by general search engines, then informed consent is less important.

- How does one preserve privacy and anonymity? Again, one can be guided by the amount of privacy that is assumed in the group. In addition, however, unless informed consent from individuals has been obtained, the researcher should avoid referring to specific postings or individuals. The researcher should even avoid anonymous quoting, as this can be used through a search engine to identify the original piece of text. Rather, the research should use aggregated data (i.e. totals, means, etc.) to give an overall impression.
- Finally, if the researcher wishes, s/he may wish to disguise the site. This is discussed in more detail below.

Transferring Ethical Responsibility

A tempting route to reducing the researchers' ethical responsibilities would be to transfer the responsibility for ethical behaviour to others, allowing the researchers to concentrate on the task at hand: the research. This might be done in three ways:

- As long as the researchers are obeying the law, they are safe from prosecution, as the laws of the State are there as a guide.
- If the researchers work at an institution that has an Ethics Committee or an Institutional Review Board (IRB), then they submit a protocol that describes the research beforehand, and then receive ethics approval for the research. The researchers may feel that they are now 'covered' and so can do whatever they like, as long as they stick to the protocol.
- Keeping data secure is a complex technical process, so one should simply have a database manager who takes full responsibility for the data. If the data are then mistakenly made public, it is the database manager who has to deal with the problem.

Researcher's Responsibility for Data Security

In July 2009, The University of North Carolina at Chapel Hill discovered that a computer had been hacked as far back as 2007. The data from the Carolina Mammography Registry containing some 180,000 mammography records (including 114,000 social security numbers) had been potentially exposed.⁶³

One of the prime concerns was of responsibility and culpability.

- The chief researcher, Professor Bonnie C. Yankaskas argued that the university IT security staff were responsible for the security of the file server.
- The university argued that the chief researcher was to blame.

Initially, Prof. Yankaskas was demoted and had her salary reduced. After a legal fight costing Prof. Yankaskas some \$350,000, her position and salary were restored, but she was forced to retire, effective at the end of 2011.⁶⁴

These, however, are not effective solutions:

- Handing this responsibility over to the law or State is not an acceptable solution as highlighted in the Nuremberg Trials, since laws do not establish ethics.
- Because of the newness of the field of health informatics, IRBs may not have representatives that are fully aware of the ethical issues and technical applications (e.g. that simply searching on a quotation from a forum allows one to find that forum immediately), or the extent to which informed consent is required.
- Ultimately, HIPs are responsible for their data. Technical staff may be responsible for the storage systems, but the overall responsibility for the material cannot be transferred to anyone else. In cases where data breaches have occurred, all parties (including the institution) may face legal prosecution, as was the case in which a clinic's data regarding HIV patients was compromised because of peer-to-peer file sharing software on their computers.⁶²

Electronic Communication with Patients and Caregivers

All medical students know that it is relatively easy to find most people's email addresses. In

the case of a practising doctor, the name, work address and telephone number will already be known to patients. Using that information, finding the email address is a small step. Because of the convenience of email communication (to both the doctor and patients), patients will wish to email the doctor on a range of topics. One of the most important benefits is that instructions given be clearly laid out, and can be referred to later by the patient; this greatly reduces the risks to the patient.

There are, however, ethical issues that need to be considered when medical personnel interact online with patients. Two guides that have already been mentioned, the AMA's *Guidelines for Physician-Patient Electronic Communications*⁴⁰ and the *Guide to Australian electronic communication in health care*⁴¹ have useful information for the practising doctor. In addition, the AMA has another guide that refers to email communication.⁶⁵

The AMA's guide begins by explaining the value of email communication, and then gives useful advice about setting up the communication channels and some medico-legal issues. This includes things like making the patient aware of who is reading the email, the types of email topics that are acceptable, use of language, and tips for the patients to ensure they can quickly reference the relevant emails. In addition, the guide advises that the physician should not use email communication with new or prospective

clients with whom no personal contact has yet been established, should maintain the same ethical standards that apply to other areas of medicine, should ensure that permission has been obtained for email communication, and should ensure that the email has a disclaimer dealing with breaches of security and privacy, identity of corresponding parties and possible delays in responses.

Practical Steps

Measures to Ensure Consent Forms and Other Documents Are Understood

This chapter has discussed informed consent at length, and research usually has to be accompanied by a consent form that is signed by the research participant. But what is the certainty that the participant has actually understood the contents of the consent form and other documents (e.g. survey forms)? In face-to-face research, the researcher can pose questions to ensure that the information has been understood; in online research this is not always possible. (Even in face-to-face research, the use of questions can be embarrassing to the research subject, and time-consuming.) A useful approach is to reduce the complexity level of the language so that the person can understand the form.

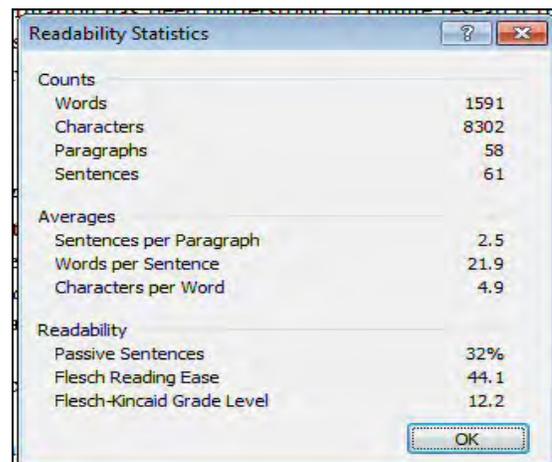
For English, there are several tests used to determine the complexity of language in a text, although the most popular are the *Flesch Reading Ease Test*, and the *Flesch-Kincaid Test*. Readers can find out more about these tests, but, essentially, the tests check various characteristics of a document, such as the average number of words in a sentence and the number of syllables in each word. The *Flesch Reading Ease Test* assigns a value of 1 – 100 (where 1 is most difficult, and 100 is easy), and the *Flesch-Kincaid Test* assigns a number that corresponds to the US school grade. This means that a document with a Flesch-Kincaid Test score of 8 could be understood by an 8th-grader, while a score of 14 would be at university level.

There are several computer applications that can perform the test. If Microsoft Office is used, the test can be implemented in MS-Word, by making the following changes to the settings:

- MS-Word 2007:
 - Click on the **Office Button**
 - Select **Word Options**
 - Select **Proofing | When correcting spelling and grammar in Word**
 - Select **Show readability statistics**
- MS-Word 2010:
 - Click on **File**
 - Select **Options**
 - Select **Proofing | When correcting spelling and grammar in Word**
 - Select **Show readability statistics**

From now on, when a spelling and grammar check is run, the final dialog box will display the readability scores, such as the example in Figure 9.5:

Figure 9.5: Readability statistics from a document in MS-Word 2007



In addition to the percentage of passive sentences, the dialog box will also give the Flesch-Reading Ease and the Flesch Kincaid Grade scores. These statistics can be used to modify documents, and the tests re-run until the results are satisfactory.

Note that it is easy to ‘trick’ the tests. The aim is not to trick the tests, but rather to use the results of the test as a guide for your own research. For instance, if the document referred to in Figure 9.5 were a document for university students, it would probably be suitable. If it were a consent form to be given to children, it would probably require extensive revision.

Simple Data Protection

Security breaches at medical facilities occur on an almost daily basis.⁶⁶ While network administrators will probably implement several strategies to assist with security, users can also do their part. This is particularly important if one is using a computer in a shared location (such as at home) or using a laptop, which has a high risk of being stolen.

- Several encryption programs allow entire disk partitions and/or folders of files to be encrypted. A free encryption tool is *TrueCrypt* (available from <http://www.truecrypt.org/>). Combined with this is the practice of encrypting folders and files that contain nothing of value at all, designed to act as red herrings to lure would-be snoopers away from the real material, and waste their time. One should be aware that users may be legally compelled to reveal their encryption passwords.⁶⁷
- Passwords and document encryption: most operating systems allow users to password-protect their computer. In addition, most word processing, spread sheet and database programs have in-built password and/or encryption protection.
- A computer anti-virus program should be used and kept up to date. There are several good, free anti-virus programs, such as *AVG Free* (available from http://free.avg.com/ww-en/home_page).
- Anti-spyware and malware software should also be installed on every computer. A good, free anti-spyware program is *SUPERAntiSpyware Free Edition* (available

from <http://www.superantispyware.com/>). Malwarebytes Anti Malware (free, available from <http://www.malwarebytes.org/>) is good anti-malware software.

- Before the computer is discarded or given away, ensure that all data are properly removed. Normal deletions, and removal from the Trash are not good enough, as these files can easily be restored. Users may wish to use several methods in combination, including defragmentation, formatting, and using a free tool like Eraser (<http://eraser.heidi.ie/>).
- Finally, one might wish to use virtual private networks (VPNs) or any of the mail services that offer protected email, or a plugin, such as *Mailvelope* (free), which uses encryption for email. These solutions, however, are sometimes costly or technically difficult, and also offer no guarantee, especially in light of recent revelations regarding encryption cracking.⁶⁸ If used, they should be seen as an extra layer of security only.

Professionalism in Social Networking sites

The general atmosphere of social networking sites like Facebook and Twitter is one of friendliness, community, joviality. Indeed, the very structure of a social network relies on the free flow of information.⁶⁹

Health professionals, however, need to be aware that they have a professional presence, and that needs to be maintained. They should not be lulled in a false sense of security when social networks promise secure areas and privacy settings, as these secure areas are less secure than one might believe, privacy settings can change at a whim, and the end-user agreement usually allows the social network free access to the material. Research indicates that young medical professionals are not applying privacy restrictions or ensuring that potentially damaging personal information is not posted.⁷⁰ Material posted, even when “deleted,” is both persistent and searchable. It is important to understand that information is currency and

content; if it were entirely private, the social network would cease to exist.

In addition, social networks are not homogeneous, and what is considered acceptable in one network is not necessarily so in another. Even within networks, differences appear. For example, an acceptable posting in one area (subreddit) of Reddit might be unacceptable in another.

When using social media sites, these rules will help to guide users:

- If the decision is made to use social networking sites for personal information, be aware that patients will be able to see this, and may react inappropriately. Physicians may choose to use these sites exclusively for professional purposes, as is frequently recommended, but even this route has difficulties.^{71,72}
- Health professionals may deal with patients at their most vulnerable. Online descriptions and photographs of such situations should not be posted into social networking site, as was done by a Portland nursing assistant.^{73,74} It is important to remember that such postings are generally not protected by free-speech laws.⁷⁵
- If any videos are produced for Youtube or similar sites, ensure that all copyright rules are followed. Also insert subtitles (so that hard-of-hearing persons can access them), either by using Youtube's *Caption* feature, or software like *Jubler* (free) and *Avidemux* (free) to add sub-titles.
- Assume that all the rules of patient and research subject confidentiality apply, and be aware of other laws such as those concerning libel and copyright. This will apply even if one re-tweets somebody else's tweet. See Scanion 2012⁷⁶ for some of the general legal risks of using Twitter in the UK. Other countries will have similar laws.
- There have been several documented cases of employers requiring staff to reveal their Facebook and other passwords. One needs to be aware of the ethical obligations and the

relevant laws in your country regarding the response to such demands.

Removal of identifying material from electronic files and databases

While electronic files are invaluable for medical and health research, great care should be taken to remove identifiable information from these files and databases. This is always important, but even more so when working with conditions (such as HIV/AIDS or psychiatric conditions) that have social stigmas.⁴⁸ There are steps to be taken to anonymize data. Unfortunately, the anonymization process is not fool-proof, and the processes of "de-anonymizing" by combining various snippets of information from different databases are also sophisticated.^{13,77-80}

Some information (e.g. a patient's face, sound of voice), might be obvious to remove, but others might be less so. There have been multiple instances where doctors have removed information, only to find that lack of technical expertise or experience has left traces of identifiable information in the files.⁸¹ There are several steps that can be taken to reduce the risk of patients' and research subjects' being identified, using free or inexpensive software. These include:

- Using *Paint.Net* (free) to remove or blur out parts of images.
- Blurring parts of a video frame can be more complex, but *Avidemux* (free) can blur whole frames.
- Using *Audacity* (free) to disguise the sounds of voices, and remove non-medical information that may identify a patient.
- Using *Easy Exif Delete* (free) to remove exif metadata (e.g. author, longitude and latitude) that is automatically embedded in .jpg photograph files).
- Ensuring filenames are anonymous. Researchers usually take care to ensure that the patient cannot be identified; for easy classification, however, file names often contain patients' names, and these should also be anonymized.

Limiting collection of visitor data to your website

If an individual or organisation has a website, it is useful to gather information about your visitors. This can be accomplished either by creating your own tracking cookies, or by using some of the many third-party tracking tools. This can be done to collect a wide range of visitor data, usually without consent or even notification, and easily distribute the data to third-party vendors who are not held accountable.

Although this is widely practised, even by well-respected world medical organisations,⁸² it violates several laws and ethics' principles. If visitor information is gathered, one needs to obtain the visitors' consent, ensure that only exactly what is needed is gathered, and stipulate clearly:

- What information will be gathered
- How it will be stored and secured
- With whom it will be shared
- For how long it will be kept until being destroyed.

If the website is being run by a third party, one should ensure that these requirements are all met. This can be tested using a free Firefox plugin like *Ghostery*, to analyse the various data collection systems that are running on the web site

Disguising of web sites or bulletin boards researched.

Unfortunately, no matter how much one tries to protect research subjects, there will be some people who will attempt to discover their true identity.^{52,57} This may be because they view it as their right, or do not work to the same ethical model, or who simply see it as a detective game to be played. In medical research, there is a tradition of intentionally changing information in order to prevent people using it to identify the subjects. For example, one may change people's names, cities or even experiences and medical conditions, as long as it does not directly

impact on the nature of the research. This is considered "heavy disguise,"⁵⁷ and is also employed by some researchers who research web sites.⁸³⁻⁸⁵

If research is being performed on bulletin boards in a web site, and there is a wish to disguise the research web site so that it has little chance of being discovered, one may wish to create a dummy web site (or "Maryut site"⁵²) that is specifically designed to lure investigators away from the real site. The ethics of making Maryut sites, in the interests of safe-guarding the non-disclosure, may be a point of discussion by IRBs and ethics' committees. A danger with this method is that the Maryut site may inadvertently point the detectives to a valid secondary site that has nothing at all to do with the research.

Ensure IRBs, Ethics Committees and other administrative structures are aware of health informatics ethics issues.

This chapter has already referred to the fact that representatives on IRBs may not be familiar with ethical issues in health informatics. It is the responsibility of researchers and other HIPs to inform their IRBs of the health informatics ethics issues. This will allow the IRB to better understand the preventative actions taken by HIPs, and also to understand the motivations behind such actions.

This information-sharing can take the form of workshops and reports, supported by practical implementation when applying for research and grant approval.

Health Informatics Ethics and the Medical Student

The final portion of this chapter deals with medical students. Medical students are already health professionals, simply at the early stages of their careers. Medical students are usually bound by the rules of their national medical professional organisations; in the same way, they should feel bound by the ethical rules of health informatics.

Online Behaviour in Social Networking and Other Interactive Sites

As health professionals, students need to remember that everything they post online may stay online for a long time – even if it is deleted, it may be stored in electronic archives. With this in mind, students should be extremely careful about online comments and photographs of themselves, colleagues and patients. (This applies to all students, not only medical students).⁸⁶

A survey amongst US medical schools recently found that as many as 60% reported incidents in which students had posted inappropriate material online. Students were usually given warnings, but, in some cases, were dismissed.⁸⁷ Figure 9.6 is a Twitter post by a student who received a poor mark on an app project, and reacted by threatening the lecturer with death. (The Arabic reads: “[Lecturer’s Name], We worked on that App for more than 2 hours and the final result is like that!”). A posting like this might have dire consequences.

Figure 9.6: Student tweet threatening a lecturer for a poor project grade. (Source: Twitter.)



There is something of a tradition of medical students’ posing with their cadavers, sometimes merely as illustrations for teaching, but very often for other purposes, such as humour.⁸⁸ Times have changed, however, and the posting of such photographs on to the Internet is generally not accepted by medical schools.⁸⁹ (see Figures 9.7 and 9.8)

Figure 9.7: Dissecting Room, Jefferson Medical College, Philadelphia. (Source: US Library of Congress)



Figure 9.8: Students and teachers of Civil Medical School, Constantinople. (Source: US Library of Congress)



Other student activities

Use of mobile devices with cameras.

While performing clinical studies, and in the presence of patients, one may wish to look up medical information on the mobile device. Although users are simply using the reference software, be aware that patients may have concerns of privacy if seeing a device with a camera being used. When using such devices, ensure that the camera faces away from any patients; if possible, stand at an angle that would allow them to see the device screen. If there is

any doubt, let the patient know that a general disease database is being accessed.

Research projects. Students may be involved in several research projects. Some of these may be small projects performed by one or more students (e.g. surveys of fellow students), or they may be parts of larger projects set by other researchers. In all cases, it is important to remember that one is bound by the same ethical rules that are raised in this chapter. In cases of doubt, speak to the staff, one's supervisor, or members of the Ethics Committee or IRB.

Plagiarism. Similarly, professional conduct extends to plagiarism. Although plagiarism is not specific to health informatics, because of the ease with which information can be copied-and-pasted, there is a temptation to plagiarise others' material. At most institutions, students found guilty of plagiarism may be expelled from their institutions.

Use of Paper Mills. It may be tempting to make use of "Paper Mills." Paper Mills are web sites that allow students to submit assignment details, and somebody else will write the assignment (for a fee). Again, however, if students are caught, they are usually expelled immediately.

Manipulation of electronic files. Electronic files (whether text, audio, video, or still graphics) are easy to manipulate. There are many acceptable reasons for doing so (see above). When performing such manipulation, one must ensure that copyright or other laws are not broken. In addition, one must ensure that the finished product does not present false information.

Recording of lectures and other class activities. It may be tempting to video- or audio-record classes or lectures. This may be useful for students, so that they can watch and/or listen to the lectures afterwards. Before doing this, one must ensure that the lecturer's consent is obtained. In most cases, the permission from fellow students will be needed. As a guide, refer to the discussion on informed consent above.

Using pirated, 'cracked' or other illegal digital files. In most countries, the use of pirated, 'cracked' software or other digital files (e.g. downloaded from 'torrent' sites) is illegal. Being caught performing such operations or with such software will usually lead to prosecution and expulsion. Frequently, such software is also a back-door for viruses and other unwanted software.

Accessing documents illegally. Frequently, while performing research, one will find an abstract to an article, and will wish to read that article. Unfortunately, a great deal of information is available in books or journals that charge subscription fees (i.e. the requestor has to pay to access the journal or individual articles or books). In most cases, an university library will already have paid a fee, and will be able to grant legal access to these resources. In some instances, however, they have not, and so requestors do not have legal access to the resource.

Because students (and qualified doctors) want access to these resources, they are tempted to use sites that share such articles.^{90,91} Alternately, they use websites that share usernames and passwords to library databases.⁹² The justification for doing so is that, ultimately, patients will benefit from the knowledge that the health professional has gained. Unfortunately, this practice is usually both illegal and unethical.

There are other, both legal and ethical, methods that one may wish to try. These include:

- Searching for the resource in a legitimate site. Frequently, publishers allow authors to place copies of their articles on their own web sites, and in publicly-accessible repositories. These can be searched and the articles freely downloaded.
- Contacting the authors. Authors are usually permitted to send copies of their articles to a limited number of people who request them. Students can contact the author and make such a request. (The author's contact details will usually be visible on the same page that showed the abstract).

Future Trends

Because health informatics ethics relies on practices from diverse and continually-evolving fields, it is difficult to make predictions about future trends. That said, however, based on the recent history, there are a few likely scenarios:

- Because medicine and informatics are diverse fields, balancing the ethical practices of health informatics will always be difficult for the HIP. The various codes of ethics will be continually updated to take technological developments into account, but will always lag some way behind these developments.
- Digitised medical data will play an increasingly important role as a commodity in patients' lives.
- Because of these changes and the continual emergences of new technologies, HIPs (including students) will be faced with new ethical challenges. They will need to use the basic principles as guides, and their consciences where the principles do not take these developments into account.
- The tension between ethics, culture and law will not become easier in the short term.
- Health informatics ethics is likely to emerge as a field of study by itself.

Key Points

- Health informatics ethics stems from medical ethics and informatics ethics, and combines principles from both fields.
- The IMIA Code of Ethics for Health Information Professionals contains guidelines in a range of categories, namely: fundamental ethics principles, general principles, subject-centred duties, and duties towards HIPs, institutions/employees, society, the profession and oneself.
- The relationship between ethics, law, culture and society is extremely complex and fluid, and varies internationally and chronologically. The HIP must become acquainted with the issues that have a direct bearing on his or her practices.
- The most pertinent ethical principles in health informatics ethics relate to: right to privacy, guarding against excess, security and integrity of data, informed consent, data sharing, wider responsibilities, beneficence and non-maleficence and non-transferability of responsibility. All these must be seen within the legal and medical ethics context.
- There are several examples of the application of the principles to research and other situations. These applications can be used as a guide for the HIP, beginning with the HIP as a student.

Conclusion

At Nuremberg, a total of 23 defendants (of whom 20 were medical doctors) were tried for medically-related crimes. Seven were acquitted of all charges. Of the 16 found guilty, seven were sentenced to death. These seven, including Dr. Karl Brandt, were executed on 2nd June 1948.

From one of the darkest periods of medical history, codes of ethics evolved. From these codes and codes in informatics ethics, health informatics ethics codes have further evolved. Although these codes have varying degrees of effectiveness, they do provide essential principles for the medical student and health informatics professional who will work with electronic data. It is essential that these principles are understood and applied as conscientiously as possible.

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Chapter 10

Consumer Health Informatics

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Learning Objectives

After reading this chapter the reader should be able to:

- Identify the origin of consumer health informatics
- Identify and discuss consumer health informatics (CHI) tools
- Discuss the features and formats of personal health records
- Identify electronic tools for patient to physician communication
- Outline barriers to CHI adoption
- Discuss the future of consumer health informatics

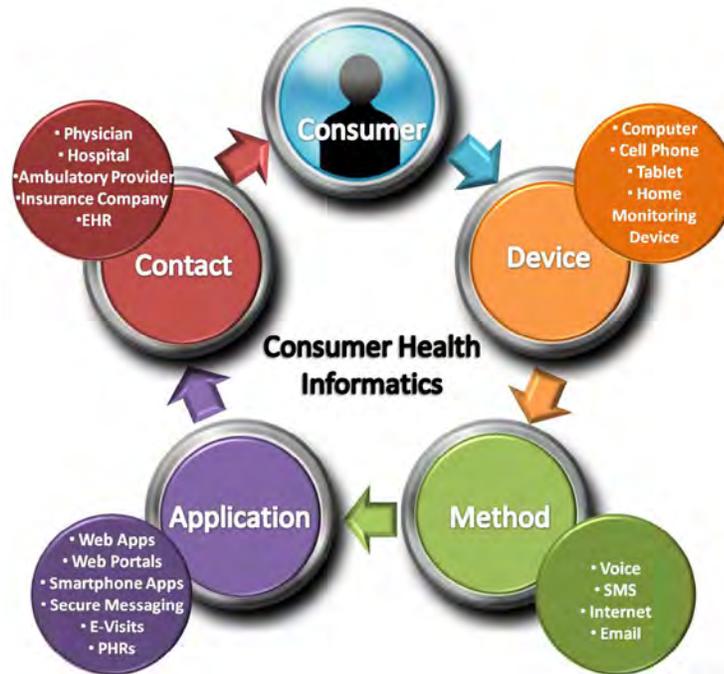
Introduction

Considerable interest is emerging concerning the potential of information and communications technologies that are tailored to consumers and used within the context of managing health or healthcare issues. This emerging focus has been referred to as consumer health informatics (CHI). The federal government is fully supportive of CHI as demonstrated by the Federal Health IT Strategic Plan 2011-2015 goal to “[e]mpower individuals with health IT to improve their health and the health care system.”¹ Also, several Meaningful Use objectives address health information technology’s (HIT) impact on patients, addressed later in the chapter.

It should become obvious after reading that these topics are interrelated and not separate. In addition, many of these features may be integrated with electronic health records and health information organizations. Figure 10.1 displays multiple interrelationships extant in consumer health informatics.

This chapter discusses several consumer health informatics topics: patient health information applications, home telemedicine devices, patient portals, personal health records, electronic patient - physician communication and social media. The chapter will first begin with a discussion of the origins and current state of consumer health informatics.

Figure 10.1 Consumer health informatics interrelationships



The Origins of Current State of Consumer Health Informatics

Several factors including the widespread availability of the internet, the spread in home broadband adoption and the growth of wireless/mobile internet access have contributed to the growth and interest in consumer health informatics. On October 13, 1994, the internet became available, for the first time, to thousands of individuals.² Seventeen years later, the internet has reached into just about every facet of life.² In the early days just 15% of individuals were using the internet and they were doing so primarily via Bulletin Board Services or proprietary businesses like CompuServe and Prodigy.

Today, internet use continues to soar with 85% of Americans over the age of 18 being internet users.³ This includes approximately 98% of individuals between the age of 18 and 30, more

than 8 in 10 (83%) of individuals over the age of 50 and more than half (56%) of all seniors over

the age of 65.³ It also includes 93% of teens aged 12-13 and 96% of teens aged 14-17.⁴⁻⁵ Among adult internet users, 72% of internet users say they looked online for health information within the past year³ and now more U.S. adults are using the Internet than doctors to obtain health and medical information.⁶ In addition, 70% of U.S. adults report getting information, care, or support from a doctor or other health care professional while 60% of adults report getting information or support from friends and family and 24% of adults report getting information or support from others who have the same health condition. Finally 35% of U.S. adults have gone online specifically to try and figure out a medical condition. Fifty percent of these then followed up with a visit to a medical professional.³

While more Americans are using digital health content, it appears that digital health content has considerably more influence over consumer

health decisions and actions than traditional channels like print, TV and radio. Although the role of consumer oriented online health information has soared over the past decade, healthcare professionals still appear to have the strongest effect on consumer health behavior.⁷

Collectively, these data strongly suggest that although doctors remain an essential part of an individual's health management, consumers are increasingly comfortable using the Internet as a research tool for condition and treatment information and as a first line of defense to help them manage their health concerns.

Several national and societal trends have also contributed to the growth of the field of Consumer Health Informatics. For example, the predominant diseases that afflict our society today are chronic diseases like cancer, cardiovascular disease and diabetes mellitus. Today chronic diseases are among the most common health problems in the U.S. In 2005, almost 50% of adults (133 million) had at least one chronic illness.⁸ These diseases often afflict individuals for 20 or more years. This is drastically different from those acute infectious diseases that were prevalent when our healthcare system was being formed, yet our healthcare system is still largely oriented to treat acute episodic illnesses rather than ongoing chronic ailments.

Another national trend contributing to the growth of interest in consumer health technologies is the significant demographic changes occurring in our society itself. Soon, in the US, approximately 30% of the population (70+ million) will be over the age of 65 and 20% will be over the age of 85.⁹ This presents challenges to our healthcare system, because in addition to being at much higher risk for having a chronic disease, seniors often have from two to five concurrent chronic illnesses.¹⁰ As such, seniors have more complex chronic disease related needs and they also have these needs for many more years than those living generations ago.

A third factor contributing to the growth of Consumer Health Technology was the passage of

the Patient Protection and Affordable Care Act (ACA) in 2010. While the law remains controversial to many, through taking advantage of opportunities provided by the law to innovate within the health care industry it will be possible to move closer to the goal of making health care more affordable and more accessible to all people. Upon close examination of the law, several components including the Individual Mandate, the Employer Mandate, Accountable Care Organizations (ACOs), Wellness Programs and the CMS Innovation Center provide significant opportunity for consumer health innovation.¹¹

For example, the Individual Mandate, requires all Americans to maintain health insurance. As such, it will bring a large population of currently uninsured individuals into the healthcare system and likely increase demand on an already-burdened system. There will then be great need for new care delivery models that leverage both technology and less-credentialed practitioners to deliver care for more routine health concerns.¹¹

The Employer Mandate, requires all employers with 50 or more full-time-equivalent employees to offer health insurance benefits and increases the financial requirements on employers to provide health care coverage for their employees. Inevitably, in order to control costs and preserve quality employers will seek alternate models of health information, support, healthcare delivery and even insurance. This could facilitate a substantial disaggregation in the insurance industry and open opportunities for new and disruptive direct-to-employee technology based health supports shown to be effective.¹¹

Finally, the ACA's provisions that support the development of Wellness Programs require health plans to offer wellness-focused components targeting preventive and self-directed care. Innovative companies are working to create technology based products and/or services that improve patient wellness and could significantly impact the current healthcare delivery system if these products prove effective and are disseminated widely.¹¹

Healthcare then, in the context of these realities, is undergoing substantial change. First, unlike years gone by, most of the care and support for health concerns provided to patients with chronic diseases is provided by family and community caregivers. This is largely because over the course of a lifespan, most individual spend relatively little time in a hospital, clinic, ER or doctor's office. Within this context, as our healthcare system struggles to find ways to enhance access to care while reducing costs and as patients and caregivers seek for needed health information and support, particularly in the time periods between hospitalizations and doctor visits, interest in the potential of consumer health technologies has continued to grow significantly.

It is on this backdrop of national trends and improvements in healthcare quality and access that the term *e-Health* was born. First used by industry leaders and marketing executives in 1999, it was an attempt to convey the promises, principles and excitement around the application of e-commerce (electronic commerce) to the health arena. The earliest definition indicated that "e-health represents the intersection of medical informatics, public health and business and referrers to health services and information delivered or enhanced through the internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology."¹² This definition clearly suggested that the emergence of the internet and related electronic technologies presented new opportunities for healthcare to enable (1) consumers to interact directly with the healthcare system online; (2) improved possibilities for institution-to-institution transmissions of data; and (3) new possibilities for peer-to-peer communication among patients, caregivers and consumers.¹² Soon thereafter the term *consumer health informatics* emerged to distinguish the explicit and primary incorporation of the needs and perspectives of

the patient in emerging electronic tools from those of healthcare providers in the development of emerging "medical tools." The field was originally defined in 2001 by Eysenbach as a branch of medical informatics that "analyzes consumers' needs for information, studies and implements methods of making information accessible to consumers, and models and integrates consumers' preferences into medical information systems."¹³ Since that time however the field and the definition itself has undergone significant evolution. In 2001, Houston et al. wrote that CHI incorporated a broad range of topics, the most common being patient decision support and patient access to their own health information.¹⁴ Currently, the Agency for Healthcare Research and Quality defines consumer health informatics applications as "any electronic tool, technology or electronic application that is designed to interact directly with consumers, with or without the presence of a healthcare professional that provides or uses individualized (personal) information and provides the consumer with individualized assistance to help the patient better manage their health or health care."¹⁵

The federal government has been very supportive of consumer health movement as evidenced by the Meaningful Use goals of "engaging patients and families" and "empowering individuals."¹⁶ For example, in Stage 1 (1) clinicians must provide electronic copies of health information (2) clinical summaries of office visits (3) timely access to electronic health information (4) patient education (5) patient summaries for transitions of care. ¹⁶ This active involvement of patients/consumers with their electronic health information makes them more active participants with technologies such as electronic health records and patient portals.

Classification of Consumer Health Informatics Applications

Many consumer health informatics tools have been developed over the last decade. To date the

total number of individual mobile apps in the marketplace has surpassed one million and approximately 15,000 apps become available each week.¹⁷ As of June 2013 there were 43,689 health apps available in the iTunes Apple store alone.¹⁸

Consumer health informatics tools can be classified in several different ways. For example at least 6 basic categories of Consumer Health Informatics tools can be defined. These include mobile Apps or consumer health applications designed for mobile devices, Health information oriented websites, interactive health games, sensor based tracking systems, health oriented social media and virtual reality programs. Within each of these categories hundreds and in some cases thousands of products are available for use by patients and consumers. A comprehensive and exhaustive review of all types of consumer health informatics products is beyond the scope of this chapter. However several illustrative examples will be discussed in more detail.

A recent review of the over 40,000 health apps available on iTunes defined a mobile application (or mobile app) as a software application designed to run on smartphones, tablet computers and other mobile devices and are usually available through application distribution platforms, operated by the owner of the mobile operating system. However, not all health apps are widely available to consumers. Some medical apps not designed to target general consumers. Some apps have been designed for healthcare practitioners, others are for patients but require a prescription, and others are intended for only a small subset of the population and hence are not added to the general app stores. This chapter will focus only on the healthcare apps that are widely available to the general public and designed to aid in the consumer's everyday health and healthcare management needs.¹⁸

Approximately 20,000 of the 43,689 apps in iTunes can be considered only loosely or minimally associated with health. The remaining apps 23,682 are genuinely related to health. Of these, 7407 were designed for use by

a health care professional and 16,275 designed for use by patients and consumers. An analysis of these consumer health apps reveals that they can be categorized into 1) Apps that Inform or provide information in a variety of formats (text, photo, video) 2) Apps that Instruct or provide instructions to the user 3) Apps that Record or capture user entered data 4) Apps that Display or Graphically display user entered data/output user entered data 5) Apps that Guide or provide guidance based on user entered information, and may further offer a diagnosis, or recommend a consultation with a physician/a course of treatment 6) Apps that Remind/Alert or provide reminders to the user 7) Apps that Communicate or provide communication with healthcare professionals, patients and/or provide links to social networks.¹⁸

Approximately two thirds of apps (10,840) provide simple information. Just under six thousand (5,823) provide instructions, 5,095 capture data entered by the user and 1,357 apps have a remind/alert function built into them. Approximately 10% of apps (1,622) have none of these capabilities at all, but help with things like relaxation and sleep. In addition there are 159 apps which link to sensors. These are predominately fitness and weight apps which monitor pulse rates when exercising and measure weight and body mass index (BMI). Fewer than 50 of these 159 apps relate to actual condition management or provide tools and calculators for users to measure their vitals.¹⁸

When viewed from the perspective of potential health and care activities in which patients and consumers are engaging 8786 app assist with Prevention/Healthy Lifestyles, 304 assist with Self-diagnosis or Symptom checking, 931 provide help with finding a provider or facility, provides doctor reviews, referrals and second opinions. Another 562 aid with diagnosis or provide education, medical information, condition management information or post-diagnosis emotional support. Two hundred apps assist with filling prescriptions, finding a pharmacy, or insurance coverage and finally another 225 apps assist with compliance.¹⁸

As can be seen from the discussion above some mobile apps enable the remote monitoring of vitals that can be communicated back to healthcare providers. This offers the potential to enhance the value of healthcare by taking advantage of this patient reported data and embedding it into the clinical care plan. As such, consumer health apps have the potential to reduce the frequency and cost of direct interventions by healthcare professionals because monitoring of vitals can be done remotely, and communication with healthcare professionals can be done without the patient having to physically meet with them.¹⁸

Health Education & Information Applications

As addressed earlier, two-thirds of adults use health related web sites as their premier resource for health information. One reason for this is that patients are becoming more discriminating in their choices of all aspects of healthcare. No longer do they automatically accept the opinion of their physicians. Or, in some cases they look on line for answers they were too timid to ask their physician or forgot to ask. In a Harris poll it was shown that 57% of patients discussed their internet search with their physician and 52% searched the internet after talking to their physician. Eighty-nine percent (89%) felt their search was successful demonstrating confidence in the internet as the new health library.¹⁹ Excellent medical web sites exist but searches can yield low quality answers, particularly when personal web sites are searched. As an example, in one study of internet searches for the treatment of childhood diarrhea, 20% of results failed to match guidelines published by the American Academy of Pediatrics.²⁰

Patient Education/Health Information Web Sites

The following are only a sample of the many

valuable patient education web sites available today.

WebMD. With more than 30 million people visiting this site monthly, it should be considered one of the true standard bearers. They have an extensive health library with top topics listed for men, women and children. Treatment and drug information is available, as is medical news. A symptom checker tool provides a patient with a simple differential diagnosis based on their symptoms, age and gender. A daily e-mail newsletter is offered that can be customized to a patient's concerns. The only negative about this site is the commercial influence of advertisements.
<http://www.webmd.com/>

Everyday Health. This free web site offers disease information, forums, health calculators, a physician finder and symptom checker. Members can search Health Experts columns for detailed data in multiple areas. There is limited commercial influence in the form of ads.
<http://www.everydayhealth.com/>

MedlinePlus. This is the premier free patient education site developed by the National Library of Medicine and the National Institutes of Health that links to the best and most respected web sites, such as the Mayo Clinic. MedlinePlus was ranked as the top information/news web site on the American Customer Satisfaction Index of federal government web sites.²¹ In spite of its high marks, many patients and clinicians do not know about this site and many healthcare organizations pay for patient education content that could be obtained for free. Figure 10.2 shows the results of a search for abdominal pain, showing the high quality references and the convenient folders on the left. Features of the web site include: 800+ health topics, drug information, health encyclopedia, 165 tutorials, videos of surgical procedures, topics available in 40 languages, tools such as quizzes, calculators and self-assessments, health dictionary, physician and hospital locator, link to clinicaltrials.gov and health news.
<http://www.nlm.nih.gov/medline plus/>

Figure 10.2: Search results for abdominal pain (Courtesy MedlinePlus)

The screenshot shows the MedlinePlus website interface. At the top left is the MedlinePlus logo with the tagline 'Trusted Health Information for You'. To the right, it states 'A service of the U.S. National Library of Medicine NIH National Institutes of Health'. Below the logo are navigation links: Home, About MedlinePlus, Site Map, FAQs, and Contact Us. A search bar contains the text 'abdominal pain' and a 'GO' button. Below the search bar are three main navigation buttons: 'Health Topics', 'Drugs & Supplements', and 'Videos & Cool Tools', along with an 'ESPAÑOL' button. On the left side, there is a 'Refine by Type' sidebar with a list of categories and their counts: All Results (2,272), Health Topics (51), External Health Links (1,390), Drugs and Supplements (70), Medical Encyclopedia (618), Videos and Tutorials (111), News (19), MedlinePlus Magazine (9), Other Resources (5), and Multiple Languages. The main content area is titled 'Abdominal Pain' and includes a 'Search Help' link. The text in this area explains that the abdomen extends from below the chest to the groin and contains many important organs. It notes that pain can come from any one of them and that severe pain doesn't always mean a serious problem, while mild pain doesn't mean a problem is not serious. It advises calling a healthcare provider if mild pain lasts a week or more or if you have pain with other symptoms. A 'Read more' link is provided. To the right of the text is a small image of a woman in profile, looking upwards. At the bottom of the main content area, it says 'Results 1 - 10 of 2,272 for abdominal pain'.

Healthfinder. This government funded web site provides resources on a wide range of health topics selected from over 1,600 government and non-profit organizations. It is coordinated by the Office of Disease Prevention and Health Promotion and its health information referral service, the National Health Information Center. <http://healthfinder.gov/>

Everyday Health. This web site with more than 100 participating health centers provides information on the diagnosis, management and prevention of diseases and conditions, as well as on healthy lifestyles. It has an *ask-the-expert* question and answer section and multiple patient communities. It is part of Everyday Health, Inc. that has Everyday Health and multiple partnership web sites that also provide patient information and services. <http://www.everydayhealth.com/>

Healthwise. Multiple companies sell patient education for use on commercial medical web sites. Healthwise is a not-for-profit company that provides more than 6,000 medical topics in their knowledgebase. Their patient education suite includes decision making tools, take action tools for chronic diseases, health coaching and over 1,000 illustrations.

<http://www.healthwise.org/>

UpToDate. This extremely popular physician education site also has a patient education site, aimed at college educated patients, unlike many sites that are aimed at high school educated patients. There is no charge for limited access to this site that covers more than 20 medical categories. <http://www.uptodate.com/home/uptodate-benefits-patients>

FamilyDoctor. The American Academy of Family Physicians sponsors this comprehensive free site. They cover all age groups as well as over the counter (OTC) drugs and a large library of health videos.²² <http://familydoctor.org/familydoctor/en.html>

Lab Tests Online. This free site allows for searching by test, disease condition or screening. The site is well organized with excellent resources for those seeking more information about clinical tests, why they are drawn, the results and what abnormal results mean. In addition, they have a topics in the news section for recent developments. <http://labtestsonline.org/>

Home Telemedicine Devices

Home telemonitoring is an important aspect of telemedicine or the remote delivery of care, which is discussed in much greater detail in the chapter on telemedicine. A myriad of new devices are being produced that are capable of wireless uploads to the internet, electronic health records and personal health records. Data can then be tracked and trended, analyzed and shared. It remains to be seen who will be reimbursed to manage this growing volume of data. In all likelihood, medical practices will eventually be reimbursed for telemedicine but it will be a nurse who is part of a disease management program who will manage the data. Most authorities believe that home telemonitoring will be part of the accountable care organization (ACO) model.

Health informatics is also witnessing convergence in technologies, for example, there are digital scales and blood pressure monitors that not only display on a smartphone but also are backed up via WiFi to a web server as a dashboard for others to view and analyze. Results can also be sent to Microsoft HealthVault. This is an attractive combination for both patient and physician for disease management.²²

There are multiple comprehensive home telemonitoring units available. For example, Meditech home care portal system consists of several physiologic monitors that synchronize to a web site on the internet or to the Meditech electronic health record. Figure 10.3 shows the patient monitor and peripheral devices.²³

The following is a list of features that many home telemonitoring/telemangement systems have in common:

- Medication and health related task reminders with compliance documentation.
- Educational content about medications or disease entities with interactive instruction.
- Touch screen main monitor.
- Patients can report symptoms and this information is forwarded to caregiver or medical office.
- Data from monitors (blood pressure, weight, oxygen levels and blood sugar) with transmission by WiFi or 3G.
- Common to connect bi-directionally to smartphones
- Alerts can be created and sent to physician if the monitoring results are out of range.

Figure 10.3: Home telemonitoring unit (Courtesy Meditech Home Care)



Patient Web Portals

Web portals are web-based programs patients can access for health related services. A web portal can be a standalone program or it can be integrated with an electronic health record. Patient portals began as a web-based entrance to a healthcare system for the purpose of learning about a hospital, healthcare system or physician's practice. They clearly began as a marketing ploy to attract patients who are internet savvy, but have now become a patient expectation in more advanced healthcare systems. It is likely that web portals will be a common means for patients to receive summaries, lab results, etc., compatible with Meaningful Use goals.

Common features of patient web portals are listed in Table 10.1.

Most patient portals offer multiple services, whereas others like TeleVox offer a specific service, like lab results notification. This secure

web-based program, known as LabCalls™ enables patients to access a web site and obtain lab results. The nurse or doctor leaves the results along with a canned explanatory message. Patients can also receive a text message on their cell phone that lab results are ready. This program integrates with the practice management system or the EHR.²⁴

A minority of web portals actually integrate with an EHR, which means that most patient data has to be manually inputted. In the future when EHRs become more widespread and comply with Meaningful Use, selected patient lab results will automatically upload to the patient portal, thus saving time and money. Patients will also be able to access parts of their electronic records. A 2006 Harris Interactive study showed that 83% of patients wanted lab tests online and 69% wanted online charts to manage chronic conditions.²⁵ A 2012 Harris Poll repeated the message that far fewer patients have access to multiple online services through a patient portal than those desiring access.²⁶

Table 10.1: Web portal features

Feature	Comments
Online registration	Allows patients to complete insurance and demographic information before an office visit or hospitalization
Medication refills	Secure messages can be left for physicians to refill or renew medications, instead of telephone calls
Laboratory results	Patients can find results on recent tests as well as an explanation
Electronic visits	Portals exist that facilitate e-visits and the payment process
Patient education	Links to common educational sites
Personal health records (PHRs)	Allows patients and their families to create and update their PHR
Online appointments	Allows patients to see what appointments are available and when
Referrals	Patients can request referrals to specialists, e.g. OB-GYN
Secure messaging	More convenient than playing phone tag
Bill paying	Online payment using credit card is faster than "snail mail"
Document uploading	Several portals allow uploading of medical records to their site
Tracking function	Portal allows patients to upload diet, blood sugars, blood pressures, etc.

Although several studies have shown patient interest in having access to lab results it remains to be seen if that would change consumer behavior or clinical outcomes. Are these patients primarily college educated and tech savvy? Do they desire results because physicians' offices are too slow to provide results? In a study at Beth Israel hospital, patients who accessed their portal PatientSite were younger and with fewer medical problems. They tended to access lab and x-ray results and use secure messaging more than a non-enrollee group.²⁷ Will enhancements such as the Blue Button increase the likelihood of patients downloading content from their medical charts?

In another survey by Connecting for Health, the following are the responses to what consumers thought their health information online would do: clarify doctor instructions (71%); prevent medical mistakes (65%); change the way patients managed their health (60%); and improve the quality of care (54%).²⁸

Little is written about the benefits of patient web portals for the general consumer. Group Health Cooperative, a large mixed-model healthcare organization studied the effect of integrating its new comprehensive patient portal MyGroupHealth with its Epic electronic health record. The highest monthly user rates per 1,000 adult members were: test results, med refills, after-visit summaries and patient to provider messaging. A patient satisfaction survey revealed that the satisfaction rates were: 94% were satisfied overall, 96% for med refills, 93% for patient to provider messaging and 86% for test results. Although early use of the web portal was low there was a steady increase over time. Attrition rates were not reported.²⁹⁻³⁰

Patient Portal Examples

MySaintAls is the portal for Saint Alphonsus Medical Center located in Boise, Idaho. This comprehensive portal offers all of the standard features as well as the unique Patient Vault. They charge \$10 monthly to upload (scan) and store patient records on their server. Lab results are accompanied by a separate program that

explains the significance of the results and likely reduces the number of routine questions. www.MySaintAls.com

Epic MyChart is a patient portal integrated with a well-established electronic health record system. They also offer a standalone PHR known as *Lucy*. MyChart functions: view test results, view and schedule appointments, pay bills, receive health maintenance reminders, view educational material, request refills, secure messaging, view child's record and manage care of elderly parents. An interactive demo is available on the web site. <http://www.epic.com/software-phr.php> Access via a mobile app is available on the Apple Store and Google Play. The most successful implementation of this technology has been by Kaiser Permanente and its My Health Manager portal. As of mid-2102 they experienced 4 million sign-ons or 67% of registered members. Patients can access medical records, exchange secure messages, order refills and schedule appointments.³¹⁻³²

Intuit Health Patient Portal is a portal that offers multiple features for patients and medical offices. They claim to have a user base of 4,000+ physician offices. They also have an extensive knowledge library of 6,000 medical conditions to expedite an e-visit. A new area of involvement is the patient centered medical home model where they supply the technology to connect patient with physician. A free return on investment (ROI) calculator is available on their site <http://healthcare.intuit.com>. Additional features include:

- Front office solution to deal with patient registration, forms, appointments, check-in and patient messaging
- Back office solution for online bill payment, billing messaging and a virtual credit card payment system
- Clinical solution includes medication renewal and refills, secure messaging, personal health records, referral management, virtual visits, symptom assessment, laboratory results and reminders

- **ReachMyDoctor.** This site is aimed at improving communication with the doctor's office. www.reachmydoctor.com. The program offers two options:
 - Free: schedule appointments, request medication refills, request a referral and address billing and insurance issues
 - Subscription: for \$8.95 monthly a patient can ask the physician non-urgent questions via secure e-mail. Physicians must be part of the network
- **My HealthVet.** This portal integrates with the Veterans Health Administration's EHR (Vista) and offers lab wellness reminders, appointments, a personal health record (PHR), medication refills, patient education and online monitoring of: activity, food intake, oximetry, blood pressure, glucose and weight. In the 2011 time frame they added secure messaging, online appointments and lab results (hematology and chemistry). The blue button feature on the web site permits veterans to view, print or download results and a continuity of care record can be generated. They offer a basic, advanced and premium option for access to records. For the premium account there is a higher level of personal authentication and they have extensive access to all key areas of their electronic health record.
<http://www.myhealth.va.gov/>

Personal Health Records (PHRs)

According to the American Health Information Management Association (AHIMA) the personal health record (PHR) is: "an electronic, universally available, lifelong resource of health information needed by individuals to make health decisions."³³

Ideal PHR Features

In spite of the fact that PHRs are available in many formats, experts believe that PHRs should

have the following features in order to be successfully adopted:

- Portable, i.e. information will transfer even when there is a job, insurer or clinician change
- Interoperable, i.e. standardized PHR format can be shared among disparate partners, such as using the Continuity of Care Document (CCD) discussed in the chapter on data standards
- Auto-populated with clinical and test results that would be inputted automatically
- Controlled by the patient
- Longitudinal record and not just a snapshot
- Private and secure
- Integrated into the clinician's workflow and not be a separate process

The reality is that no organization has the ideal solution, with all of the above features.³⁴

PHRs can be tethered (to an EHR or application), untethered; can be web based or mobile (smart card, smartphone or USB drive). The reality is this technology space is moving towards PHRs integrated with EHRs and most likely residing in "the cloud." Given the plethora of PHRs available only two examples will be presented:

- **Microsoft HealthVault.** Program includes a PHR and interfaces with other third party health applications. This platform released the source code of the HealthVault.NET Software Development Kit and the XML interfaces under the Open Specification Promise (OSP). This will enable third party developers to develop HealthVault compatible applications. They are a health information service provider (HISP) so they participate in the Direct Project, explained in the chapter on health information exchange. The platform is able to receive Continuity of Care Documents (CCDs) and Continuity of Care Records (CCRs) from physicians or hospitals. As of October 2013 they can integrate with 126 applications and

215 devices. The program is also available for the Windows and iOS mobile operating systems. DICOM medical images can also be stored on this platform. Pilot projects with integrated delivery networks are underway but results are unknown.³⁵

- World Medical Card is a Norwegian commercial untethered PHR platform that has three components: a web based PHR, mobile PHR and an emergency wallet card. Their goal is to become the international standard for portable medical records. Diagnoses can be linked to ICD-10 codes and the software can be translated into 18 languages.³⁶

PHR Barriers and Issues

Although the science base is growing, much more work needs to be done to definitively characterize the impact of PHRs on patient behavior and outcomes. In particular there is no consensus regarding the following questions:

- What PHR functionality is needed in the areas of data collection, sharing, exchange and self-management?
- What is needed to improve adoption of PHRs by patients and clinicians? Research should focus on specific populations like the elderly, patients with chronic diseases, etc.
- What is needed to ensure privacy and security?
- What PHR architecture or model is likely to be most effective? Tethered? Untethered?
- What is the business case for PHRs and are the incentives aligned for patients and physicians?³⁷

Thus far, personal health records have been voluntary, placing the burden of downloading and maintaining health information on the patient. A busy physician's office is not likely to want this additional responsibility without reimbursement. Meaningful Use requirements for reimbursement will likely make interaction with PHRs more palatable for physicians. The vision is to have records stored in repositories like Microsoft HealthVault in a format (XML)

that is compatible with EHRs, HIOs, etc., but this will likely take years to accomplish, for those patients who are interested. As PHRs develop more user friendly features, perhaps the appeal to the average consumer will increase. Some PHRs, for example, will provide alerts such as *medications about to expire* or *upcoming medical appointments*. An ideal business model for personal health records does not exist. Some studies suggest patients are willing to purchase their own PHRs if the price is low and others suggest insurance companies are the entity most likely to play a major role. Theft of personal health information (PHI) is a definite concern to the average patient and personal health records is just one more platform of concern.

Electronic Patient-Physician Communication

“Digital Rx: Take two aspirin and e-mail me in the morning”

- *New York Times*, March 2, 2005

Secure Patient to Physician E-Mail

Email is easy to use, widely available across the world, and inexpensive. Despite the ubiquity of email, its use in the healthcare system is increasing but still not routine. Factors driving the trend of increasing email use include an increasing number of people comfortable with using technology-driven care solutions, and increasing demands on healthcare resources.³⁸⁻³⁹ Recent surveys suggest that from 16% to 72% of physicians use email to communicate with patients and caregivers with the volume of email communication averaging from 7.7 emails per month to 8.6 emails per week. Email communication is being used to request prescriptions, booking appointments and for non-urgent clinical consultation.³⁸⁻³⁹

Several factors are likely to continue to drive the trend of increasing email use, including increasing patient demand, increasing proportion of doctors (and patients) comfortable with using technology-driven care solutions, and

increasing per capita demand on healthcare resources.³⁸⁻³⁹

Providers as well as patients prefer email over telephone consultations for non-urgent problems. Those providers who use email for clinical consultations think it is a useful addition to conventional methods of consultation, being easy to use and improving communication. Email may also enhance management of chronic diseases, improve continuity of care and increase healthcare professionals' flexibility in responding to non-urgent issues.³⁸⁻³⁹

Although email is not appropriate for all forms of clinical communication it may be useful for a) triage-based systems for messages about health concerns, prescription renewals and referrals, all controlled by a nurse 'navigator' b) Sensitive or embarrassing issues that they may not otherwise discuss, c) ongoing and close monitoring and support of patients with chronic diseases. Patients may also be able to communicate health data such as blood pressure levels or glucose levels to their healthcare professional for monitoring. This type of service can improve continuity of care, reduce the number of face-to-face consultations required, and improve quality of care and quality of life. D) encourage adherence to treatment, and to solicit responses about side effects of medication. E) follow up, for instance after an appointment with a physician, when clarification or added information may be required. F) pre-appointment updates from patient to physician,

and to replace outpatient appointments after day surgery.³⁸⁻³⁹

The key advantages of email for clinical communication between patients and healthcare professionals include a) Timely and low cost delivery of information (compared to conventional mail) b) Convenience c) Email addresses usually stay constant when an address or telephone number changes making this a reliable way of maintaining communication with transient patients. D) may improve access for non-urgent and simple enquiries. Potential drawbacks include a) privacy, confidentiality and potential misuse of information. B) increased provider workload. C) quick patient response expectations. D) potential to widen health inequalities via the digital divide e) lack of information security.³⁸⁻³⁹

Despite the popularity of email in general and its increasing but modest use for patient clinician communication a recent literature review by the Cochrane Collaboration failed to find any evidence of beneficial impact from using email for clinical communication.³⁸⁻³⁹

Electronic Visits

Electronic visits (e-visits or virtual visits) are an example of telehealth or telemedicine where medical care is delivered remotely (telemedicine is covered in much more detail in another chapter). Virtual visits are available as a continuum of care (Figure 10.4).

Figure 10.4: Remote patient communication continuum



A Price Waterhouse study estimated that 20% of outpatient visits could be eliminated by using e-visits.⁴⁰ Virtual visits have the advantages of much better security and privacy and the ability to have a third party involved in the billing process. The consensus is that minor complaints can be dealt with more efficiently electronically, thereby allowing sicker patients to be seen in person. Furthermore, patients miss less time from work for minor issues. It has also been pointed out that if the patient provides a history during the e-visit and still has to be seen face-to-face, the physician has the advantage of knowing why the patient is there, therefore saving time. Numerous vendors such as Intuit Health Patient Portal provide the platform for e-visits in addition to their patient portal features. Guidelines need to be established to define what constitutes an e-visit in order for insurance companies to reimburse for the electronic visit.

Questions remain about e-visits, regarding reimbursement (who will pay for what), privacy and what if initiating e-visits causes a drop in office visits leading to reduced office income?

A new free secure messaging service is available and known as HouseDoc. It supports a virtual asynchronous visit, a request for medication refills, a request for appointments and test results. Security is provided by SSL encryption. If the clinician charges the patient, the web service charges \$2 and services are paid for by credit card.⁴¹

Telephonic visits: The concept of virtual visits has spawned innovation in the delivery of healthcare. As an example, *TelaDoc* is a telephone-based consult service that is intended to supplement the care delivered by the primary care physician. This web-based application guarantees a clinician will return a phone call in three hours and the average charge is \$35. They claim to have one million members and offer services 24/7. The clinician will prescribe and handle refills but not prescribe narcotics or order labs. Interestingly, they save the patient encounter as a Continuity of Care Record (CCR) that can be shared with others and accessed at the next visit. Aetna offered this service to its patients in Texas and Florida in 2011; it is

therefore likely data will soon be available to measure the impact of this innovation.⁴²

After hours answering service: Ringadoc™ is a new service where patients can contact the answering service and leave a verbal message that is forwarded to the physician's smartphone. He or she can call back, leave a verbal message or forward to the office.⁴³

Audio-Video Televisits: Another innovative virtual visit service worth mentioning is *American Well*. Patients can interact with clinicians using web-based videoconferencing, as well as secure chat, secure messaging, voice over IP and telephonic communication. They are promoting 24/7 access for patients from home and aim to coordinate care with the primary care clinician (PCM) and insurance company. The service locates an appropriate clinician (including specialists), initiates a live audio-video conversation with a clinician and forwards the results to the PCM. For the clinician there is automatic claims submission and a per-consultation malpractice insurance coverage is offered. In addition, clinical practice guidelines are promoted for standardized care, known as *online care insight*. This vendor is promoting this application for the patient-centered medical home model and accountable care organizations. In 2010, they introduced *Team Edition* with the goal of supplying on-demand specialty care as part of the team. Delta Airlines will make American Well services available to all employees and Rite-Aid will use the platform for in-store consultations with its pharmacist network. The approximate cost for an e-visit is \$45.⁴⁴

MDLiveCare was an on-demand telehealth company that was acquired by MDLIVE, Inc., in July 2012. MDLiveCare provided patients with remote access via video, phone, and secure email to board certified doctors and licensed therapists. Currently MDLive offers Online and on-demand health care delivery services and cloud-based software platform to provide access to health care 24/7/365 anytime, anywhere. Connect with a nationwide network of Board Certified physicians and licensed therapists through secure video or phone.⁴⁵

3G Doctor is a United Kingdom-based audio-visual consulting service available for the smartphone. The charge for the visit is £ 35.⁴⁶

Little has been reported about the medical value of e-visits. A 2010 article did confirm that e-visits seem to be a successful alternative to standard care for the follow-up treatment of acne by dermatologists. The intervention group used a web portal, aided by digital photographs sent to the physician every six weeks. Patient and physician satisfaction was high. The intervention saved time for patients and was time neutral for Dermatologists.⁴⁷

Social Media

“Web 2.0” is an umbrella term that is used to refer to web-enabled applications that are built around user-generated or user-manipulated content, such as wikis, blogs, podcasts, and social networking sites.⁴⁸ For many, even from the earliest days of the internet, the importance of going online has been more closely related to the social aspects of doing so than any information seeking needs they may have. As early as 2001, researchers found that the online world was not merely a digitized library, but rather a vibrant social universe where many Internet users enjoy serious and satisfying contact with online communities. These online groups were made up of tens of millions of Americans who shared information about passions, beliefs, hobbies, or lifestyles online.⁴⁸ As both online consumers and electronic applications matured, the focus of web utilization began to shift from primarily information seeking to online interaction with goods, services and others who were online.

In 2004, the term “Web 2.0” was introduced to describe this shift in both consumer demand and application functionality.⁴⁹ Although there are different definitions, most have several aspects in common, with the main difference between Web 1.0 (the first generation of the Internet) and Web 2.0 being interaction.⁴⁹ Web 1.0 was mostly unidirectional information seeking, whereas Web 2.0 allows the user to add

information or content to the Web, thus enabling interaction, information sharing and collaboration.^{48,50} Increasingly the terms social media and social networking began being used to describe the essential attributes of Web 2.0 tools, applications and functions.

As of May 2013, 72% of online adults use social networking/media sites with more than two thirds (67%) using Facebook while 20% are using LinkedIn.⁵¹ It's not just that more Americans are using social networking sites, but also that they are doing so for health purposes. Fully 80% of internet users (59% of all adults have looked online for information about any of 15 health topics such as a specific disease or treatment. Half of these individuals (34% of internet users, or 25% of adults) have engaged in one or more types of social media based activities for health purposes.⁵¹ These include reading someone else's commentary or experience about health or medical issues on an online news group, website, or blog. One quarter of internet users have watched an online video about health or medical issues while another 25% have consulted online reviews of particular drugs or medical treatments. Just under 1 in 5 internet users have gone online to find others who might have health concerns similar to theirs while 16% of internet users have consulted online rankings or reviews of doctors or other providers and 15% have consulted online rankings or reviews of hospitals or other medical facilities.⁵¹

Finally, almost one fourth of adult social network site users have followed their friends' personal health experiences or updates on the site, while 17% have used social networking sites to remember or memorialize other people who suffered from a certain health condition. Fifteen percent of social network site users have obtained health information from the site.⁵²

While social media use has grown dramatically across all age groups, older users have been especially enthusiastic over the past year about embracing new networking tools. Social networking use among internet users ages 50

and older nearly doubled—from 22% in April 2009 to 42% in May 2010. Between April 2009 and May 2010, social networking use among internet users ages 50-64 grew by 88%—from 25% to 47%. During the same period, use among those ages 65 and older grew 100%—from 13% to 26%. By comparison, social networking use among users ages 18-29 grew by 13%—from 76% to 86%. One in five (20%) online adults ages 50-64 say they use social networking sites on a typical day, up from 10% one year ago. Among adults ages 65 and older, 13% log on to social networking sites on a typical day, compared with just 4% who did so in 2009.⁵³

Currently more than 80% of individuals ages 18–24 are willing to share health information through social media, while nearly 90% would engage in health activities or trust information found via social media. Less than half (45%) of individuals ages 45–64 would be likely to share via social media, and 56% would be likely to engage in social media oriented health activities.⁵⁴

Finally, 45% of consumers indicate that information found via social media would affect their decisions to seek a second opinion. More than 40% report that information found via social media would affect the way they coped with a chronic condition or their approach to diet and exercise.⁵⁴

As can be seen from the discussion above, social media is changing the nature of interaction and presents new opportunities for how individuals manage their health, whether researching a particular illness or joining a support group to share experiences. The virtual aspect of social media enhances communications by creating a comfortable, often anonymous, environment for engaging and exchanging information. “People like to access and connect with other people’s stories, even if they’re unwilling to share their own, Facebook and YouTube are the most commonly used social media channels for viewing health-related information.⁵⁴

While much more work needs to be done, using social media in health care “is about changing the locus of control to the patient” and altering

the relationships between care givers and care receivers. In this view, patient portals, EHR platforms, blogs, video chat, and “tweets” won’t merely substitute for many one-on-one encounters with providers, but will also allow for richer engagement and deeper doctor-patient relationships.⁵⁵

Recommended Reading

The following are articles extracted from the recent medical literature that add some evidence-based insight into the new world of CHI.

- *HealthPartners' Online Clinic for Simple Conditions Delivers Savings of \$88 Per Episode and High Patient Approval* *HealthPartners*, a Minnesota based integrated delivery network reported that an online clinic aimed at simple primary care problems resulted in a savings of \$88 per episode and was associated with high patient satisfaction. The clinic is available on the web (www.virtuwell.com) 24/7 and treats about 40 common conditions, with supervision by mid-level providers. More than 40,000 patients have been seen, the cost is \$40 per visit and roughly 85% have been associated with an insurance claim, to include Medicare. No in-person follow up visit was required in about 90% of cases.⁵⁶
- *A Comparison of Care at E-visits and Physician Office Visits for Sinusitis and Urinary Tract Infection*. Researchers from the University of Pittsburgh Medical Center reported on a comparison of routine care and e-visit care for sinusitis and urinary tract infections. Only 9% of visits were virtual for sinusitis and 3% for urinary tract infections. Physicians were less likely to order a test associated with an e-visit for a UTI but were more likely to order an antibiotic. Follow up visits were the same between groups. Patients were selected on diagnostic codes and not chief complaint and it was unclear about selection criteria for e-visits.⁵⁷

- *The Impact of Electronic Patient Portals on Patient Care: A Systematic Review of Controlled Trials.* Dr. Ammenwerth et al. reported on what is known about patient portals in 2012, covering years 1990-2011. Only 5 papers were abstracted and when two randomized controlled trials were reviewed there was no difference between the intervention and control group in terms of health outcomes. The patient portal was associated with a decrease in office visit rates and fewer telephone contacts and better adherence to treatment.⁵⁸
- *Inviting Patients to Read Their Doctor's Notes: A Quasi-experimental Study and a Look Ahead.* This one year study provided an electronic link for patients to view their own office notes. A majority of patients took advantage of this access and a majority felt more in control of their care. A majority noted improved medication adherence with a minority worrying about privacy. The volume of electronic messages did not change. A majority felt they should be able to add comments to the notes and 99% wanted the open notes initiative to continue.⁵⁹
- *Association of Online Patient Access to Clinicians and Medical Records with Use of Clinical Services.* This was a before and after study of the use of Kaiser-Permanente's MyHealthManager, a patient portal on services. After implementation there was an increase in office visits, telephone encounters, after hours visits, emergency room visits and hospitalizations. This observation was seen irrespective of age or presence of chronic conditions. The cause of this increased utilization of services after access to the system is unclear and discussed by the authors.⁶⁰
- *Systematic Review and Evaluation of Web-Accessible Tools For Management of Diabetes and Related Cardiovascular Risk Factors by Patients and Healthcare Providers.* The authors evaluated 57 studies (25 randomized controlled trials) for effectiveness, usefulness, sustainability and usability. Many of the tools were not available for testing and because the studies were so different a meta-analysis could not be performed. The authors commented that many of the applications were associated with improvement but there were frequent study design and usability issues, limiting the generalizability of results.⁶¹
- *Understanding the Factors That Influence the Adoption and Meaningful Use of Social Media by Physicians to Share Medical Information.* This study was based on responses from a questionnaire by 485 physicians. Using the Technology Acceptance Model (TAM) they looked at how social media is perceived in the medicine. On a weekly basis 61% of respondents looked at social media and 46% actually contributed. A little over half perceived social media to be a positive influence on medical care. Neither age nor gender impacted adoption or perception of social media.⁶²
- *Access, Interest and Attitudes Toward Electronic Communication for Health Care Among Patients in the Medical Safety Net.* This study evaluated electronic communication needs by adults attending safety net clinics in the San Francisco area. The self-reported survey indicated that 60% of respondents used email and 71% desired secure messaging with physicians. The implication is that although the respondents were socioeconomically disadvantaged they still had interest in electronic communication with the healthcare system.⁶³

Barriers to CHI Adoption

Despite the explosion in the development of CHI tools, a recent review of the evidence suggests that many barriers may still exist to the widespread utilization of these tools and strategies.¹⁶ User barriers can pertain to either the clinician or the consumer. Although providers do not generally use CHI tools, clinician endorsement affects consumer choice,

and thus negative attitudes of clinicians may be a barrier to consumer use.¹⁷ Other consumer barriers include lack of home internet access, concerns about privacy, limited literacy and knowledge, language hurdles, cultural issues, and lack of technologic skills.¹⁷ Application usability or user-friendliness, patient knowledge, literacy, and lack of needed computer skills have all been identified as barriers to CHI utilization. Privacy concerns, control of information, lack of trust, lack of consumer acceptability, usefulness, credibility, expectations are common barriers to CHI use.¹⁷ Finally, physical or cognitive disability, computers use anxiety, lack of built in social support, lack of personal contact with clinicians and the belief that IT would not be an improvement to current care have all been cited as barriers to the adoption and utilization of CHI tools and applications.¹⁷

Future Trends

The large number of CHI tools available to consumers might be taken to suggest the value of these applications. Unfortunately, in the overwhelming majority of cases, the efficacy of the CHI tools has not been evaluated.¹⁵ Among those that have been evaluated, most tend to focus on one or more domains of chronic disease management.¹⁵ While this is very important and clearly needed, insufficient attention has been

given to the role of CHI applications in the acute exacerbation of symptomatology or other urgent and emergent problems that may occur in home and community-based settings. Thus, the role of CHI applications in primary, secondary, and tertiary prevention needs to be more adequately explored.¹⁵

Given the prevalence of mental health and psychiatric issues, the value of CHI applications in the context of mental health, coping, and stress should also be thoroughly evaluated. Sociocultural factors are increasingly important determinants of health care outcomes. The potential impact on social factors including social isolation and social support and perhaps even broader social determinants of health need to be evaluated and may prove useful in helping patients address select health concerns in the home- and community-based setting.¹⁵

Meaningful use objectives are likely to increase consumer involvement in their care. Not only will patients have an opportunity to have access to summary notes, some institutions such as the Cleveland Clinic plan to provide full patient access to the electronic health record (less mental health notes) by 2014. This will include pathology records, physician notes and x-ray reports.⁶⁴ Evidence thus far from one study of full access to veteran's electronic records has been positive, but it is too early to know if it will impact future patient outcomes.⁶⁵

Key Points

- Healthcare consumers are becoming more sophisticated and more demanding.
- Newer healthcare delivery models such as the patient centered medical home and accountable care organizations will further enhance patient engagement and the need for patient centered HIT.
- Patients would like the same convenience of an ATM machine in healthcare.
- Patients are using the World Wide Web as the medical library of choice.
- Patient web portals are now available that are standalone or integrated with electronic health records that offer a multitude of patient-oriented services.
- Everyone is talking about personal health records but it is unknown who will pay.
- Secure patient - physician e-mail and e-visits have great potential to expedite acute care visits, once reimbursement becomes standard.

Conclusion

Despite a large and growing number of CHI tools and applications, overall the CHI field is new and still evolving, particularly as it relates to evaluation and documentation of the effectiveness of these tools.¹⁵ The evidence from those tools that have been evaluated suggests that while there may be a role for CHI applications to reach consumers at a low cost and obviate the need for some activities currently performed by humans, it is likely that a more important role is to enhance the efficacy of interventions currently delivered by humans. The literature also suggests that at least three critical elements are most often found in those CHI applications that exert a significant impact on health outcomes. These three factors are (1) individual tailoring, (2) personalization, and (3) behavioral feedback.¹⁵ Personalization involves designing the intervention to be delivered in a way that makes it specific for a given individual. Tailoring refers to building an intervention, in part, on specific knowledge of actual characteristics of the individual receiving the intervention. Finally, behavioral feedback refers to providing consumers with messages regarding their status, wellbeing or progression through the intervention.¹⁵

These messages may come in many different forms. They can be motivational (You did great today!) or purely data driven (You completed 80% of your goal today). Interestingly, it is not clear from this literature that CHI-derived behavioral feedback is any better than feedback originating from human practitioners or others. Rather, it appears that the feedback must happen with an appropriate periodicity, in a format that is appealing and acceptable to the consumer, not just the provider.¹⁵

Generally speaking, the scientific literature also suggests that CHI applications may positively impact healthcare processes such as medication adherence among asthmatics. CHI applications may also positively impact intermediate outcomes across a variety of clinical conditions and health behaviors, including cancer, diabetes mellitus, mental health disorders, smoking, diet,

and physical activity. CHI applications may not have much impact on intermediate outcomes among individuals who are obese or suffer with asthma or COPD. In addition, the evidence appears relatively strong in support of the positive impact of CHI on selected clinical outcomes, particularly mental health outcomes.¹⁵

To facilitate uniform reporting and improve the quality of the work in this field, consideration should be given to development of a national CHI applications design and development registry and CHI applications trials registry with uniform reporting requirements. However, the developers of these applications come from a wide and diverse array of backgrounds. Some have significant technical expertise while others are clinicians. Research in this multidisciplinary field would be greatly enhanced by an accepted vocabulary, nomenclature or ontology. Currently, there is much confusion among the varied developers of CHI tools, between the platform upon which the application is built, the technical specifications of the CHI application and the educational or behavioral content of the messages included in the application. While a strict rendering of the current definitions of these elements allows for little conceptual overlap, the literature is replete with examples of investigators who describe the technical platform on which the CHI application (cell phone) runs yet provide no further technical specifications regarding the application.¹⁵

More work will need to be done to explicate the role of human factors, socio cultural factors, human computer interface issues, literacy and gender. Currently most CHI research is being primarily conducted among white/Caucasian adult patients, and it is not clear how the findings apply to non-white populations. The importance of this limitation is heightened by the fact that the internet will be the primary means of the consumer's ability to use and take advantage of CHI tools. While technological platforms may vary, most CHI applications will, in one way or another, rely on the internet to perform its functions. Consumer internet familiarity and utilization trends will have

significant impact on the ability of CHI applications to be successful across all consumer populations.¹⁵

Interestingly most of the evaluative research being done is being conducted among middle aged adult populations; significant opportunities exist for additional research among other age groups of consumers. It may even be that the impact of CHI applications may be greater among non-middle aged adult consumers because these consumers may be most likely to adopt CHI applications (children, adolescents and young adults) and they may have the most to gain from using effective CHI applications (elderly).¹⁵

Also most CHI applications that have been evaluated to date are designed to run on desktop computers. More work will need to be done to understand the role of other technological platforms including cell phones, PDA's, TV, satellite, on Demand, health gaming platforms (Wii, XBOX, GameCube, etc.). Related to technological platforms used for CHI applications is the potential role of social networking applications. Very few currently evaluated CHI applications explored the dynamics and potential utility of using social

networking applications (Skype, Twitter, MySpace, Facebook, You Tube, blogs, Second life, Yoville and Farmville, Patients like Me, etc.) to support behavior change or improve health outcomes. While it may be challenging to envision the elderly twittering, use of these applications may open opportunities to address health problems impacted by trust, social isolation, cognitive stimulation and low literacy). This type of research may inevitably lead to a broader array of interactivity among patients and their caregivers with measurable psychological and physiological health benefits for users and patients. In so doing, CHI applications may accrue greater appeal and effectiveness among patients because these applications are assisting patients to address real life issues that in the past may have been unrecognized barriers to achieving optimal health.¹⁵

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Chapter 11

Mobile Technology and mHealth

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Learning Objectives

After reading this chapter the reader should be able to:

- Describe the evolution from personal digital assistants to smartphones and the emergence of mHealth
- List the various ways mobile technology is currently being used in healthcare
- Compare and contrast mobile technology for clinicians and patients
- Identify the limitations of mobile technology

Introduction

In the first edition of this textbook the use of personal digital assistants (PDAs) in the field of medicine was discussed. With the advent of smartphones and tablets, such as the iPad, mobile technology is a broader and more appropriate term. Handheld technology or mobile electronic devices are also acceptable. Mobile technology is a logical transitional step from the personal computer. With improving speed, memory, wireless connectivity and shrinking form factor (size and shape), users desire a mobile platform for their information and applications as well as phone capability, e-mail and access to the internet. Without a doubt, mobile technology is one of the fastest evolving topics in this textbook and could be considered disruptive technology. Because of its pervasive and popular nature mobile technology has become a component of many consumer informatics, disease management and tele-

medicine strategies. Standalone mobile software programs (apps) will be discussed but the larger picture is system wide integration of mobile technology into the enterprise healthcare system.

Many would argue that healthcare professionals and consumers have entered the mHealth (mobile health) era in which mobile technology will play a much larger role in healthcare. mHealth, a subcategory of eHealth, can be simply defined as the “delivery of healthcare services via mobile communication devices.”¹ Currently, this chapter will include cell phones, smartphones and tablets as mobile electronic devices, but this is arbitrary and subject to change. Also, a new section on wearable health IT used to measure, track and trend various health parameters has been added.

This chapter will begin with the history of mobile technology.

History of Mobile Technology

Cellular Mobile Telephony

The history of modern mobile technology is relatively recent. Primitive mobile phones arose in the 1970s but didn't gain popularity until 2G cellular networks appeared in Finland in the early 1990s. Worldwide adoption with 3G cellular networks became a reality in the 2001

time frame.² Figure 11.1 demonstrates worldwide mobile cellular telephone subscriptions from 2001 to 2013. Adoption of mobile cellular phones is universal but varies greatly by country. For example, in 2012 in Somalia only 6/100 inhabitants had a cell phone, compared to 98/100 in the United States and 284/100 in Macao, China.³ The timeline for cellular mobile technology from 1973-2013 can be found at this site.⁴

Figure 11.1: Global telecommunications (Courtesy International Telecommunications Union)³

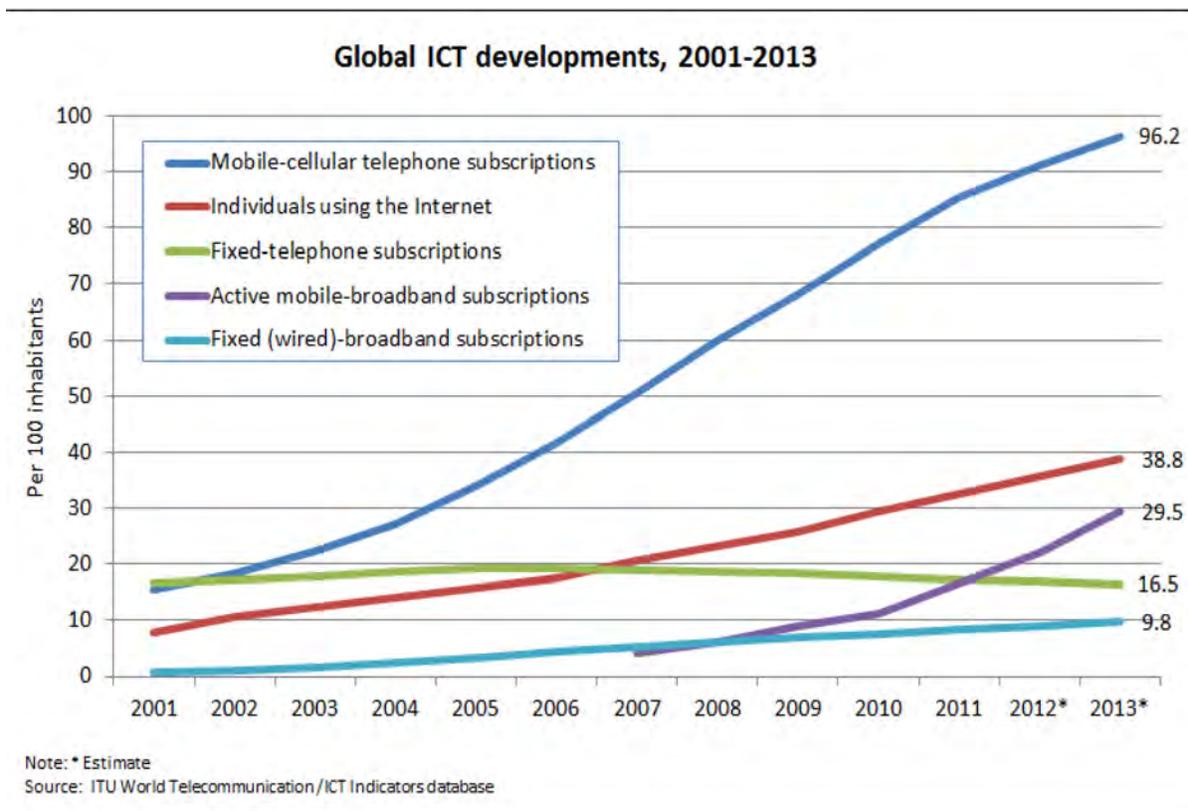


Table 11.1 compares the usage of telephony between developed and developing countries. Growth has occurred in developing countries; in fact, some countries have “leapfrogged” ahead and skipped the landline phase of telephony with widespread wireless cellular adoption.³ In addition, countries are moving from 3G to 4G, discussed in the chapter on the architectures of health information systems. How some countries have leveraged cellular technology for healthcare improvement will be addressed in another section.

Table 11.1: 2013 Worldwide Telephony usage

Subscriptions	Per 100 inhabitants in 2013*		
	Developed	Developing	World
Fixed-telephone	41.6	11.1	16.5
Mobile-cellular	128.2	89.4	96.2
Active mobile-broadband	74.8	19.8	29.5

Table 11.2 compares Internet usage in various regions of the world from 2005 to 2013.³

Table 11.2: Internet Usage Worldwide from 1005-2013

Individuals using the Internet	(%)		
	2005	2009	2013
Africa	2.4	7.8	16.3
Arab States	8.3	19.8	37.6
Asia & Pacific	9.4	18.9	31.9
Europe	46.3	63.2	74.7
The Americas	35.9	46.1	60.8

Personal Digital Assistants (PDAs)

In the early 1990s the Apple Newton PDA appeared with a monochrome screen, a weight of .9 lbs., measurements of 7.25 x 4.5 x .75 inches, 150 K of SRAM, a processor speed of 20 MHz, short battery life and a cost of \$700.⁴ It obviously did not succeed because it was too big, heavy, slow and costly for the average consumer.

The next handheld product to catch the public’s attention was the Palm Pilot 1000 released in 1996.⁵ It was smaller, less expensive and had 128K of memory, but did not become popular with the medical profession until the *killer application* Epocrates was released in 1999.⁶ First, there was the excitement of knowing that drug facts could be retrieved much more rapidly with the PDA compared to the Physician Desk Reference (PDR) and secondly, the program was free. The PDA was also a platform to store all medical “pearls” rather than stuffing notes into the pockets of a white coat. Other companies got on the bandwagon rapidly to produce PDAs. This was followed by PDAs with phone capability, Internet access, WiFi and multimedia capability. As wireless cellular communication caught on worldwide, consumers desire for one platform resulted in a convergence of technologies. The shift from PDAs to smartphones was rapid, occurring over only six to eight years.

Smartphones

There is no industry-wide definition of a smartphone. Some define it as having an operating system that can support the execution of third party applications and others define it as simply having more functionality than conventional cell phones. For the purpose of this chapter the term smartphone will be used and include only those that have operating systems capable of hosting medical software. With the evolution of cloud computing, more and more medical programs will be hosted in the cloud and not on the device. Therefore, one could eventually state that a smartphone is one that is Internet capable. There are likely to be further convergence of handheld technologies,

as devices such as the Apple iPad blur the distinction between smartphones and laptop/tablet/slate computers. It is known that in 2013 physicians are making rounds and/or evaluating patients in an exam room using tablet computers but the actual impact on productivity is not known. The obstacles to this approach, such as privacy and impact on the physician patient interaction, are not completely understood. There is a paucity of evidence to prove this type of mobile technology is superior to the standard desktop computer, but this is likely to change over time.⁷

A 2012 study by the Pew Research Center found that 85% of US adults own a cell phone and 53% of those own smartphones. Fifty two percent of smartphone owners use their device to search for healthcare related matters. Eighty percent of cell phone owners report they send or receive text messages but only 9% receive a healthcare alert via this mechanism. About 19% of smartphone users have at least one health app on their phone. The highest users were the financially well off and well educated young individuals, however, a significant number of minorities were also smartphone users.⁸ Manhattan Research reported in 2011 that 81% of physicians used smartphones, compared to 30% in 2001.⁹ A 2013 Deloitte survey claimed that 43% of physicians used their mobile devices specifically for clinical purposes to include EHR access, e-prescribing and physician-to-physician communication. This usage statistic did not include medical apps such as Epocrates. Non-users in this survey stated that their work setting, privacy concerns and non-helpful apps were the reasons for non-adoption.¹⁰

Tablet PCs

The first generation of tablet PCs were all Windows operating system-based and required a stylus and keyboard for input. Additionally, they were heavy, expensive and had short battery life. Clinicians tried to use this technology in exam rooms and on hospital rounds but few continued, due to the stated limitations.

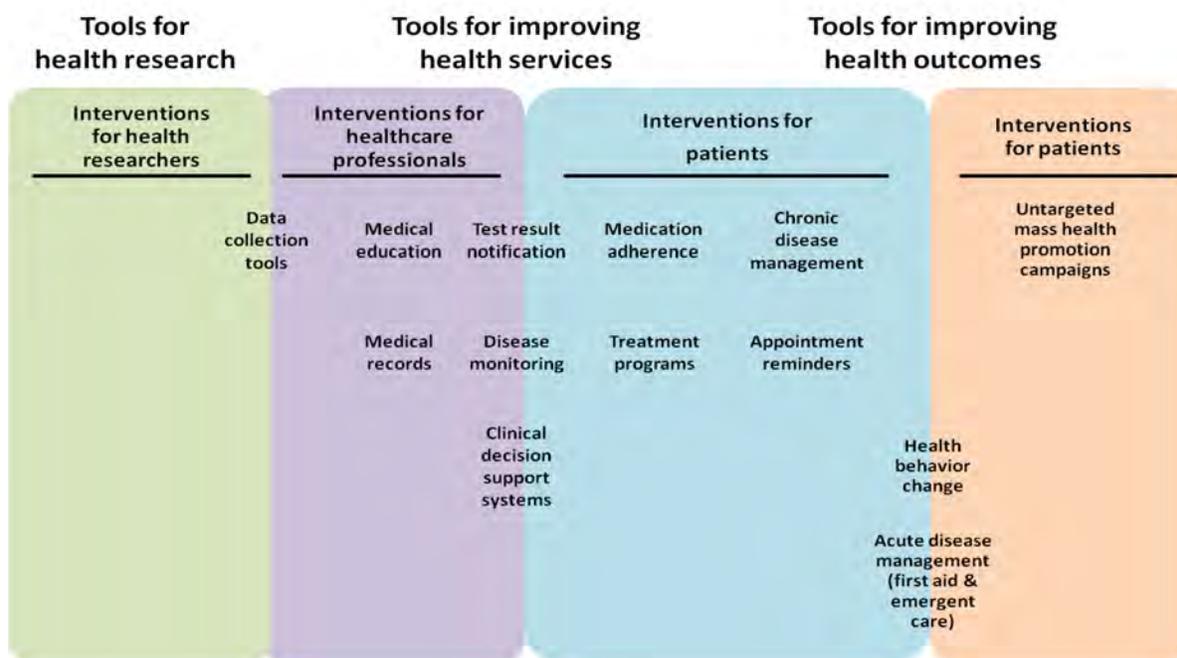
There has been an avalanche of tablet computers, such as the Apple iPad and Android devices, since 2010; by 2012 108 million tablets were shipped.¹¹ The new tablets are light weight, have prolonged battery life, excellent screen resolution, extensive medical apps, instant-on capability and a convenient form factor. The hardware landscape over the past two years has been volatile with offerings from HP running WebOS being completely discontinued, and a bleak outlook for the BlackBerry Playbook from RIM. The two top contenders are currently the iOS powered iPad line and the vast array of devices running the Android operating system. Microsoft has entered the arena with Windows 8 in both the real-time (RT) embedded and core (x86) varieties, however there hasn't been significant market buy-in at this point. According to Manhattan Research in 2011, 30% of surveyed physicians use the Apple iPad to view electronic health records (EHRs) or digital images and communicate with patients and a later survey by the same group indicated that 72% of physicians owned a tablet in 2013 and used it for a variety of purposes.^{9,12} Physicians are both self-adopting (purchasing the devices for themselves facilitating the bring your own device or BYOD model) as well as having their organizations purchase and roll out the devices.

Mobile Health (mHealth)

Conceptual framework

In order to evaluate the rapidly changing mobile technology landscape an organizational schema is required. A modified version of the conceptual framework of Caroline Free et al., is displayed in Figure 11.2 and will be used to organize the discussion about mHealth (mobile technology in healthcare).¹³ The three themes are “tools for health research,” “improving health services” and “improving health outcomes.” Interventions for patients will be discussed in this chapter. The tools for health research will be discussed in the chapter on e-research.

Figure 11.2: Conceptual framework for mobile technology
(adapted from Caroline Free¹²)



Mobile Technology and Patients

Devices. As already stated, most adult patients worldwide own a cell phone and the percent that own a smartphone or tablet PC is steadily increasing. It is important to keep in mind that smartphones and tablets have access to the internet so in addition to software applications (apps) that can be downloaded to the device, multiple web-based programs can be accessed. Access to the internet is extremely important as it has become the default health library, as discussed in the chapter on consumer informatics. Many patient-oriented web programs will be discussed in other chapters e.g. telemedicine.

Text Messaging. Short Message Service (SMS) or text messaging began in 1992 and consisted of 160 character messages sent between two cell phones. It is a service available for the simple cell phone and smartphone. SMS is a worldwide

telecommunication service phenomenon because the technology is inexpensive and ubiquitous. It has been shown to be more cost effective than phone or mail communication. While the United States has been behind the rest of the world, in terms of text messaging, and one of the few countries to charge for receiving text messages, it is catching up. According to a 2011 Pew Research poll 83% of American adults own cell phones and 73% send and receive text messages. Cell phone owners between the age of 18 and 24 exchange more than 50 text messages daily and would prefer SMS over voice calls.¹⁴ Importantly, minority groups are heavy users of this technology as well.¹⁵

Text messaging has been utilized to help solve multiple healthcare issues worldwide. In general, SMS use in healthcare falls into the following categories:

- Appointment reminders. Several international studies have shown improved outpatient clinic attendance with text

messaging, compared to no reminder or other technologies.¹⁶⁻¹⁷ A systematic review of telephone (manual) and SMS (automated) reminders to improve attendance at hospital appointments reported moderate improvement with both manual and automated reminders.¹⁸

- **Education.** A variety of educational programs have been well received, such as Text4Baby to educate pregnant mothers and SEXINFO that provides sexual health messages to teenagers.¹⁹⁻²⁰
- **Disease management.** SMS has been shown to improve chronic disease management for diabetes mellitus and asthma.²¹⁻²²
- **Behavior modification.** Text messaging has been successfully used for smoking cessation reminders to improve quit rates.²³
- **Medication compliance.** According to Manhattan Research, 49% of ePharma consumers would be interested in email or text reminders for medications and refills.²⁴ One study showed a very significant improvement in compliance with HIV medications after receiving text messages.²⁵
- **Laboratory results notification.** SMS has been used to notify patients and physicians about lab results. One study showed much quicker time to treatment for patients with chlamydia (sexually transmitted infection), when notified by SMS.²⁶ A second study showed a much faster clinical response time to an elevated serum potassium using SMS.²⁷
- **Public Health.** Text messaging is a new and interesting approach that can be used by local, state and federal public health programs worldwide. For instance, the Seattle and King County Public Health department is exploring the use of SMS to notify patients for emergencies and routine issues such as immunization reminders.²⁸ In 2009 The Centers for Disease Control and Prevention (CDC) embarked on a SMS project to send alerts to patients in the United States covering topics in general health, as well as emergency preparedness and response. A subscriber enters their age,

gender, role and zip code and they receive tailored messages weekly and can alert users in that zip code about public health emergencies.²⁹ A HHS Text4Health Task Force released recommendations to leverage text messaging to improve US health in September 2011.³⁰

Because individuals in most developing countries own a cell phone and not a smartphone they utilize as many features of voice communication and SMS as possible. The 2009 report by the United Nations and Vodafone Foundations *mHealth for Development* stressed the following objectives using this technology: increase access to healthcare, particularly remote populations; improve ability to diagnose and track illness; provide more actionable public health information and expand patient education and training of health workers.³¹ It should be kept in mind that the majority of SMS studies reported were small pilot projects and not randomized controlled trials. Therefore, the results should be considered preliminary.³² The info box below shows an example of mobile technology projects in Mexico.³³

There are simply too many health-related text messaging initiatives internationally to mention, so readers are referred to these additional resources³⁴⁻³⁶ and the chapter on public health informatics.

Medical software categories for patients.

In this section and the following section categories of medical software are mentioned that are located in the Apple iTunes App Store and Google Play because the vast majority of apps, popular with patients and clinicians are located there. While it is known that thousands are available for download and the download statistics, it is not known how many are regularly used and their actual impact on behavior or patient outcomes. Software is also available for the iPad and Android tablets, but the app choices are not as extensive. The tablet device is clearly superior when a larger field of view is required.

Mexico mHealth



CardioNET is a text messaging service to remind patients to diet and exercise as obesity is a national issue. It also provides a cardiac risk assessment tool.

VidaNET (LifeNET) is a network to educate and remind HIV patients about their illness and the importance of appointment, medication and lab testing compliance.

DiabeDiario is their most recent and ambitious mobile technology project to tackle diabetes that affects 10% of Mexicans. It will combine web, email and text messages to monitor and treat diabetes.³³

Table 11.3: Medical software categories for patients and examples (AS = Apple App Store, GP = Google Play)³⁷⁻³⁸

Software Category	Examples	Functionality
Connect with healthcare system	Group Health (AS,GP)	Patient portal to check on appointments, lab results, etc.
Personal health record	MobiSecure (AS, GP) GenieMD (AS)	Mobile PHR platform that backs up to the cloud
Telemedicine	Skype Mobile American Well Consult a Doctor	With forward facing camera video-teleconferencing is possible for virtual visits
Medication reminders	MedCoach (AS)	Medication and refill reminder. Can connect to your pharmacy
Fitness coach	RunKeeper (AS, GP)	Tracks activity and fitness
Mind fitness	Brain Trainer (AS)	Cognitive training
Immunization guides	Shots 2011(GP)	Guide for what immunizations are needed based on age and gender. Other important info.
Disease management	Diabetes Manager (AS), iHealth BPM (AS)	Monitors meals, blood sugar and insulin doses Blood pressure cuff or weight scale sends results to iPhone/iPad
Prevention guide	AHRQ ePSS (AS, GP)	Guide for national recommendations for preventive care based on age, gender, smoker, etc.
Diagnostic	MelApp (AS)	Phone camera takes picture of skin lesion and estimates risk of malignant melanoma
Vital sign monitoring	SecureFone Health (AS, GP)	Dashboard of vital signs (pulse, respirations, activity, body position) transmitted from sensor patch to smartphone or to remote server
Mental Health	BioZen, Breath2Relax, PE Coach, PTSD Coach (AS, GP)	Programs to relieve stress, particularly for deployed or returning military memories

Medical Apps for Healthcare Consumers.

IMS Institute for Healthcare Informatics published a monograph that provided an excellent summary of the current status of apps aimed at healthcare consumers. Out of 40,000 apps available, 16,275 were deemed consumer oriented. Forty-seven percent were free apps. In terms of demographics-specific apps, 50% were for women's health, 48% children's health and 2% senior health. In terms of app function taxonomy: 66% informed, 36% instructed, 31% recorded, 14% displayed, 9% guided, 8% reminded and 2% communicated with physicians. Further breakdown revealed that 8786 apps dealt with healthy lifestyle, 304 were related to self-diagnosis, 931 related to locating a physician or facility, 562 were education oriented, 200 dealt with prescriptions and 225 assisted compliance.³⁹

Enterprise integration. It is not surprising that both the Mayo Clinic and Kaiser Permanente offer smart phone apps for a better consumer experience. In the case of the latter healthcare system, use of the app (Kaiser Permanente) allows access to the electronic health record (allergies, immunizations, lab results, current conditions and medications), pharmacy (status of a medication order), appointment center, message center (to communicate with the physician) and facility search engine.³⁸

Mobile Technology and Clinicians

Devices. Routine cell phones and clinicians will not be discussed, although there are few initiatives that use text messaging to alert physicians. As previously defined, smartphones have an operating system that allows medical software to be installed. Additional capabilities include phone service, e-mail, internet access, calendars, contact lists, task lists, cameras and video capability. Synchronization to a computer can be by Bluetooth, WiFi, USB connection or even via the cloud with apps such as Evernote or via features built into the operating system such as Apple's iCloud on iOS. Touch screens and

speech recognition have made data entry easier, compared to a stylus. Security concerns and access controls can be handled via biometric readers such as the integrated fingerprint scanner on the iPhone 5s. Internal memory is no longer an issue with smartphones because most have slots for mini SD cards, available in the 1 to 64 GB range. Physicians who may have carried a pager, cell phone and PDA can have a single multi-purpose device to receive routine phone calls, text messages or voice mails. Moreover, with much faster internet access one can anticipate more interest in using smartphones to e-prescribe, access online resources, access EHRs, access images and many more functions.

More web sites are producing mobile versions of their web sites to accommodate the smaller screen size of most smartphones. Web sites can detect the browser version requesting a page from the server, and can redirect the browser to a mobile-only page or use style sheets made specifically for the mobile platform to display the content in a more compact and easier to browse manner. In addition to layout changes for these platforms, support for the touch screen, camera and additional hardware on a smartphone can be leveraged by mobile versions of the sites.

Tablets, particularly the iPad, have been implemented by many clinicians and healthcare organizations. The tablet is being used in offices and in the hospital to access the Internet and the electronic health record. Many EHR vendors offer a specific iPad software package for clinicians.

AmericanEHR conducted a late 2012 study based on 846 clinicians to determine the utility of tablet devices for those who also adopted an EHR. About one third of EHR users used a tablet in their practice but only one third were satisfied with their tablet and applications. The top ten tablet apps were: Epocrates, Medscape, UpToDate, MedCalc, Skyscape resources, doximity, Micromedex drug, Lexicomp, QXMD Calculate and AHRQ ePSS. The most common activity was sending and receiving emails (73%), accessing EHRs (70%) and researching medication information (68%).⁴⁰

With the inception of the iPad 3 in 2013 there is better screen resolution, an iSight camera and HD 1080p video recording capabilities. Several recent studies shed some light on the use of iPads in the academic setting. Patel et al. studied the impact of iPads on internal medicine resident efficiency. Their study of 115 residents suggested improved subjective and objective efficiency when the mobile device was used to enter orders into their EHR.⁴¹ A second study evaluated the expectations and perceptions of iPad implementation in 2010 by residents at the same academic center. They concluded that most residents believed the use of the iPad was worthwhile but didn't always live up to

expectations.⁴² Another study of outpatients at one academic medical center reported overwhelmingly positive feedback on the use of tablets in the exam room.⁴³

Medical Software categories for clinicians. Table 11.4 categorizes popular medical software programs that are free or fee-based that can be obtained from the Apple App Store or Google Play and provides examples of each category. This list is not intended to be exhaustive as both stores have thousands of health, fitness and medical software programs listed. The Apple App Store lists which apps are available for the iPhone, iPad or both.

Table 11.4: Medical software categories for clinicians and examples (AS = Apple App Store, GP = Google Play) ³⁷⁻³⁸

Software Category	Examples	Functionality
Drug information	Epocrates (AS, GP), Epocrates Bug and Drug (AS, GP), Medscape Mobile (AS, GP), Mobile Micromedex (AS, GP)	Extensive drug library, drug interactions, pill ID, disease reference, calculators, etc.
Calculators	MedCalc (AS, GP), Archimedes (AS, GP), Calculate QxMD (AS, GP)	Perform multiple common calculations used by most physicians
	Framingham risk scores (AS, GP)	Calculates 10 year risk of heart disease based on risk factors
	ABG Interpreter (GP),	Blood gas interpretation
	Infusion rate (GP)	Calculates IV infusion rates
Database programs	HandBase (AS, GP)	Relational database
	GoCanvas (GP)	Mobile forms with geolocation that back up to server
Immunization guides	Shots 2011(GP)	Guide for what immunizations are needed based on age and gender. Other important info.
Medical resources	5 Minute Clin. Consultant (AS, GP)	Covers 715 topics succinctly

Software Category	Examples	Functionality
	Sanford Guide (AS, GP), Johns Hopkins Guide (AS, GP)	Popular guides to direct care for infectious disease
	UpToDate (AS, GP), DynaMed (AS, GP)	Extensive resources covering most sub-specialties
	iCXR (AS)	Chest x-ray educational resource
	Heart EKG Guide (AS, GP)	EKG educational resource
	Derm101: Point of Care	Dermatology resource
	LabDx (AS), Pocket Lab Values (AS)	Laboratory results resources
	Procedures Consult (AS)	Procedures resource by specialty
	mTBI Pocket Guide (GP)	Pocket resource for TBI
	Relief Central (AS, GP)	Extensive resource for relief workers
	WISER (AS)	Hazardous material responder resource
Prevention guide	AHRQ ePSS (AS, GP)	Guide for national recommendations for preventive care based on age, gender, smoker, etc.
Diagnostic	Eye Chart Pro (AS)	Electronic eye chart
	iExaminer (AS)	Uses iPhone plus hardware to take pictures of retina
	Diagnosaurus (AS, GP), uChek (AS)	Search 1,000+ differential diagnoses Urinalysis testing with smartphone app
	ThinkLabs Stethoscope (AS) Mobisante Ultrasound (AS)	Digital stethoscope Portable ultrasound
Sensor	Masimo iSpO2 (AS)	Pulse oximetry
Image viewer	Resolution MD Mobile (AS)	Mobile access to image server
	Mobile MIM (AS)	Mobile image viewer that can be used by radiologists
Journal	BMJ (AS), Chest (AS), NEJM (AS, GP)	Provides access to major medical journals, podcasts and videos

Software Category	Examples	Functionality
Medline search	PubMed Mobile (AS, GP)	Mobile means to access Medline
Monitoring	AirStrip OB, AirStrip Cardiology (AS, GP) AliveCor Heart Monitor (AS)	Mobile views of multiple physiologic parameters
Coding	MD Coder (AS, GP), Hospital Rounds (AS), E/M Code Check (AS)	Charge capture apps
Medical translator	Medibabble (AS)	Translates history and physical exam elements in five languages
EHR access	Epic Haiku (AS, GP), Quest360 mobile (AS)	Mobile access to EHRs
Telehealth	Online Care Mobile (AS) Consult a Doctor Skype Mobile (AS, GP)	Mobile means to access American Well's Online Care Suite for e-visits Can be used for virtual visits
Dictation	Dragon Dictation (AS, GP)	Mobile means to dictate
Remote data collection	Canvas (AS, GP) doForms	User can create a mobile form or select from multiple health related templates

mHealth Developed Countries. By and large, what has been presented in this chapter represents standalone solutions and applications. That is likely to change as more healthcare organizations and clinicians adopt mobile technology and security issues are adequately managed. As mobile electronic devices, such as the iPad improve, it is likely they will become the platform of choice for the exam room and hospital rounding. This will be influenced by comprehensive integration with the healthcare system's EHR, lab and radiology information systems, financial systems and data warehouse. It will also be influenced by better voice recognition to augment the touch screen and integration with technologies that provide real-time vital sign, cardiac and OB

monitoring.⁴⁴ The field is already seeing enterprise solutions appearing that are, in part, based on a mobile solution and offer charge capture, patient schedules, mobile dictation and clinical results (lab, xray, medications, vitals, office/hospital notes).⁴⁵ The case study iPhysician describes the mobile physician who benefits from mobile technology with enterprise connections.

mHealth Developing Countries. Mobile technology is being used nationally and internationally as part of a variety of healthcare initiatives. mHealth has the potential to empower patients with medical information so they can control their own health and wellness. It also has the potential to connect patients with medical offices and public health which they

Case Study: The iPhysician

A physician uses an iPad to connect to his EHR while seeing patients in the exam room. This same platform displays digital x-rays and other images that are useful for patient education. It's lightweight with long battery life, qualities missing in other mobile electronic devices he has tried. He can easily access medical apps like Epocrates for simple drug related questions, the 5 Minute Clinical Consultant for straight forward issues and UpToDate or DynaMed for more complex medical questions. He dictates into his iPad using voice recognition software. His mobile device helps display anatomical drawings for patients so they better understand e.g. coronary artery disease. He is able to use a digital camera feature to record a large skin nevus he intends to follow closely.

He relies on this same technology when he makes hospital rounds, except now he uses software such as Hospital Rounds to keep track of the patients he sees and intends to bill. Because he is a hospital attending he is credentialed to have access to the hospital EHR and its information systems that now includes real time monitoring of vital signs, EKGs, O2 sats, etc. While making rounds an outpatient calls him to discuss an acute problem and he is able to access office charts on his iPad because his EHR is web-based.

That evening when he returns home he reviews a digital medical newsletter and the latest online issue of the New England Journal of Medicine on his tablet. He receives an email from a very concerned patient and decides to have a virtual visit with the patient using MedFusion and his tablet. After a round of *Angry Birds*, the iPad is set up to charge and he heads to bed.

might not be able to do otherwise. If mHealth programs succeed with increasing access to medical information and care they will reduce costs and morbidity and thus transform medical care. mHealth programs are very diverse and usually deal with epidemiology, chronic disease monitoring and treatment and research usually as part of public health or population health. Most developing countries have an intact telecommunications network for routine cellphone technology. As economic circumstances improve so will the adoption of smartphone technology with its enhanced ability to access the internet and download medical apps. More information about mHealth in developing countries can be found in this reference.⁴⁶

Mobile Technology to Track Health Habits and Physiological Signs

Many of the more popular apps available for the iPhone and Android operating systems have been addressed. In the past two years a variety

of new devices and sensors have appeared that monitor diet, exercise, sleep, heart rate, heart rate variability, respiratory rate, oxygen level, skin temperature, hydration, etc. These could be considered part of the mobile technology armamentarium. Most of these new devices/applications have several features in common:

- They are consumer and not clinician oriented and measure some aspect of health. Some have referred to this personal measuring and tracking process as "Quantified Self".⁴⁷ Users can opt to share their results via social media sites such as Twitter or Facebook.
- Most of the devices communicate with a smartphone via Bluetooth LE (discussed in the chapter on architectures of information systems). This permits the user to see how they performed the same day. The smartphone then uploads data via 3G/4G to a web site dashboard for more long term trends. Alerts and summaries can then be sent back via email to the user.

Smart watches are also appearing on the scene in the 2013-2014 time frame and can measure parameters that display on the watch and/or on the smartphone and later on a web dashboard. For example, the Basis Watch can wirelessly monitor sleep, activity, heart rate, perspiration and skin temperature using a set of wrist sensors.⁴⁸

Multiple other sensors are available for health conscious and tech savvy consumers. The Zephyr BioHarness 3 is one example of a chest harness that measures multiple physiological parameters (acceleration, heart rate, heart rate variability, breathing and location) and can broadcast to a smartphone or record and store offline.⁴⁹

Perhaps the most intriguing device that will appear in 2014 is Scanadu, a tricorder device placed briefly on the forehead (area of excellent blood supply) so consumers can measure heart rate, oxygen level, temperature, EKG, heart rate variability and pulse wave transit time (related to blood pressure).⁵⁰

One company has taken advantage of this new trend by offering the ability to aggregate disparate devices into one dashboard for analysis and trending.⁵¹

While this is a huge step forward, in terms of sensor technology, this new movement raises more questions than it answers. How accurate are these devices? What are the medico-legal ramifications of self diagnosis? Will they secure FDA clearance? Where are the articles in the medical literature supporting this approach? Many of these parameters such as heart rate variability are controversial and not commonly measured by physicians, so how will they be evaluated by patients? Will healthcare organizations and payers support the Quantified Self movement?

Mobile Telemedicine Projects

Electronic Comprehensive **Mobile Health** **Open-Source Application**

(eMocha) is a free open source initiative developed by Johns Hopkins Center for Clinical Global Health Education. The program consists of two components: (1) *Android Os phone*: Uses XML-based forms to collect data in multiple formats (text, pictures, bar codes, audio and video) that is geo-stamped and backed up to a server. eMOCHA can deliver multimedia courses and lectures (MP4 format) that can be accompanied by quizzes on the phone. Phone can be used for voice calls and e-consultations using the phone camera. (2) *Remote server*: Data from the phone is sent to a MySQL database which can also send information to the mobile device such as forms, videos, webcasts and lectures. Data is then available for mining. This platform is currently being used for HIV care in Uganda. In late 2011 an Android app for tuberculosis was released that has a symptom algorithm and educational material.⁵²

Sana Mobile is a similar project developed by volunteers from many departments at the Massachusetts Institute of Technology (MIT). Remote healthcare workers can input data into the phone, including images and they are sent to the EHR OpenMRS where specialists can view the record and respond back to the healthcare worker. Projects are underway with this platform in Africa, Brazil, Greece, India, Philippines and Columbia.⁵³

Recommended Reading

Mobile technology is extremely popular worldwide but it is new enough that research is limited. Most reported studies are small (pilot) studies. That also means they are frequently not randomized or lack a control group so they suffer from a lack of internal and external validity. That being said, the following represent some recent interesting medical articles that evaluate mobile technology.

- *A Systematic Review of Healthcare Applications for Smartphones*. Fifty seven articles discussing 83 applications were presented. The applications were those intended for healthcare professionals

(including medical and nursing students) and patients, covering a wide variety of topics. This review can also serve as a mobile technology resource for the next section.⁵⁴

- *Smartphones More Accurate, Faster, Cheaper For Disease Surveillance.* Kenyan study where surveillance was conducted for influenza using either smartphones or paper. The results suggest more complete data, faster data uploading and lower upfront costs. The authors suggest that smartphones more accurate, faster and cheaper for disease surveillance.⁵⁵
- *Increasing Physical Activity With Mobile Devices: A Meta-Analysis.* Four studies were considered of good quality and seven fair quality. SMS was the primary technology studied, rather than smartphone apps. They concluded that this platform was an effective means to influence physical activity.⁵⁶
- *Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control.* This was a study to see if mobile app coaching and access to a web portal would result in better diabetic control (reduced glycated hemoglobin), compared to usual care over a 1 year period. 163 patients were studied in 26 primary care practices. The mean hemoglobin A1c decline in the intervention group was 1.9%, compared to a decline of 0.7% in the usual care group. No other changes in parameters such as blood pressure or lipids were observed between the groups.⁵⁷
- *Integrating Technology Into Standard Weight Loss Treatment* was a study of 70 type 2 diabetics that were divided into usual care or usual care plus mobile technology (PDA to self monitor diet and activity) and biweekly telephone coaching for six months. The mobile plus group lost an average of 3.9 kg more than the usual care group at one year.⁵⁸
- *Comparison Of Traditional Versus Mobile App Self-Monitoring Of Physical Activity And Dietary Intake Among Overweight Adults Participating In An Mhealth Weight Loss Program.* This study assessed a six month randomized trial of diet and weight loss of overweight men and women using a variety of self-monitoring devices. The physical activity (PA) app users exercised more often and monitored themselves more often and had a lower BMI at the end of the trial. Diet monitoring apps did not result in any greater weight loss, compared to website or paper journal. Study findings limited by the fact it was not randomized, included mainly highly educated individuals and all data was self-reported.⁵⁹
- *How Smartphones Are Changing The Face Of Mobile And Participatory Healthcare: An Overview With Example From Ecaalx.* The authors describe an app created by the European Union funded project known as eCAALX that is intended for older patients with multiple diseases. The Android-based app receives input via a body area network (BAN) from body sensors and GPS and communicates that data remotely to healthcare professionals. They also discuss the known barriers to widespread adoption of similar smartphone apps.⁶⁰
- *Flourescent Imaging of Single Nanoparticles and Viruses on a Smart Phone.* A UCLA team reported in 2013 their success in visualizing nanoscale particles using a small device that utilizes a laser diode and connects to a commercial smartphone. The ultimate goal is the make this attachment commercially available for looking at, for example malaria parasites, in a remote area.⁶¹
- *Clinical Management Apps: Creating Partnerships Between Providers and Patients.* The Commonwealth Fund released this 2013 monograph that discussed comprehensive health apps to support disease management. The examples they used were for diabetes and asthma. It is their premise that well designed apps will

better educate and manage patients and improvement the connection between the doctor and patient.⁶²

- *Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review*. The authors noted that there are over 3000 apps for mental health related problems but few are evidence based. They found only 8 articles in the literature that discussed 5 apps. Two apps were commercially available in app stores. Results suggest that the apps did result in reduction in depression, stress and substance abuse.⁶³

Mobile Technology Resources

- iMedicalApps www.imedicalapps.com
- Skyscape www.skyscape.com
- Downloadable Apps for Mobile Devices. Uniformed Services University. www.lrc.usuhs.mil/local/MobileDevice/devices.html
- mHealthInitiative www.mobih.org
- mHealth Alliance www.unfoundation.org/global-issues/technology/mhealth-alliance.html
- Management and Security of Health Information on Mobile Devices www.ahima.org
- Mobilehealthnews www.mobilhelalthnews.com
- Wireless Healthcare www.wirelesshealthcare.co.uk

Mobile Technology Challenges

Smartphones and tablet computers were not initially intended to replace PCs or laptops, in spite of their impressive evolution. However, with better performance, more features, longer battery life, better input methods, to include portable keyboards, this is no longer the case. As with all technologies, there are universal

limitations that need to be intelligently managed:

- Cost is a factor, but in spite of the initial charge for hardware and the monthly data charges, healthcare workers are purchasing smartphones and tablets in large numbers.
- Technical:
 - Inputting information is slow but improving constantly with technologies such as voice recognition and pattern recognizing soft keyboards.
 - Small screen size is an issue for smartphones but not tablets so clinicians are likely to own both, unless they converge in the future.
 - Interoperability is an issue but most medical software is now available for multiple platforms.
- Security will always be an issue so additional protection, such as encryption is necessary. Integrated biometrics will aid in this area. Mobile devices may carry confidential personal and/or corporate information. In addition, spyware and malware may occur on mobile devices and mandate appropriate anti-viral software, encryption software, etc. Employers have to develop bring your own device (BYOD) policies for privacy and security because so many workers use their smartphone for business and personal reasons at work.
- Regulatory. The Food and Drug Administration (FDA) has jurisdiction over “devices” and it therefore released guidance on mobile medical apps in September 2013. They are only interested in regulating mobile medical applications that might impact patient safety, such as an EKG app that gives misleading information. A mobile medical app is defined as an application “to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device”. In Appendix C of their guidance they provide further details and examples. In 2013, roughly 100 medical apps were cleared

as medical devices. Class I medical devices are associated with minimal risk such as bandages. Class II devices have mild potential risk such as powered wheelchairs. Class III medical devices support or sustain life, such as pacemakers.⁶⁴ It is possible that other countries will follow suit and release similar guidance. In the same time frame the FDA released the unique device identification (UDI) for medical devices. Most medical devices will be required to have a unique number that should help with reporting problems and issuing recalls. A master database will be created that will be searchable for device-related problems. A timeline for implementation of UDI is listed on the FDA web site.⁶⁵

While medical specialties will not likely regulate medical apps, they may make recommendations based on the sheer volume of apps being released. For example, in 2013 it was reported that there were 229 dermatology-related apps available that were free or fee-based.⁶⁶ How many of these apps are accurate and reliable? Will they be updated to reflect new knowledge in the field and be vetted by medical experts?

The United Kingdom has chosen to create a Health Apps Library so they can make recommendations and narrow the field.⁶⁷ In the United States at least two organizations have begun the process of vetting apps and making recommendations.⁶⁸⁻⁶⁹

In spite of the lack of proof that mobile technology improves patient outcomes or

significantly impacts clinician productivity, this has not stopped many clinicians from embracing new mobile technology. Better research is needed to objectify the use of mobile technology

Future Trends

Mobile technology is extremely popular in developed and developing nations, based on its pervasive nature, convenient form factor, affordability, expanded applications and scalability. A myriad of smartphone and tablet applications (1 million+) are available for patients and clinicians alike. Integration with electronic health records and other hospital information systems is already occurring. New uses for mobile technology in healthcare are arising at an unprecedented rate. Large US federal institutions such as the Department of Defense and the Department of Health and Human Services have developed and released smartphone apps.⁷⁰⁻⁷¹ As new peripheral devices are adapted and integrated with smartphones one can expect innovations heretofore never conceived. Similarly, tablet PCs may become the medical mobile platform of choice for clinicians in exam rooms and on hospital rounds. Already, several EHR vendors offer their software on mobile platforms.

One can also expect mobile technology to get smaller, faster, less expensive and be better integrated in the near future. Patient and clinician apps will continue to proliferate. Telemedicine will likely expand remote delivery of care using mobile technologies.

Key Points

- Handheld technology has moved quickly from personal digital assistants (PDAs) to smartphones and tablets
- This is the era of mHealth where mobile electronic devices will be employed to assist in healthcare worldwide
- Multiple medical software programs are available for mobile platforms that are free, shareware or fee-based
- Healthcare is starting to see enterprise level integration of mobile technology so interoperability is becoming less of an issue

Conclusion

Mobile technology continues to improve and gain popularity in the medical profession worldwide at an amazing pace. Mobile technology is being used for storing medical information, telephonic communication, patient monitoring and clinical decision support. In the not too distant future, it will likely be used commonly for geo-location of patient populations and disease, and connectivity to electronic health records and other hospital networks. Smartphones have replaced PDAs, as processor speed, memory, network access and multimedia features continue to improve. Interest in smartphones will continue to increase due to more medical and non-medical applications developed, as well as evolving 4G

recognition has improved to the degree that it may become a prominent means of inputting for mobile devices in the not too distant future. Competition among the various operating systems is intense, driving functionality up and cost down. However, mobile technology has definite limitations and further research is needed to determine their actual impact and place in the armamentarium of most physicians. An excellent review *How Smartphones Are Changing Health Care for Consumers and Providers* by the California HealthCare Foundation appeared in 2010 that addresses the current and future state of smartphones and mobile technology.⁷²

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Chapter 12

Online Medical Resources

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Learning Objectives

After reading this chapter the reader should be able to:

- State the challenges of staying current for the average clinician
- Describe the characteristics of an ideal educational resource
- Describe the evolution from the classic textbook based library to the online digital library
- Compare and contrast the different formats of digital resources
- Describe the future of digital resources integrated with electronic health records
- Describe emerging Web 2.0 technologies in medicine
- Identify the most commonly used free and commercial online libraries

Introduction

Trying to keep up with the latest developments in medicine is very difficult, primarily due to the accelerated publication of medical information and the significant time constraints placed on busy clinicians. Dr. David Eddy said it best, “the complexity of modern American medicine is exceeding the capacity of the unaided human mind.”¹ It is likely that clinicians are so busy that they have no idea what new educational resources are available to them. They would like to move from the “information jungle” to the “information highway” but who will show them the way? This chapter is devoted to those seeking rapid retrieval of high quality medical information.

Challenges Faced by Clinicians

- Education. More than 700,000 articles are added to Medline yearly.² The 2012 Physician’s Desk Reference (PDR) is over 3000 pages long and its companion volume, PDR Guide to Drug Interactions, Side Effects, and Indications is equally ponderous, making it cumbersome to search for drug information.³ Standard medical textbooks are expensive and out of date shortly after publication. In addition, some argue that the descriptions of diseases are not always updated or evidence based.⁴ A recent analysis of clinical texts maintains that they are poorly organized for learning and tend to focus on severe cases rather than ones clinicians normally handle.⁵ Moreover, Shaneyfelt estimated that a general internist

would need to read 20 articles every day just to maintain present knowledge.⁶ Currently, there is a transition occurring in medical education to prepare practitioners who can find and use information when it is needed rather than to develop physicians who know everything. Physicians find it difficult not to think of themselves as experts and it often shakes their confidence, but new self-reliance can emerge in knowing how to locate needed information. Interestingly, studies show that patients do not lose confidence in physicians who look up information in front of them.⁷

- Diffusion of information. Recommendations from research organizations take time to trickle down to the generalists. There is no standard way to disseminate information that is either reliable or particularly effective. National guidelines, usually written by specialists, face the same challenges. Once there is a new standard of care for a disease such as diabetes, how is it publicized, particularly to small or remote medical practices?
- Translational. Studies have demonstrated that it may take up to ten or more years for research to be “translated” to the exam room (e.g., thrombolytics).⁸ Antman reported that experts were slow to make recommendations in textbooks even though high quality evidence was published many years prior.⁹ On the other hand, physicians are skeptical and wait for confirmatory studies. If they have been in practice for many years, physicians may have witnessed the pendulum sweep back and forth regarding, for example, the use of post-menopausal estrogens. Recent studies often contradict older studies, due in part to better study design and larger subject populations.¹⁰ Perhaps the cautious approach is best understood from a legal perspective. In a paper explaining the FDA’s role in evaluating clinical trials, Junod quotes a physician’s court statement, “The function of the formal controlled clinical trial is to separate the relative handful of discoveries which prove to be true

advances in therapy from a legion of false leads and unverifiable clinical impressions, and to delineate in a scientific way the extent of and the limitations which attend the effectiveness of drugs.”¹¹

- Evolutionary. “Classic medicine” can no longer be taught because diseases and their presentations change over time as demonstrated by new presentations for infectious diseases. For example, Rocky Mountain Spotted Fever started to disappear as Lyme disease began to appear. Additionally, diseases were detected at more advanced stages in the older literature because lab tests were lacking, making clinical presentations more dramatic. Currently, physicians tend to diagnose diseases earlier, before the patient has advanced signs and symptoms, due to better and earlier tests. Medical resources, therefore, must reflect new evidence.
- Retention. Many current studies focus on the cognitive abilities of an increasingly aging population of physicians. On average, a physician’s cognitive performance does diminish with age but with proper individual care, in addition to continuous professional development, aging clinicians will continue to be an effective part of the workforce.¹²
- Accessibility. Google is available to all but search results often lead to articles in journals only accessible by paid subscription. Medical and university libraries purchase these resources and will obtain non owned articles from interlibrary loan for their affiliates. Clinicians not affiliated with these libraries find subscriptions to a wide variety of scholarly sources cost prohibitive. This further inhibits keeping current with medical information.

Patient-Related Questions and Answers

JW Ely has conducted studies over the years that have consistently shown that many questions asked of physicians by their patients go unanswered for the following reasons:¹³⁻¹⁶

- Poorly phrased questions
- Lack of time
- Information not in available resources
- Overwhelming amount of information to search

State of Medical Libraries Today

Medical libraries have traditionally supported the information needs of physicians and other health workers by providing research assistance, subscribing to journals, purchasing books, and borrowing resources from other libraries. Ironically, at a time when health workers are struggling to keep current with the burgeoning amount of information, medical libraries are closing at an alarming rate. In fact, between 1989 and 2006, budget cuts in hospitals and the dilution of standards from the Joint Commission for the Accreditation of Healthcare Organizations relating to hospital libraries led to the closure of 40% of medical libraries in the U.S.¹⁷

Existing medical libraries currently provide much of their information online (over 90% of journal subscriptions and 26% of books are purchased in electronic formats).¹⁸ This prompted the observation by Lee in an article entitled, “Quiet in the Library,” that describes the lack of physical presence in libraries.¹⁹ Physicians, clinicians, and other health workers are able to obtain information wherever they have computer access and are not compelled to go to a library unless they want to take advantage of its study areas, collaborative rooms, and computer workstations.

Medical librarians, facing a diminishing role due to library closures and online availability of resources, have diversified their services to include managing electronic resources and providing user instruction. In 2000, the term “informationist” was coined to describe a hybrid of medical librarians and clinicians who would have medical knowledge and research capabilities.²⁰ However, in 2008, a review of the library literature showed little adoption of the concept. New directions that have proven more feasible include embedding librarians in medical teams as research assistants and adding them as contributors to evidence based resources.²¹⁻²⁴

Evolution from Traditional Library to Online Resources

In 1985, Covell identified the following print resources used by physicians to locate medical information in support of diagnoses and prescriptions:²⁵

- Medical journal articles
- Drug information textbooks
- Medical textbooks
- Self-made compendia

Historically, relevant medical journal articles were discovered primarily by using Index Medicus and Cumulative Index to Nursing and Allied Health Literature (CINAHL). These print indexes provided citations to articles that would then need to be found in journals from libraries or through individual subscriptions. In the mid to late 1980’s these indexes, among others, were transformed into fee based dial-in databases. Usually, librarians conducted dial in searches on behalf of their patrons because the logins, protocols and terminology were specific to each database and the cost per minute of searching was high. Eventually, databases were mounted on CD ROMS, which had no time or cost restraints. CD ROMS were physically available in libraries and permitted end user searching. However, these online resources were still only indexing tools and the full text articles they identified remained available through subscriptions to print journals.

The advent of the Internet revolutionized information access and accelerated the transition of print indexes and journals to online formats. Medline (the online version of Index Medicus) and CINAHL offer Boolean searching, linking to full text articles by link resolvers, date limiters, and citation searching. Not only were these resources available to end users, they were accessible from any location.

Two types of online journals emerged: the electronic version of the print journal and the born-electronic journal. Each type can be either open access (free to all users) or available by subscription. Many online journals have their own web pages that display current tables of

contents, full text articles, archival holdings, searching capabilities, and other features.

Libraries subscribe to database and journal resources in consortia deals among groups of libraries and by licensing arrangements with vendors or aggregators. This has resulted in offering researchers more extensive holdings than any individual library was ever able to provide in print. For example, just one vendor, Science Direct, contains over 3251 journals and 11,693 books, all of which are searchable and many of which have full text availability.

A current development in information retrieval is the metasearch, which uses Google as a model with its simplicity and far reaching scope. Ebsco's product, named "OneSearch," retrieves results from a variety of databases with links to full text resources if they are available. Results may be filtered by date, location, format (book, magazine, academic journal), etc. A search for *aspirin and colorectal cancer* in OneSearch yielded the following results (Figure 12.1)

Figure 12.1 OneSearch

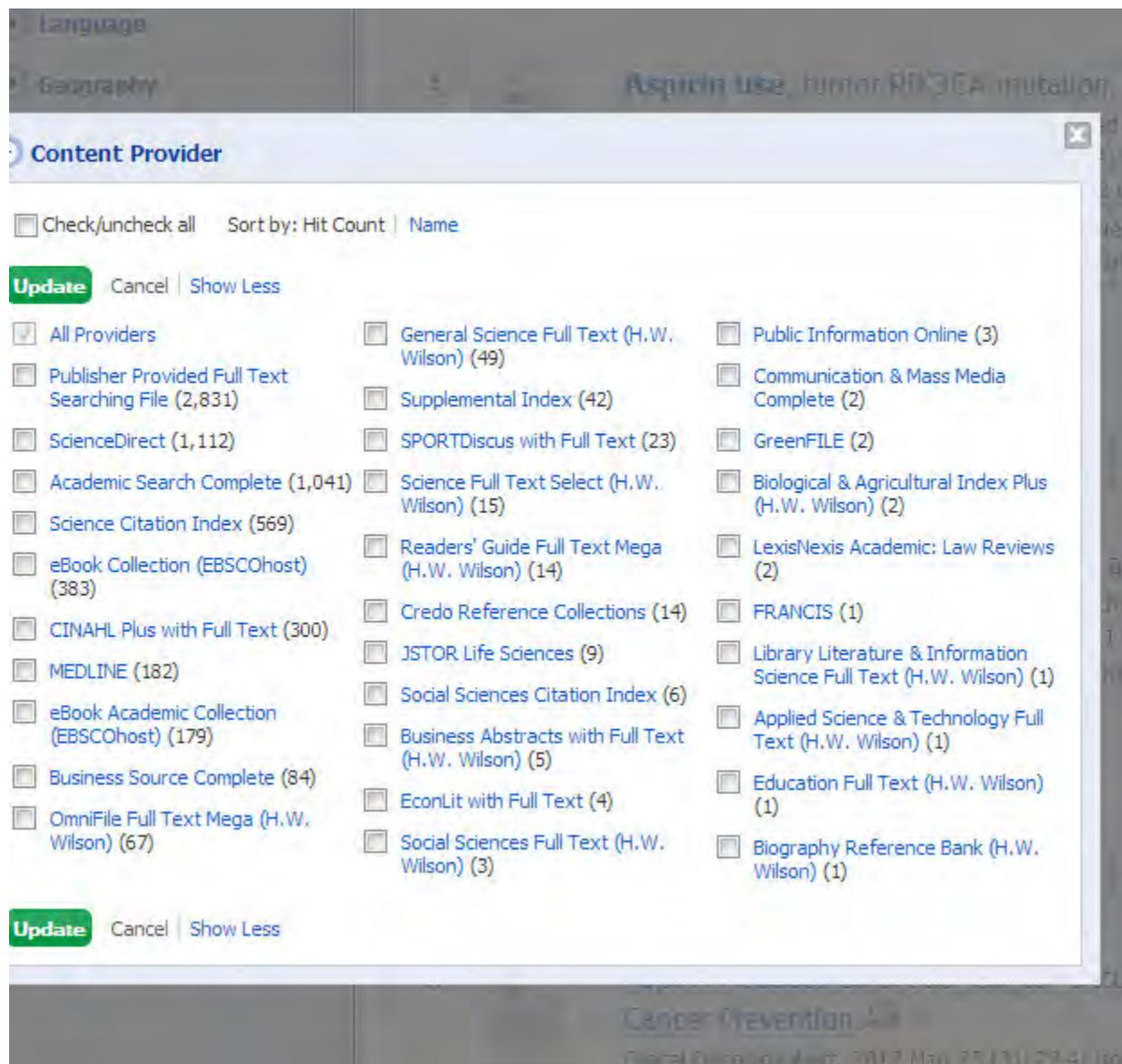
The screenshot displays the OneSearch interface with the following components:

- Search Results Summary:** 6,948 Results for... Boolean/Phrase: aspirin use AND colorectal cancer.
- Expanders:** A checkbox option to "Also search within the full text of the articles" is checked.
- Refine your results:**
 - Linked Full Text:
 - Scholarly (Peer Reviewed) Journals:
 - Available in Library Collection:
 - Publication Date: Range from 1977 to 2013.
- Source Types:**
 - All Results:
 - Academic Journals (5,195):
 - Books (697):
 - eBooks (562):
 - Magazines (450):
 - News (46):
- Subject:** A dropdown menu is visible at the bottom left.

The search results list three items, each labeled "Academic Journal":

- 1. Use of aspirin post-diagnosis in a cohort of patients with all-cause and colorectal cancer specific mortality.** (includes abstract) McCowan, C.; Munro, A.J.; Donnan, P.T.; Steele, R.J.C.; 1049-57. (journal article - research) ISSN: 0959-8049 PMID: 23182687. Subjects: Aspirin; Colorectal Neoplasms; Colorectal Neoplasms; Aged: 65+ ye. Database: CINAHL Plus with Full Text.
- 2. Use of aspirin post-diagnosis in a cohort of patients with all-cause and colorectal cancer specific mortality.** (English) ; Abstract available. By: McCowan C; Munro AJ; Donnan PT; Steele England: 1990 [Eur J Cancer], ISSN: 1879-0852, 2013 Mar; Vol. 49 (5), p. Subjects: Scotland; Aspirin therapeutic use; Carcinoma drug therapy; Carci therapy; Colorectal Neoplasms mortality; Adult: 19-44 years; Aged: 65+ ye years; All Adult: 19+ years; Female; Male. Database: MEDLINE.
- 3. Use of aspirin post-diagnosis in a cohort of patients with all-cause and colorectal cancer specific mortality.** By C. McCowan; A.J. Munro; P.T. Donnan; R.J.C. Steele. In *European Jour* 10.1016/j.ejca.2012.10.024. Subjects: Aspirin; Colorectal cancer; Survival. Database: ScienceDirect.

Figure 12.2 Multiple Database Search Results



The results from multiple databases are tabulated for the researcher to discover the most relevant databases (Figure 12.2).

Like indexes and journals, print reference materials, drug handbooks and medical textbooks have migrated to the web. To access the most authoritative information in journals, databases and other medical resources, a researcher still needs to be affiliated with a medical library or be willing to read premium medical content on a subscription or pay per view

basis. In addition to including authorized (and often costly) resources, the Internet is a limitless source of free unedited information, much of which is unreliable. Information literacy has superseded information gathering as a vital research skill. Or, as Davies expresses it in a literature review of the information seeking behavior of British doctors, "...the range of resources available is huge and the challenge is in resource selection as much as skills in using the resource itself."²⁶

In 1994, Shaughnessy stated that the usefulness of medical information is equal to the relevance multiplied by validity and divided by the amount of work to access it.²⁷ A 2004 study in the journal *Pediatrics* comparing retrieval of information from online versus paper resources reported that it took eight minutes to find an answer via an online resource as compared to twenty minutes using traditional paper-based resources.²⁸ There is little doubt about the tremendous potential of online resources for speed of access, but the quest to find the precise, authoritative answer to a clinical question within the limitations of a patient visit remains elusive. Turning to resources of known quality appeared to be an efficient choice, so converting traditional resources to online formats was the logical first step.

Harrison's Online (the online version of *Harrison's Principles of Internal Medicine*, 18th edition) and Scientific American Medicine (now known as ACP Medicine) were among the first online full-text resources. The online versions of these popular textbooks are continually updated and accessible from anywhere. Many libraries offer online access to these textbooks and individuals may purchase subscriptions to the online versions at about the same cost as print textbooks. Recent online versions offer a variety of subscription options and present their content through several portals. The print edition of *Harrison's Principles of Internal Medicine*, 18th edition, published in 2011, offers supplementary material on DVD and uses RSS feeds and podcasts to disseminate its updates. Although these textbooks make valuable expert knowledge easily accessible, they tend to cover only the basics about any subject and therefore lack depth. In spite of the fact that they have a search engine, like a standard textbook, a reader may have to review multiple book chapters to find the answer.

Increased availability of online resources has led to the development of comprehensive aggregated resources that offer books and journal articles, patient education materials, medical calculators and medical news in one product. Examples

of these aggregators are MDConsult, Medscape, Stat!Ref, and OVID. Searches of these excellent resources yield multiple references to the full-text of various documents that must be analyzed to find the answer to the clinical question. This is not ideal if one is seeking an answer while the patient is still in the exam room or during hospital rounds. Surveys of information searching behaviors report that doctors "forage" for information by quickly switching between sources of information to maximize their search success within a limited time.²⁹ Nurses rarely use medical databases and medical journals at all, preferring instead to rely on colleagues for advice or follow pre-established guidelines.³⁰ These observations support Richard Smith's theory that the "best information sources provide relevant, valid material that can be accessed quickly and with minimal effort."³¹ Thus, for most health workers, ideal medical resources are those that are:

- Evidence based with references and level of evidence (explained in the chapter on evidence based medicine)
- Updated frequently
- Simple to access with a single sign-on
- Available at the point of care
- Capable of being embedded into an electronic health record
- Likely to produce an answer with only a few clicks
- Useful for primary care physicians and specialists
- Written and organized with the end user in mind

The need for a synthesized resource that can easily provide evidence based answers to questions during the patient visit has given rise to several excellent, focused tools, often referred to as point of care or bedside information products. Examples of these resources are UpToDate, eMedicine, DynaMed, ACP-PIER and FirstConsult. They present their content so that clinicians can rapidly answer medical questions with current, comprehensive information. All these products focus on patient-oriented information but they differ in the number of topics covered, the way the

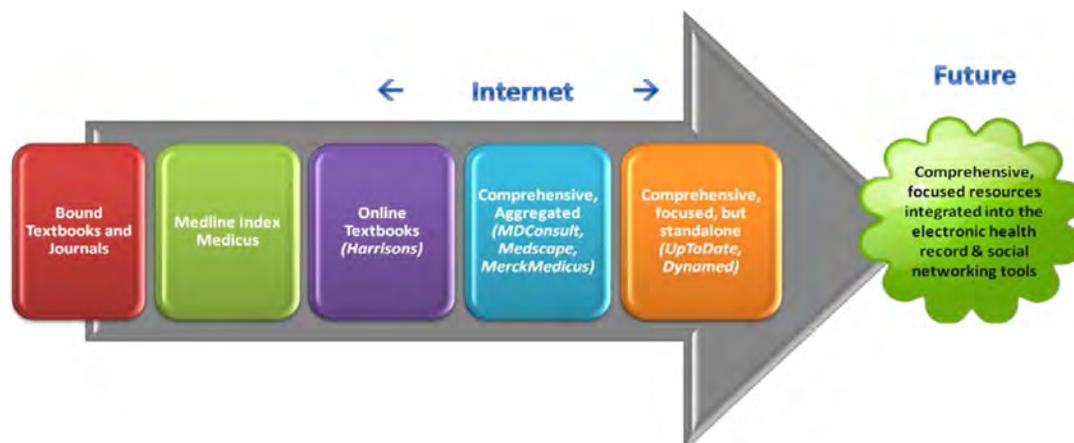
evidence is documented, and how the material is organized. Clinicians develop their preferences among these products based on user interfaces and the ability of the database to answer questions. In an evaluation of five bedside information products, Campbell and Ash took a user-centered, task-oriented approach to test their ability to answer clinical questions. One study rated UpToDate the highest in ease of interaction, screen layout and overall satisfaction, and found that users were able to answer significantly more questions quickly using this product³²; however, other researchers determined that users prefer resources such as ACP Pier and Essential Evidence Plus for the way in which evidence levels are documented.³³ A 2004 study showed that 85% of medical students easily transitioned from traditional resources to primarily online medical resources such as UpToDate and MDConsult.³⁴ In a report published in 2005, internal medicine residents were able to find answers 89% of the time and the information changed the way a patient was managed 78% of the time. Overall, the most often used resources were UpToDate and PubMed.³⁵

Use of these point-of-care tools begins with a diagnosis. In a controversial article in *BMJ* Tan

and Ng³⁶ reported that Google could function as a useful diagnostic aid whereas others argue that tools such as the new generation of clinical decision support systems are more appropriately designed to improve medical diagnosis and reduce diagnosis errors by directing physicians to the correct diagnosis. Although clinical decision support systems have been around for years, the new generation of tools as exemplified by *Isabel* (Isabel Healthcare), presented the correct diagnosis for approximately 96% of adult patients when tested with 50 consecutive internal medicine case records published in the *New England Journal of Medicine*.³⁷ Tools like *Isabel*, by assisting the physician in making the diagnosis, provide an entry point into the literature and link clinicians to resources such as UpToDate, PubMed among others in order to obtain in depth information for specific cases.³⁸

Several medical resource vendors are in the process of making the leap towards embedding resources into electronic health records. Examples of these enhanced products include iConsult, Dynamed, UpToDate and ACP PIER. Figure 12.3 demonstrates the evolution from the traditional library to the online library and integrated libraries into electronic health records.

Figure 12.3: The evolution from traditional to online medical libraries



New Tools to Stay Abreast of Ever-Expanding Online Library

Many of the information resources described above mirror print publications and are written and designed to be read as questions arise. Lee mentions that the flood of new information and the demands of simply getting through the day have become so overwhelming that many physicians no longer find the time for 'lifelong learning' through such activities as reading journals or attending grand rounds.¹⁹ To keep their medical practice current, physicians need help to make the most efficient use of their limited researching time. Fortunately, a new dimension of interactive web technologies, known as Web 2.0, has emerged that permit users to create, share, and communicate knowledge.³⁹ The dynamic nature of the information provided in these resources has the advantage of being very recent but because information may be derived from a variety of sources, content must be reviewed for accuracy and reliability.⁴⁰ Examples of technologies that facilitate generating, sharing, receiving, and commenting on medical information are:

- Weblogs or blogs – web sites that build content through dated entries. There are hundreds of medical blogs that have generated large repositories of focused medical content.⁴¹ Some of the best known are KevinMD, Cases Blog, and Clinical Cases & Images.
- Wikis (the name comes from the Hawaiian word meaning quick) – sites that allow collaboration to create peer-reviewed resources by participating users. The most famous general example is Wikipedia. Many medical wikis are available including WikiDoc and Ganfyd.⁴² WikiDoc, a collaborative online textbook, boasts over 107,537 textbook chapters and continuously updated medical news articles.⁴³ Ganfyd, “a free medical knowledge base that anyone can read and any registered medical practitioner may edit,” only allows

credentialed individuals to provide content.⁴⁴

- RSS - Really Simple Syndication (RSS) alerts researchers to changes in websites. RSS allows physicians to request content from various websites to read in a single place, known as an aggregator. Initiating this feature requires subscribing to an aggregator like MedWorm or Bloglines and identifying the RSS icon (). Physicians use RSS to receive textbook and website updates, Pub Med search results, journal tables of contents and medical news.
- Audiocasts (podcasts) and videocasts - educational programs in multi-media formats. An exciting new development in continuing education is the availability of the Open Courseware Consortium,⁴⁵ a collaborative effort among universities that permits users to access lectures and classes for no credit. TedTalks is another valuable source of succinct lectures on a variety of topics.⁴⁶ To access multiple podcasts one will need to subscribe to an audio aggregator known as a podcatcher. Podcatcher Matrix will assist the user in selecting a podcatcher that is compatible with one's operating system and mobile device.⁴⁷
- Social Networking – Facebook, Twitter, social bookmarks, tags and tag clouds are all used by health workers to actively exchange information. Social media is accessible to a large number of users, which creates a vehicle for widely spreading information about health issues and promoting interactions with others.⁴⁸

There has been a dramatic increase in the use of these innovative technologies because of their immediacy, flexibility, and accessibility. However, the open nature of these sites has raised concerns in the medical community, which led to the publication of a recent paper recommending guidelines for using these resources.⁴⁹

Sponsored Medical Web Sites

Multiple sponsored or fee-based web portals are available. Most of the sites discussed in this section have features that continue to improve. Medical education was traditionally based on reading journals or textbooks, but can also involve the presentation of interesting and unique cases. A thorough discussion of this alternative approach appeared in the February 2007 Mayo Clinic Proceedings.⁵⁰

E-meducation (www.emeducation.org)

- Free medical portal sponsored by Alfa Institute of Biomedical Studies
- Links to open access resources
- Filtered to ensure high standards
- Includes videos, cases, photo banks
- Medical search engine
- RSS news from journals and organizations
- 10+ specialties⁵¹

Medscape (www.medscape.com)

- A free all-purpose medical web site sponsored by WebMd
- Covers 30+ medical specialties as well as sections for nurses, medical students, dental professionals & pharmacists
- Over 150 Resource Centers
- Provides updates, continuing medical education (CME), conference schedules, Medline, drug searches and multiple specialty articles and an eclectic selection of journal abstracts
- Daily medical news and weekly newsletters and updates (MedPulse) and Best Evidence; both are features unique to Medscape
- Drug and Device Digest providing the latest in alerts and approvals; helpful for patient safety concerns
- A free personal web site option
- Dermatology atlas
- Clinical practice guidelines and Cochrane connection
- Sponsored by advertising⁵²

MerckMedicus (www.merckmedicus.com)

- Free portal sponsored by Merck and Company customizable for 20 specialties
- Designed for health care providers (state health professional license required for full access)
- 60+ specialty textbooks and 150+ full text journals
- Cochrane Reviews links
- Clinical podcasts
- Includes customized versions of MDConsult and OVID, DxPlain (differential diagnosis engine from Harvard), medical news and national meeting reports
- PDR Electronic Library
- Patient handout
- Unique 3-D Atlas of the human body
- Professional development using CME, board reviews, medical meetings, medical school links and Braunwald's Atlas of Internal Medicine (1,500 slides can be copied). Also, a slide image bank of other slides that can be copied
- PDA portal, formatted for use with Palm or Pocket PC, includes news, the Merck Manual, Pocket Guide to Diagnostic Tests, and TheraDoc antibiotic assistant for PDA
- Journal abstracts and the ability to do a Medline search.⁵³

Amedeo (www.amedeo.com)

- Free medical literature guide sponsored by Boehringer Ingelheim
- This service will search major medical journals for a topic one selects and then e-mail the results every week.
- Weekly webpage alerts displaying abstracts of selected journal tables of contents linked to PubMed
- Covers about 100 topics falling into 25 specialties
- Related websites include Free Books 4 Doctors www.freebooks4doctors.com and Free Medical Journals www.freejournals4doctors.com
- Similar tracking of articles also available through Google Alerts and NCBI (Pubmed)⁵⁴

Mayo Clinic (www.mayoclinic.org)

- Free multi-faceted web portal, sponsored by the Mayo Clinic
- Part of the portal is designed for medical professionals
- Information about medical developments (called Clinical Updates)
- Mayo Clinic publications
- Video presentations on a variety of health issues (entitled Grand Rounds)⁵⁵

Sponsored and Non-Sponsored Resources**E-medicine (<http://www.emedicine.com>)**

- 6,000 peer-reviewed articles by 10,000 authors covering primary care and multiple sub-specialties
- Owned by *WebMD* and incorporated into Medscape
- Continually updated Clinical Knowledge Base
- Articles are referenced and selectively cross-referenced
- References are presented at the end of each article with links to PubMed, but no footnotes in the text body
- CME available
- Sponsored and institutional version available
- Institutional version is now known as Medscape Reference offers information on drugs, diseases, drug interactions, MEDLINE, anatomy, medical images and a healthcare directory.⁵⁶

Online Epocrates**(<http://www.epocrates.com>)**

- A commercial product developed by AthenaHealth
- Online Epocrates was the obvious next step after the successful PDA/mobile software program (see chapter on mobile technology)
- Program covers 3,300 drugs and 400 alternative medications

- Fee-based program includes local formulary information, pill identifier, MEDCALC 3000, alternative medications as well and an extensive drug library
- Free online program includes pill pictures and patient education
- Cochrane library
- Mobile version available⁵⁷

MDExpress (www.mdexpress.com)

- Free portal for physicians
- Provides care information by specialty
- Has links to medical search engines
- Includes links to doctor blogs
- Health videos
- Allows links to be added⁵⁸

Consultant Live**(www.ConsultantLive.com)**

- Free online community of healthcare professionals
- Site developed by UBM Medica and supported by advertisements
- Includes blogs, photo clinics, quizzes, medical news
- Has a SearchMedica search engine
- Provides coverage by specialty
- Links to social media sites⁵⁹

Government Medical Web Sites**National Library of Medicine****(<http://nlm.gov>)**

- PubMed (discussed in search engine chapter)⁶⁰
 - Provides free access to MEDLINE, NLM's database of citations and abstracts in the fields of medicine, nursing, dentistry, veterinary medicine, health care systems, and preclinical sciences
 - Links to many sites providing full text articles and other related resources
 - Provides a Clinical Queries search filters

- feature, as well as a Special Queries feature, which have recently combined in one interface
 - Links to related articles for a selected citation
- NLM Gateway (<http://gateway.nlm.nih.gov>)⁶¹
 - Provide "one-stop shopping" for many of NLM's information resources
 - Offer citations, full text, video, audio, and images
- Toxnet (<http://toxnet.nlm.nih.gov>)⁶²
 - Cluster of databases covering toxicology, hazardous chemicals, environmental health and related areas

National Guidelines Clearinghouse (<http://www.guideline.gov>)

- Comprehensive searchable database of evidence based clinical practice guidelines and related documents
- Structured abstracts (summaries) about the guidelines and their development
- Links to full-text guidelines, where available, and/or ordering information for print copies
- Palm-based PDA downloads of the complete NGC Summary for all guidelines
- Guideline comparison utility for a side to side comparison of multiple guidelines⁶³

MedlinePlus

(<http://www.nlm.nih.gov/medlineplus/>)

- Premier online patient education site
- Service of the National Library of Medicine (MLM) and the National Institute of Health (NIH)
- Covers over 750 Health Topics in English and Spanish
- Drugs, Supplements, and Herbal Information
- Medical dictionary, encyclopedia and news
- 165 interactive video tutorials and surgical procedure videos
- Links to major patient education sites offered by health clinics, government and advocacy organizations such as Mayo Clinic, National

Institute of Health (NIH), American Heart Association, etc.

- In 2011, Medline Plus Connect was created to link patient education to personal health records and medical health records⁶⁴

Free Medical Web Sites

Free access resources are widely available on the Internet. DOAJ (<http://doaj.org>) is the largest directory of open access journals. Here are a few free open access sites that provide reliable medical journals and other health related sources:

MedKnow (www.medknow.com)

- The largest open access publisher of peer reviewed journals in STEM
- Provides free access to over 250 journals
- A search engine provides access to almost 100,000 articles⁶⁵

HighWire Press

(<http://highwire.stanford.edu/>)

- Free site created by Stanford University to produce online peer-reviewed journals and scholarly content as open access or pay per view depending on the title
- Hosts 1,270 journals with over four million full text and two million free full text articles
- Capability to search HighWire and Medline at same time with access to both free and pay-for-view articles
- E-mail alerts and RSS feeds available
- Site hosts 37 free trials of journals, 43 free journals, 249 journals that offer back issues free and approximately 1,000 pay-for-view journals
- Offers e-books and a mobile access to journals for iPhone and iPad and Kindle reader⁶⁶

Medical Algorithms (www.medal.org)

- Developed by the Institute for Algorithmic Medicine, a non-profit organization that develops online medical algorithms (step by

- step procedures for solving medical problems)
- Currently includes 17,000+ scales, tools and assessments
- Algorithms are evidenced-based with multiple references
- Many algorithms are presented as an Excel spreadsheet so one can plug in actual patient numbers and get immediate results
- Covers many unusual calculations not found in MedCalc and other similar programs⁶⁷

Medical Podcasts

(www.learnoutloud.com/Podcast-Directory/Education-and-Professional/Medical)

- Free audio learning on a variety of topics, including medicine
- The Journal of the American Medical Association, New England Journal of Medicine and other journals now offer audio article summaries as podcast
- Medical school library websites offer links to podcasts from a variety of journal
- CME providers are expanding Several medical organizations offer podcasts for medical education; mostly in audio format with some in video
- The American College of Cardiology posts “Heart Sounds” in a MP3 format as a download
- The Arizona Heart Institute and Hospital provides podcasts as part of the Cardiovascular Multimedia their use of podcasts⁶⁸

Bioline International

(<http://www.bioline.org>)

- Provides access to peer-reviewed bioscience journals from developing countries
- Includes coverage of tropical medicine and infectious diseases⁶⁹

Free Patient Education Information Sites

- Family Doctor www.familydoctor.org
- Netwellness <http://netwellness.org>
- Web MD www.webmd.com
- Kids Health <http://kidshealth.org>
- Healthfinder <http://healthfinder.gov>

Subscription (Fee-Based) Resources

MicroMedex (www.micromedex.com)

- Offers multiple drug databases
- New interface organizes the database into a point-of-care tool
- Databases include Poisondex (toxicology), Diseasedex (Disease database), Lab advisor (laboratory information), DrugDex (drug interactions), ReproRisk (human reproductive toxicology), CareNotes (patient education handouts in English and Spanish)
- Fully referenced drug database
- Downloadable to mobile device
- Includes:
 - Both renal and liver failure dosing
 - Drug-food interactions
 - Off label uses
 - Comparative efficacy
 - IV drug compatibility
 - Toxicolog
 - Extensive references⁷⁰

OVID (www.ovid.com)

- Several hundred textbooks in most specialties including drug references
- Approximately two thousand full text medical journals
- Access to journal articles is available by institutional subscription or pay per view
- Search interface supports natural language and Boolean searching
- Medline search capability linked to online full-text of journal articles
- Cochrane Library is available under the title Evidence-based Medicine Reviews
- Supports searching multiple databases simultaneously, i.e., Cochrane and Medline⁷¹

Lexi-Comp (www.lexi.com)

- Comprehensive database of unbiased drug information
- Core pharmaceutical information includes population specific dosing, indication specific dosing, IV Compatibility, drug identification, drug interactions, toxicology and more
- Diseases and disorders via Harrison's Practice
- Laboratory and diagnostic medicine
- Formulary information
- Specific modules available for medicine, dentistry and oral surgery
- Patient handouts available in 18 languages.
- Handheld version includes the five most requested databases and Harrison's disease database⁷²

UpToDate (www.uptodate.com)

- Comprehensive resource containing over 97,000 pages of original, peer-reviewed text embedded with graphics and links to Medline abstracts
- Available online and on CD-ROM
- Individual, educational and institutional subscriptions available
- Personal subscribers receive CME researching clinical questions
- Covers 20 specialties
- Logically organized
- 10,000 topics, written by 4,400 authors who review 440 journals
- Began grading recommendations for treatment and screening in
- Continuously updated with about 40% of the content being edited each quarter
- Drug database includes drug-drug interactions
- Patient information topics in English
- Integrated into GE Centricity EHR⁷³

MDConsult (www.mdconsult.com)

- 60+ textbooks
- Over 80 full text journals
- 35 Clinics of North America

- Comprehensive drug database
- 1,000 clinical practice guidelines
- 2,500 Patient education handouts
- 50,000 medical images
- Online CME and medical news
- Medline search capability
- Excellent search engine for entire site
- Individual and institutional subscriptions available⁷⁴

Stat!Ref (www.statref.com)

- Offers 200 textbooks and Medline online in a cross-searchable reference tool that includes textbooks and evidence based resources
- ACP PIER, Journal Club & AHFS DI@Essentials™
- MedCalc3000
- Institutional subscriptions available⁷⁵

ACP Medicine (<http://acpmedicine.com>)

- Publication of the American College of Physicians (ACP) and Web MD
- Previously known as Scientific American Medicine
- Evidence based and peer-reviewed
- Covers most subspecialties plus Psychiatry, Women's Health, Dermatology and Interdisciplinary medicine
- Available in print (2800 pages), CD-ROMs and Online
- Up to 120 hours CME available
- Articles are dated and references are footnoted with PubMed links to the abstract
- Monthly updates (free) to be added to chapters
- Handheld point-of-care tool, *Best DX/Best Rx*
- Individual and institutional subscriptions available⁷⁶

ACP PIER (<http://pier.acponline.org>)

- Organized into five topic types: diseases, screening and prevention, complementary

and alternative medicine, ethical and legal issues, and procedures

- Each of the 430 disease modules presents guidance statements and practice recommendations, supported by evidence
- PDA version available
- Drug resource
- Provides the medical resource content for Allscript's HER
- Updated frequently
- Disease modules continue to be added
- Available directly from the ACP and through Stat!Ref by individual or institutional subscription⁷⁷

DynaMed

(<https://dynamed.ebscohost.com>)

- Disease and condition reference
- Almost 3,200 clinical topics commonly seen in primary care
- Peer-reviewed and continually updated
- Information presented based on validity, relevance and convenience
- All topics are organized in the same categories including, general information, causes and risk factors, complications and associated conditions, history, physical, diagnosis, prognosis and treatment
- Bottom line recommendations are presented first, along with level of evidence. Links to articles will take the user to the full text article if available and free online. Other links direct users to PubMed where some are linked through medical libraries to full text articles
- Weekly e-mail of important articles; also available as podcast
- Handheld version available on popular platforms and is free with subscription
- Can be linked to an EHR with the EBSCOhost Integration Toolkit
- Individual and institutional subscriptions available⁷⁸

AccessMedicine

(<http://accessmedicine.com>)

- Provides medical reference titles, images, case files, point of use tools, and a comprehensive search platform
- Includes learning modules
- Drug database
- Includes practice guidelines
- Links to PubMed and OpenURL articles⁷⁹

Evidence Based Subscription Products

Essential Evidence Plus (formerly InfoRetriever/InfoPOEMS)

(www.essentialevidenceplus.com)

- Created by physicians for physicians. POEMS are “patient oriented evidence that matters.” The authors look for articles that are highly pertinent to patient care and patient outcomes.
- Consists of two products: DailyPOEMS and InfoRetriever
- DailyPOEMS are e-mailed to the subscriber Monday through Friday and are distilled from 100+ journals with only one in 40 accepted
- Site has 2000 POEMS
- POEM of the Week podcasts (RSS feeds available)
- Essential Evidence Plus (formerly InfoRetriever) available in online or for most smartphones
- Essential Evidence Plus tools: EBM guidelines (1,000 primary care practice guidelines, 3,000 evidence summaries and 1,000 photographs and images), Daily POEMS, Cochrane abstracts (2,193), selected practice guidelines (751), clinical decision rules (231).
- Number Needed to Treat (NNT) tool
- Derm Expert (photographic skin atlas)
- Diagnosis calculators (1,180)
- History and physical exam calculators (1,282)
- 5 Minute Clinical Consultant
- ICD-9 and E&M lookup tool
- Drug of Choice tool

- Searching results in a summary of resources on that topic categorized into typical quick reference categories like diagnosis, treatment, prognosis, etc. 5 Minute Clinical Consult monographs are listed first
- Individual and institutional subscriptions available⁸⁰

FirstConsult (www.firstconsult.com)

- Synthesizes evidence from journals and other sources into one database
- Offers concise, readable summaries of evidence that relate to patient care
- Organized into medical topics, differential diagnoses and procedures
- Updated weekly; major releases quarterly
- 475 topics
- 300 Patient education files in English and Spanish
- Procedure files and videos
- EHR ready
- Available for iPhone and iPad
- Individual and institutional subscriptions available⁸¹

Recommended Reading

The following are several articles that address new developments about online medical resources.

- *How Doctors Make Use Of Online, Point-Of-Care Clinical Decision Support Systems: A Case Study Of Uptodate.* According to a recent survey, physicians benefit from access to the quick diagnostic and treatment options offered by UpToDate, a popular online point-of-care tool. The authors of the study predict that health care professionals will develop more reliance on these online resources as they become more aware of their existence and reliability.⁸²
- *How Current Are Leading Evidence-Based Medical Textbooks? An Analytic Survey of Four Online Textbooks.* Four online evidence-based textbooks (UpToDate, PIER, DynaMed, and Best Practice) were reviewed

to determine scope and currency. Findings revealed that there was variation among these resources but all of them would benefit from more frequent updating across important topic areas. Future research investigating ways to update information efficiently is needed.⁸³

- *Use And Perceptions Of Information Among Family Physicians: Sources Considered Accessible, Relevant, And Reliable.* Family physicians still regard medical textbooks and journals as their preferred sources of information. This is interesting considering the availability of online point-of-care resources. Reliability and physical accessibility seemed to be the overriding concerns of most family physician seeking information.⁸⁴
- *A New Dimension Of Health Care: Systematic Review Of The Uses, Benefits, And Limitations Of Social Media For Health Communication.* This article presents a literature review of almost 100 sources relating to the use of social media in health care. The collaborative nature of social media potentially adds a new dimension to health care practices but further research needs to be done to assess its impact.⁸⁵

Future Trends

Without question, there will continue to be a decline in print medical textbooks and reference materials. Medical librarians will assume new roles as contributors to evidence based products, research partners in medical teams, and license negotiators of institutional online journal subscriptions from publishers and vendors like Elsevier and Ebsco. New medical information will arrive in the form of e-books, web resources, smartphones, and apps. Health workers will continue to gather, share, and interact using social networks, blogs, and other Internet resources.

Electronic content will be integrated with electronic health records. Time saving evidence based resources that provide reviews of current medical articles will be more prevalent.

Ultimately, medical resources will be context sensitive as the user navigates through the electronic health record in different areas such as laboratory results and drug prescriptions. Clinical decision support tools will educate the

user with the most current guidelines. Other medical resources similar to UpToDate (web-based and updated frequently) are likely to appear.

Key Points

- Clinicians are overwhelmed by the amount of new information
- We have shifted from traditional print textbooks in our medical libraries to online resources
- Multiple resources exist that are both free and fee-based to serve as rapid high-quality references
- Ideal medical resources should be easy to access and current information fast to retrieve

Conclusion

Online resources are becoming the medical resource of choice for healthcare workers due to depth of content and speed of retrieval. Furthermore, subject matter can be updated more rapidly in electronic formats than in traditional print textbooks and reference titles. Many excellent medical resources are free and the subscription based resources are priced competitively with traditional textbooks. Prices tend to correlate with the scope of the content offered. There are many free resources such as

Epocrates Online, MedlinePlus and Medscape that provide valuable information. Tools like UpToDate, eMedicine and DynaMed offer the greatest possibility of finding an answer in a few clicks, whereas traditional print resources may simply point users to multiple book chapters and journal articles that one must locate and sift through to find an answer. Health workers are encouraged to “test drive” these resources and adopt the ones that offer the most efficient searching and comprehensive coverage.

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Chapter 13

Medical Information Retrieval

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Learning Objectives

After reading this chapter the reader should be able to:

- State the challenges of rapid high quality medical searches
- Define the role of Google and Google Scholar in healthcare
- Describe the role of PubMed and Medline searches
- Identify the variety of search filters essential to an excellent PubMed search
- Enhance PubMed searching with third party PubMed tools
- Access NLM Mobile

Introduction

The most rapid and comprehensive way to access information today from anywhere in the world is a search of the World Wide Web via the Internet. If one assumes that the Internet is the new global library with more than three billion web sites, then it should come as no surprise that Internet search engines are the gateway. Search engines provide access to a breadth of information on medical issues targeted for the general public as well as the health professional.

Google, Yahoo!, Bing and Ask.Com are the most popular search engines because of their ease of use and accessibility. However, searchers found that usability and relevance of results varied among them. Google is the clear favorite with 2/3 of the market share in Internet searching and, as reported in a recent article comparing all four search engines, Google search results had

the highest validity and least redundancy.¹

Medical search engines exist, including Omnimedicalsearch.com,² Healthline.com,³ Tripdatabase.com,⁴ and pogofrog.com.⁵ They filter resources by eliminating commercial sites and claim to retrieve more peer reviewed information than general search engines. However, medical search engines are not as accessible as Google, which has the advantage of being well known and simple to use.

Other useful search engines that provide medical coverage are PubMed, Science Direct, Scopus, Wiley Online, CINAHL, and Web of Science. Most databases offer sophisticated features and filters that enhance search precision and improve result relevance. PubMed remains the search engine of choice for formal searches of the medical literature, although its use of controlled subject headings and search protocols

make it more difficult to navigate than general search engines. An article comparing the recall, precision, and validity of PubMed, Science Direct, and Google determined that they were all accessible and retrieved good results. The author concluded that PubMed, with its search features and comprehensive coverage was designed for in depth investigations, whereas Google provided quick overviews.⁶

Some articles comparing PubMed and Google checked the number of overlapping review articles resulting from searches using the same set of clinical questions. Earlier articles revealed that Google yielded a broader set of results while PubMed retrieved a more precise list.⁷⁻⁹ Recent literature reports that Google retrieved more articles with larger numbers of citations, which imply the identification of high impact journals, thereby increasing the validity and precision of results.¹⁰

Just as important as selecting a search engine, however, is learning to use its search features. Failure to use filters to refine a search will result in an avalanche of information returned. This chapter will focus primarily on Google/Google Scholar and PubMed, the two search engines used most by medical professionals

Google

The name Google is derived from the word *googol*, which is the mathematical term for the number 1 followed by 100 zeroes.¹¹ Its success is based largely on its intuitiveness, retrieval speed and productive results. Google is listed as one of the ten forces to flatten the world in Thomas Friedman's book *The World is Flat*.¹²

Google is a fascinating company with a myriad of continuous innovations. It was developed by Larry Page and Sergey Brin in 1996 when they were graduate students at Stanford University. They created the "backrub" strategy, which meant that a search would prioritize results by ranking the page that is linked the most often first (page ranking).¹³ This is parallel to the concept of citation searching, which is an accepted indicator of the relative importance of research. A shortcoming of this

approach is that new important web sites might take time to be linked.

As the world's largest and fastest search engine, Google performs one hundred billion searches each month by utilizing thousands of servers running the Linux operating system.¹⁴ It provides a global review, returning articles from the lay press, medical journals, magazines, etc. Because Google yields so many results in an average search, it is important to narrow or filter a search.

Google cites Medline abstracts and full text articles if they are available; so for an informal search it is reasonable to start with Google and expect to find an answer in the first few citations listed. It is likely one will find an acceptable answer in less time than it takes to use PubMed, particularly if an advanced search strategy is used to narrow the search with additional descriptors. Meats et al. demonstrated that clinicians searching for medical information prefer to use a simple strategy of inputting the disease term and the population in question.¹⁵ Google makes that type of searching possible, albeit inefficient, if advanced search techniques are not also employed. For example, if the searcher uses the terms "type 2 diabetes foot checks frequency" they will likely retrieve clinical articles that describe how often foot checks should be performed in diabetics. Successful searching depends on maximizing Google search options such as the ones listed below:¹⁶

- List the most important term first
- Search for synonyms by placing ~ in front of a search term or by using "or" as the operator (cancer **or** carcinoma will recover results dealing with either cancer **or** carcinoma)
- "**And**" is implied in Google and not necessary (e.g., a search for diabetes diet will recover results about diabetes **and** diet)
- Put quotation marks around the words to search for an exact phrase, e.g. "University of West Florida" so searchers don't retrieve every citation with the words Florida, West or University

- Remember that searches are not case sensitive and punctuation is not needed
- Spelling errors are automatically corrected with Google's Spell Checker
- Type "*define:*" before a word or phrase to have Google serve as a dictionary
- Enter an arithmetic string and Google will function as a calculator
- Search the name of a drug and Google will display a summary, description, dosage recommendations, side effects, and precautions from NIH

Google's settings and advanced options are available from the results page using the gear icon



- Setting Preferences
 - Language preferred (e.g. English)
 - Number of search results per page (e.g. 10 or 20)
 - Whether the search should launch in a new window (recommended because when the current page is exited, the search is lost.)
- Advanced Search Options¹⁷
 - Includes **and, or, not** capabilities
 - Narrows results by language and region
 - Limits results to certain domains (e.g., .edu for education, .gov for government, .org for organizations)
 - Selects search by *File type*: Word, Excel, PDF, PowerPoint, etc.
 - Limits by reading level or license rights
 - Under *Find webpages that have...* the search can target a term or terms in the title only or in the body or both

Google Scholar

Google Scholar is an offspring of Google that searches the full text of peer-reviewed scholarly journal articles at publishers' websites, including citations and abstracts provided online by the

National Library of Medicine through PubMed. Unlike many proprietary databases, Google Scholar is free and easily accessible. It will link to full text articles but there may be a cost to retrieve them if they are not open access or if the researcher is not affiliated with a library that subscribes to the journals. In late 2013 they added the option to save articles to a personal library.

Google Scholar was implemented in 2004 and describes itself as

"...a simple way to broadly search for scholarly literature. From one place, you can search across many disciplines and sources: articles, theses, books, abstracts and court opinions, from academic publishers, professional societies, online repositories, universities and other web sites."¹⁸

Early in its inception, there were some drawbacks to Google Scholar, especially its focus on highly cited studies that tended to be older. This has been largely overcome with the "Since Year" filter that allows the researcher to find more recent publications. There is also a sort feature that will display publications by date.¹⁹ In addition, current reviews of Google Scholar note its improvement in recall and precision.²⁰⁻²² Chen stated that his "...empirical study found that more than five years after its debut...Google Scholar is able to retrieve any scholarly journal article record from all the publicly accessible Web sites and from subscription based databases."²³

PubMed Search Engine

PubMed is a web-based retrieval system developed by the National Center for Biotechnology Information (NCBI) at the National Library of Medicine (NLM).²⁴ PubMed is one of twenty-three databases in NCBI's retrieval system, known as *Entrez*, that index information in toxicology, bioinformatics and genomics from a variety of sources including textbooks.

PubMed provides free access to MEDLINE,

which contains 22 million citations from the world's medical literature from the 1940s to the present. PubMed covers the fields of medicine, nursing, dentistry, veterinary medicine, health care administration, the pre-clinical sciences and some other areas of the life sciences.²⁵ NLM licenses its data to vendors to be used through proprietary interfaces, but the PubMed search interface for MEDLINE is only available from the National Library of Medicine.

For simple answers to common problems PubMed may not be the ideal place to start, but it is the primary search engine for physicians seeking information on unusual cases and research topics. Although the PubMed search process is labor intensive, healthcare workers who seek evidence based medical answers should learn to use it and it is especially important to master in an academic

or research environment. As is the case with most sophisticated databases, PubMed has filters, features, and capabilities that produce relevant search results. But without proper training, PubMed searching can be challenging and frustrating. This section emphasizes the important features and shortcuts that make a search easier and more successful. Excellent tutorials exist on the PubMed site to teach one the basics of a good search. Also, several helpful review articles have been written about PubMed tools and features.²⁶⁻²⁹

The query box in PubMed (Figure 13.1) accepts keyword, Medical Subject Heading (MESH) and natural language (Google-type) entries. Search terms may be entered alone or connected by Boolean search operators "AND" or "OR."

Figure 13.1: PubMed homepage³⁰

The screenshot shows the PubMed homepage with a blue header containing the NCBI logo, "Resources" and "How To" dropdown menus, and a "Sign in to NCBI" link. Below the header is the PubMed logo and "US National Library of Medicine National Institutes of Health" text. A search bar contains the text "PubMed" and a "Search" button. A "Help" link is visible on the right. Below the search bar is a "PubMed" banner with the text: "PubMed comprises more than 22 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher web sites." To the right of the banner is a "PubReader" banner with the text: "A whole new way to read scientific literature at PubMed Central" and an image of a hand holding a tablet displaying a document. Below the banners are three columns of links: "Using PubMed" (PubMed Quick Start Guide, Full Text Articles, PubMed FAQs, PubMed Tutorials, New and Noteworthy), "PubMed Tools" (PubMed Mobile, Single Citation Matcher, Batch Citation Matcher, Clinical Queries, Topic-Specific Queries), and "More Resources" (MeSH Database, Journals in NCBI Databases, Clinical Trials, E-Utilities, LinkOut).

PubMed citations include the author, title, journal, publication date and PubMed identification number (PMID) as shown in

Figure 13.2 (only 65% of Medline citations include an author abstract). PubMed does not search the full-text of cited articles.

Medical Subject Heading (MeSH): Journal articles are categorized by NLM indexers in order to facilitate searching. Articles are assigned two or more subject headings from a structured vocabulary called MeSH. Understanding what these terms are and how they can refine a search is an important first step in harnessing the power of PubMed. As one

can imagine, terms such as low back pain could be labeled lumbar pain, osteoarthritis of the lumbar spine, etc. It will improve the search significantly if the preferred term is used. MeSH can be accessed in the drop down menu in the PubMed search window or by choosing the MeSH Database from the menu section entitled More Resources.

Figure 13.3 shows how the term “low back pain” is organized in MeSH. The MeSH entry shows a definition of the term and its synonyms, and displays a set of subheadings that can be used to narrow a search on low back pain.

Figure 13.2: Medline citation (Courtesy National Library of Medicine)

[Randomised controlled trial of integrated care to reduce disability from chronic low back pain in working and private life.](#)
 Lambeek LC, van Mechelen W, Knol DL, Loisel P, Anema JR.
 BMJ. 2010 Mar 16;340:c1035. doi: 10.1136/bmj.c1035.
 PMID: 20234040 [PubMed - indexed for MEDLINE] [Free PMC Article](#) [Free text](#)
[Related citations](#)

Figure 13.3: MeSH term display (Courtesy National Library of Medicine)

The screenshot shows the MeSH term display for "low back pain". At the top, there is a search bar with "low back pain" entered and a "Search" button. Below the search bar, there are options to "Save search", "Limits", and "Advanced". The main content area is titled "Low Back Pain" and includes a definition: "Acute or chronic pain in the lumbar or sacral regions, which may be associated with musculo-ligamentous SPRAINS AND STRAINS; INTERVERTEBRAL DISK DISPLACEMENT; and other conditions." Below the definition, there are "PubMed search builder options" and "Subheadings". The subheadings are organized into two columns of checkboxes, including terms like "analysis", "epidemiology", "physiopathology", "anatomy and histology", "ethnology", "prevention and control", "blood", "etiology", "psychology", "cerebrospinal fluid", "genetics", "radiography", "chemically induced", "history", "radionuclide imaging", "classification", "immunology", "radiotherapy", "complications", "metabolism", "rehabilitation", "congenital", "microbiology", "statistics and numerical data", "cytology", "mortality", "surgery", "diagnosis", "nursing", "therapy", "drug therapy", "organization and administration", "ultrasonography", "economics", "parasitology", "urine", "embryology", "pathology", "veterinary", "enzymology", "physiology", and "virology". There are also checkboxes for "Restrict to MeSH Major Topic" and "Do not include MeSH terms found below this term in the MeSH hierarchy". At the bottom, there are "Tree Number(s)" and "Entry Terms" including "Back Pain, Low". On the right side, there is a "PubMed search builder" section with an "Add to search builder" button and a "Search PubMed" button. Below that, there is a "Related information" section with links to "PubMed", "PubMed - Major Topic", "Clinical Queries", "NLM MeSH Browser", and "MedGen". At the bottom right, there is a "Search details" section with a search box containing the query: "low back pain" [MeSH Terms] OR low back pain [Text Word] and a "Search" button.

Figure 13.4 illustrates a search for sinusitis in MeSH. Different types of sinusitis are listed and at the bottom of each MeSH entry is the categorical display or “MeSH Tree” as shown in Figure 13.5. MeSH is valuable in broadening or narrowing a search query. Searching the term, sinusitis, lists the categories that sinusitis would

be classified within. Using a category such as nose diseases would broaden the search. Conversely, reviewing sinusitis in MeSH allows one to discover the term for a specific type of sinusitis so that the searcher selects the one that best fits the query.

Figure 13.4: MESH term search

The screenshot shows the MeSH search interface. At the top, there is a search bar with 'MeSH' selected and 'sinusitis' entered. Below the search bar are links for 'Save search', 'Limits', 'Advanced', and 'Help'. The main content area displays 'Results: 7' and a list of five MeSH terms for sinusitis, each with a checkbox and a brief description:

- [Sinusitis](#)
1. Inflammation of the NASAL MUCOSA in one or more of the PARANASAL SINUSES.
- [Sphenoid Sinusitis](#)
2. Inflammation of the NASAL MUCOSA in the SPHENOID SINUS. Isolated sphenoid **sinusitis** is uncommon. It usually occurs in conjunction with other paranasal **sinusitis**.
Year introduced: 1990
- [Maxillary Sinusitis](#)
3. Inflammation of the NASAL MUCOSA in the MAXILLARY SINUS. In many cases, it is caused by an infection of the bacteria HAEMOPHILUS INFLUENZAE; STREPTOCOCCUS PNEUMONIAE; or STAPHYLOCOCCUS AUREUS.
Year introduced: 1990
- [Frontal Sinusitis](#)
4. Inflammation of the NASAL MUCOSA in the FRONTAL SINUS. In many cases, it is caused by an infection of the bacteria STREPTOCOCCUS PNEUMONIAE or HAEMOPHILUS INFLUENZAE.
Year introduced: 1990
- [Ethmoid Sinusitis](#)
5. Inflammation of the NASAL MUCOSA in the ETHMOID SINUS. It may present itself as an acute (infectious) or chronic (allergic) condition.
Year introduced: 1990

On the right side of the interface, there is a 'PubMed search builder' section with a search box, 'Add to search builder' button, and 'Search PubMed' button. Below it is a 'Find related data' section with a 'Database: Select' dropdown and a 'Find items' button. At the bottom right, there is a 'Search details' section showing the query: '"sinusitis"[MeSH Terms] OR sinusitis[Text Word]' and a 'Search' button.

Figure 13.5: MeSH categories

[All MeSH Categories](#)
[Diseases Category](#)
[Respiratory Tract Diseases](#)
[Nose Diseases](#)
[Paranasal Sinus Diseases](#)
Sinusitis
[Ethmoid Sinusitis](#)
[Frontal Sinusitis](#)
[Maxillary Sinusitis](#)
[Sphenoid Sinusitis](#)

PubMed Limits Option allows a search to be narrowed by date, age of subjects, gender, humans or animals, and language. The searches can be limited to retrieve only full text and free full text articles and abstracts. (Keep in mind that most articles before 1975 did not contain abstracts.) The search can also be limited by:

- Author or journal name
- Searchable main publication types include Clinical Trial, Editorial, Letter, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, and Review
- Searchable topic subsets include AIDS, Bioethics, Cancer, Complementary Medicine, History of Medicine, Systematic Reviews and Toxicology
- Field tags. The search can stipulate whether the search term should be in the title or body of the article.

These are just a few of the limiting options. There are multiple other choices available as well.

Entering a Search in PubMed

PubMed is based on an architecture that uses indexed concepts (MeSH Headings) and Boolean logic to retrieve information. Search questions should be analyzed and broken down into concepts that are described using MeSH Headings or text words. These search terms are then joined together by AND to retrieve articles that contain both concepts, or joined together by OR to retrieve articles that contain either concept. (Boolean operators should be capitalized.) To search for articles on sinusitis caused by bacteria, search **sinusitis AND bacterial infections** (See Figure 13.6).

Although the search box in PubMed looks very much like Google, the words entered in the search box are processed based on concept searching rather than by natural language searching. Recognizing that most searchers are accustomed to Google, PubMed is developing a natural language search engine that works with the concept search engine to retrieve articles.

Figure 13.6: Combining MeSH terms with Boolean operators

The screenshot displays the PubMed search results for the query "Sinusitis[Majr] AND Bacterial Infections[Mesh]". The search results are displayed on page 1 of 77, showing 1 to 20 of 1523 results. The first four results are:

- 1. Ptoxis, erythema, and rapidly decreasing vision.**
Zanation A, Fleischman D, Chavala SH.
JAMA. 2013 Jun 12;309(22):2382-3. doi: 10.1001/jama.2013.5517. No abstract available.
PMID: 23757086 [PubMed - indexed for MEDLINE]
[Related citations](#)
- 2. A multicentric, open label, randomised, postmarketing efficacy study comparing multidose of lincomycin hydrochloride capsule 500 mg with multidose cefpodoxime proxetil tablet 200 mg in patients with tonsillitis, sinusitis.**
Kothadiya A.
J Indian Med Assoc. 2012 Aug;110(8):580-3.
PMID: 23741829 [PubMed - indexed for MEDLINE]
[Related citations](#)
- 3. Host-microbial interactions in patients with chronic rhinosinusitis.**
Hamilos DL.
J Allergy Clin Immunol. 2013 Apr;131(4):1263-4, 1264.e1-6. doi: 10.1016/j.jaci.2013.02.020. Review. No abstract available.
PMID: 23540620 [PubMed - indexed for MEDLINE]
[Related citations](#)
- 4. Acute sinusitis in children.**
Brook I.
Pediatr Clin North Am. 2013 Apr;60(2):409-24. doi: 10.1016/j.pcl.2012.12.002. Epub 2013 Jan 20. Review.
PMID: 23481108 [PubMed - indexed for MEDLINE]
[Related citations](#)

The interface also includes filters for article types (Clinical Trial, Review, etc.), text availability (Abstract available, Free full text available, etc.), publication dates (5 years, 10 years, etc.), and species (Humans, Other Animals). A 'Results by year' bar chart is visible, along with a section titled 'Titles with your search terms' showing related articles like 'Bacterial meningitis after sinusitis and otitis med' and 'Relation of acute bacterial (suppurative sinu)'. There is also a section for '34 free full-text articles in PubMed Central'.

Selecting limits: Once the concept search has been entered one may limit the search with filters. In addition to searching for articles that list sinusitis as the main topic (sinusitis [MAJR]), we have limited our search by age (Adult: 19 to 44), humans, core clinical journals

(all of which are in English), the past five years, and those with links to free full text. (We could have also selected clinical trial, random controlled trial or review, or checked the box for all four.) (See Figure 13.7)

Figure 13.7: Selecting multiple search limits (Courtesy National Library of Medicine)

The screenshot shows a PubMed search results page for the query "sinusitis". The page displays search results with various filters and options. A red arrow points to the "Additional filters" dropdown menu, which is currently open and shows a list of filter categories with checkboxes. The filters are: Article types (checked), Text availability (checked), Publication dates (checked), Species (checked), Languages (unchecked), Sex (checked), Subjects (unchecked), Journal categories (unchecked), Ages (checked), and Search fields (checked). The "Show" button is visible at the bottom of the dropdown menu.

The search results are displayed in a list format, showing the title, authors, journal information, and a link to the full text. The first result is "Ptosis, erythema, and rapidly decreasing vision." by Chavala SH. The second result is "A randomized, postmarketing efficacy study comparing hydrochloride capsule 500 mg with multidose tablet 200 mg in patients with tonsillitis, sinusitis." by Brook I. The third result is "The significance of Streptococcus anginosus group in intracranial complications of pediatric rhinosinusitis." by Deutschmann MW, Livingstone D, Cho JJ, Vanderkooi OG, Brookes JT.

The page also includes a sidebar with various filter categories such as Article types, Text availability, Publication dates, Species, Sex, Journal categories, Ages, and Search fields. The "Additional filters" dropdown menu is currently open, showing a list of filter categories with checkboxes. The "Show" button is visible at the bottom of the dropdown menu.

Other features visible on the page include a "Results by year" bar chart, "Titles with your search terms" section, "34 free full-text articles in PubMed Central", "Find related data" section, and "Search details" section.

The search with limits greatly decreased the number of returned citations and improved the quality of the results (Figure 13.8).

Requesting free full text articles also reduced the search considerably. Changing the search to any abstract, instead of free full text articles, returned 85 citations.

- Note that the most current articles are listed first.
- Many articles are associated with an abstract that summarizes the article (Figure 13.9)
- One must go to the full text article for more detail

Figure 13.8: Search for sinusitis with multiple limits (Courtesy National Library of Medicine)

The screenshot shows the PubMed search interface. The search query is "Sinusitis"[Majr] AND bacterial infections [mh]. The results are displayed in a list format, with 7 results shown. The filters applied are: Article types: Clinical Trial, Review, More...; Text availability: Abstract available, Free full text available, Full text available; Publication dates: 5 years; Species: Humans; Sex: Female, Male; Journal categories: Core clinical journals, MEDLINE; Ages: Adult: 19-44 years.

Search results:

- Amoxicillin for acute rhinosinusitis: a randomized controlled trial.**
Garbutt JM, Banister C, Spitznagel E, Piccirillo JF. JAMA. 2012 Feb 15;307(7):685-92. doi: 10.1001/jama.2012.138. PMID: 22337680 [PubMed - indexed for MEDLINE] [Free PMC Article](#) [Related citations](#)
- Microbiology of acute and chronic maxillary sinusitis in smokers and nonsmokers.**
Brook I, Hausfeld JN. Ann Otol Rhinol Laryngol. 2011 Nov;120(11):707-12. PMID: 22224311 [PubMed - indexed for MEDLINE] [Related citations](#)
- Tsunami sinusitis.**
Baba S, Kondo K, Kanaya K, Suzukawa K, Sato T, Kurata H, Hiruma T, Fujita H, Yahagi N, Yamasoba T. Lancet. 2011 Sep 17;378(9796):1116. doi: 10.1016/S0140-6736(11)60832-5. No abstract available. PMID: 21924991 [PubMed - indexed for MEDLINE] [Related citations](#)
- Bacterial coinfection and antimicrobial resistance in patients with paranasal sinus fungus balls.**
Wang JH, Lee BJ, Jang YJ. Ann Otol Rhinol Laryngol. 2010 Jun;119(6):406-11. PMID: 20583740 [PubMed - indexed for MEDLINE] [Related citations](#)
- Pott puffy tumor complicating frontal sinusitis.**
Adejumo A, Ogunlesi O, Siddiqui A, Sivapalan V, Alao O. Am J Med Sci. 2010 Jul;340(1):79. doi: 10.1097/MAJ.0b013e3181b0db5b5. No abstract available. PMID: 20442649 [PubMed - indexed for MEDLINE] [Related citations](#)

Titles with your search terms

- Bacterial meningitis after sinusitis and otitis media [Neuro Endocrinol Lett. 2007]
- Relation of acute bacterial (suppurative sinusitis) and viral [J Asthma Res. 1971]

34 free full-text articles in PubMed Central

- Nontuberculous Mycobacteria in household pluml [Emerg Infect Dis. 2012]
- Evaluation of a rapid immunochromatograph [PLoS One. 2012]
- Amoxicillin for acute rhinosinusitis: a randomized controlled trial. [JAMA. 2012]

Find related data

Database: [Select] [Find items]

Search details

"Sinusitis"[Majr] AND "bacterial infections"[MeSH Terms] AND ("2008/07/11"[PDat] : "2013/07/09"[PDat] AND [Search] See more...

**Figure 13.9: Example of an abstract
(Courtesy National Library of Medicine)**

The screenshot shows the PubMed.gov interface. At the top left is the PubMed logo and the text "US National Library of Medicine National Institutes of Health". To the right is a search box containing "PubMed" and a dropdown menu. Below the search box is the word "Advanced".

Below the search bar, there is a "Display Settings:" section with a checked box for "Abstract" and a "Send to:" section with a checked box.

The citation is: [Ann Otol Rhinol Laryngol](#). 2010 Jun;119(6):406-11.

Bacterial coinfection and antimicrobial resistance in patients with paranasal sinus fungus balls.

Wang JH, Lee BJ, Jang YJ.

Department of Otolaryngology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea.

Abstract

OBJECTIVES: The aim of this study was to investigate the incidence of bacterial coinfection and antimicrobial resistance in cases of fungus balls of the paranasal sinuses.

METHODS: Between December 1991 and August 2008, 229 patients underwent endoscopic sinus surgery or the Caldwell-Luc procedure for paranasal sinus fungus ball treatment. From 123 of these patients, a total of 124 specimens were obtained for aerobic and anaerobic culture. Antimicrobial susceptibility tests were performed.

RESULTS: Ninety-one cultures (73.4%) were positive for bacteria, and 33 showed no bacterial growth. A total of 134 bacterial organisms were isolated: 65 gram-positive, 55 gram-negative, and 14 anaerobic. The most frequently isolated organisms were coagulase-negative *Staphylococcus* (14.9%), *Staphylococcus aureus* (12.7%), *Enterobacter aerogenes* (12.7%), viridans-group streptococci (8.9%), and *Pseudomonas aeruginosa* (8.2%). Among the gram-positive cocci, 12.2% were resistant to ciprofloxacin, 27.6% to clindamycin, 30% to oxacillin, 35.8% to erythromycin, 35.9% to trimethoprim-sulfamethoxazole, 56.5% to penicillin, 56.8% to gentamicin, and 0% to teicoplanin and vancomycin. Among the gram-negative rods, fewer than 10% were resistant to imipenem, piperacillin-tazobactam, amikacin, gentamicin, ceftazidime, cefepime, and tobramycin, whereas more than 80% showed resistance to ampicillin and cefazolin. When we compared the data from the periods 1991 to 2000 and 2001 to 2008, there were no significant differences in the isolation rates of particular bacterial species and no significant differences in resistance rates except for clindamycin-resistant gram-positive cocci and cefazolin-resistant gram-negative rods.

CONCLUSIONS: Bacterial coinfections were identified in more than two thirds of patients with fungus balls and purulent secretions. This finding suggests that bacterial infection may influence the development and persistence of clinical symptoms in a substantial portion of fungus ball cases.

PMID: 20583740 [PubMed - indexed for MEDLINE]

MeSH Terms [dropdown arrow]

LinkOut - more resources [dropdown arrow]

Other options

Using the Advanced Search Screen:

During the search, PubMed records the search statements. To review the previous searches and to combine search

strategies, go to Advanced Search. Combine the statements by clicking search statement numbers and choosing the appropriate Boolean operator from the menu (See Figure 13.10).

**Figure13.10: Example of Advanced Search Screen
(Courtesy National Library of Medicine)**

NCBI Resources How To PubMed Home More Resources Help

PubMed Advanced Search Builder

Filters activated: published in the last 5 years, Humans, Core clinical journals, Adult: 19-44 years [Clear all](#)

Use the builder below to create your search

[Edit](#) [Clear](#)

Builder

All Fields [Show index list](#)

AND All Fields [Show index list](#)

[Search](#) or [Add to history](#)

History [Download history](#) [Clear history](#)

Search	Add to builder	Query	Items found	Time
#24	Add	Search ("Sinusitis"[Majr]) AND bacterial infections [mh] Filters: published in the last 5 years; Humans; Core clinical journals; Adult: 19-44 years	7	12:44:58
#31	Add	Search ("Sinusitis"[Majr]) AND bacterial infections [mh] Filters: published in the last 5 years; Core clinical journals; Adult: 19-44 years	7	12:44:54
#30	Add	Search ("Sinusitis"[Majr]) AND bacterial infections [mh] Filters: Core clinical journals; Adult: 19-44 years	85	12:44:20
#29	Add	Search ("Sinusitis"[Majr]) AND bacterial infections [mh] Filters: Full text available; Core clinical journals; Adult: 19-44 years	70	12:44:17
#28	Add	Search ("Sinusitis"[Majr]) AND bacterial infections [mh] Filters: Free full text available; Full text available; Core clinical journals; Adult: 19-44 years	9	12:43:33
#27	Add	Search ("Sinusitis"[Majr]) AND bacterial infections [mh] Filters: Free full text available; Full text available; Humans; Core clinical journals; Adult: 19-44 years	9	12:42:25

To see how the search was executed by PubMed, click on **Details**. On the Advanced Search Screen pull down menu entitled "More Resources" at the top of the page one will find navigation links for access to other PubMed modules.

Single Citation Matcher: When a specific article is sought and there are only fragments of the citation, the option Single Citation Matcher is helpful. Type the information known into the form to find the article of interest. One can search by author, journal, date, volume, issue,

page or title words.

Clinical Queries: *Clinical Queries* provides built-in filters to search for articles reporting the results of randomized controlled trials. The research methodology behind the filters was created at McMaster University. One can search for randomized controlled trials by etiology (cause), diagnosis, therapy, prognosis or search for clinical prediction guides. Searches can be modified to be either broad/sensitive or narrow/specific.

Systematic reviews: These are types of reviews that critically appraise multiple random controlled trials to give conclusions more strength (covered in more detail in the chapter on evidence based medicine), can also be searched from the Clinical Queries page.

Display Settings: On the search results page use the “Display Settings” pull down menu to select:

- The format (default is summary) – select abstract, Medline, XML and others
- The number of items shown on the page (default is 20) – options range from 5 to 200
- Sort preference (default is recently added) – results can be displayed by publication date, author, journal or title

Options for Saving Results (Listed on “Send To” pull down menu)

- *Clipboard:* store up to 200 citations for up to eight hours.
- *E-mail:* send selected results to a colleague or to oneself.
- *File:* put the results into a format that is suitable for a bibliographic software program.
- *Order:* send the citation to an affiliated library under the *Loansome Doc* program for document delivery.
- *Citation Manager:* export results to an external citation manager (e.g., RefWorks, EndNote).
- *Collections and My Bibliography (or My NCBI,* located on upper right hand corner of the main screen) provides a valuable storage area for searches and collections of articles retrieved allowing one to:
 - Save searches (otherwise gone in eight hours)
 - Set up e-mail alerts to notify when new articles are published on the topic of interest
 - Display links to online full-text of articles (*LinkOut*)
 - Choose filters that group search results

- Registration is required for this free service

Other Features

Related articles and links:

To the right of each article one will see a:

- List of articles citing the article
- List of related articles
- PubMed Central (www.pubmedcentral.nih.gov) links to articles in free and full text. Unfortunately, many articles are located in minor journals of recent vintage. They are also more weighted towards a bioinformatics search.
- Link Out – links to external resources such as OVID or those subscribed to by the library affiliated with the user.
- Patient information from MedlinePlus
- Information including related citations, keywords, and MedGen
- Link to PubReader and PubMed Mobile for Handhelds
- PubMed PICO search, part of PubMed for Handhelds– aids in the construction of a well thought out question prior to initiating a search. This tool divides the question into sections defining the patient or problem, intervention, comparison and outcome (P.I.C.O). The URL or web address could be a desktop icon shortcut or a program on a handheld for fast searches.³¹
 - (P)atient or problem – describe the patient group of interest
Elderly? Male?
 - (I)ntervention, prognostic factor or exposure – Drug? Lab test? Tobacco?
 - (C)omparison – with another drug or placebo?
 - (O)utcome – what needs to be measured? Mortality? Reduced heart attacks?

Figure 13.11: PubMed PubReMiner search on sinusitis and bacterial infections in title and abstract

PubMed PubReMiner

Your query resulted in 105 references

Goto PubMed with query

Manual adjustment: SINUSITIS[TIAB] AND BACTERIAL INFECTIONS[TIAB]

AbstractLimit: 1000 Search with Manual Adjustment

columns to display

- author standard
- country
- journal
- mesh
- substance
- word (ti_ab_mh_m)
- year

Click on a hyperlink to add that element to your query and Re-Mine or select terms (OR boxes) and press 'Search Again'

Click on the P to directly goto PubMed and view ALL references for that element

Save the results as a txt-file

Operator: AND Merge similar words: YES Minimalcount: 2 Search Again

# OR Year	# OR	Journal	# OR	Author	# Count OR	Word	# OR	Mesh	# OR	Substances	# OR	Country		
4 2008	11	Jpn J Antibiot	6	ABE T	105	551	-	INFECT *	103	Humans	26	ANTI-BACTERIAL AGENTS	23	UNITED STATES
3 2007	7	Drugs	6	NEGISHI S	104	330	BACTERIAL		51	Male	10	Cephalosporins	7	NEW ZEALAND
3 2006	3	Clin Infect Dis	6	TAJIMA T	104	129	HUMAN *		50	Female	7	Anti-Infective Agents	4	GERMANY
4 2005	3	Otolaryngol Head Neck Surg	4	HAGIWARA N	104	219	SINUSITIS		36	Child	6	Immunoglobulin A	3	INDIA
9 2004	2	Acta Otolaryngol	4	KONDO Y	77	345	PATIENT *		32	Child, Preschool	4	Immunoglobulin G	2	CANADA
7 2003	2	Acta Otorinolaryngol Belg	4	NISHIMURA S	73	241	THERAPY *		31	Adult	3	Antiviral Agents	2	FINLAND
10 2002	2	Antimicrob Agents Chemother	3	BROOK J	68	246	DRUG *		28	Infant	3	Cefotaxime	2	GREECE
8 2001	2	Clin Microbiol Infect	2	SCOTT L J	61	143	CLINIC *		27	Adolescent	3	Ceftazidime	2	NETHERLANDS
6 2000	2	Curr Allergy Asthma Rep	2	CROOM K E	59	106	THERAPEUTIC *		27	Bacterial Infections/drug therapy	3	Cefuroxime	2	UNITED KINGDOM
3 1999	2	Enferm Infecc Microbiol Clin	2	CURRAN M P	59	140	TREAT *		7	Bacterial Infections/drug therapy/microbiology	3	Fluoroquinolones	2	CHINA
3 1998	2	Microbiol Clin	2	GOA K L	52	58	MALE *		3	Bacterial Infections/drug therapy/metabolism/microbiology	3	Immunoglobulin M	1	FRANCE
2 1997	2		2	HATA M	52	99	TRACT *		2	Bacterial Infections/drug therapy/metabolism	-	Immunoglobulins	1	
1 1996	2		2	HIGA A	51	116	DISEASE *							

Third Party PubMed Tools

The National Library of Medicine (NLM) makes its database of citations freely available to the public for searching, and it also makes its data available through an application programming interface (API). The API allows interested users to write programs that mine MEDLINE. There are many applications designed to optimize MEDLINE searching and others are emerging continually in an effort to exploit the MEDLINE data and make it more accessible to the user. The first example, PubReMiner is a data mining tool that helps refine search terms:

PubMed PubReMiner: PubReMiner allows the searcher to enter keywords or PMIDs related to a query and then analyzes the relevant PubMed citations and their indexing to develop frequency tables. The tables list the most active journals, authors and associated keywords related to the search terms. Items from the tables can then be added to the search and run in PubMed. PubReMiner is available

directly from the website. (See Figure 13.11)³²

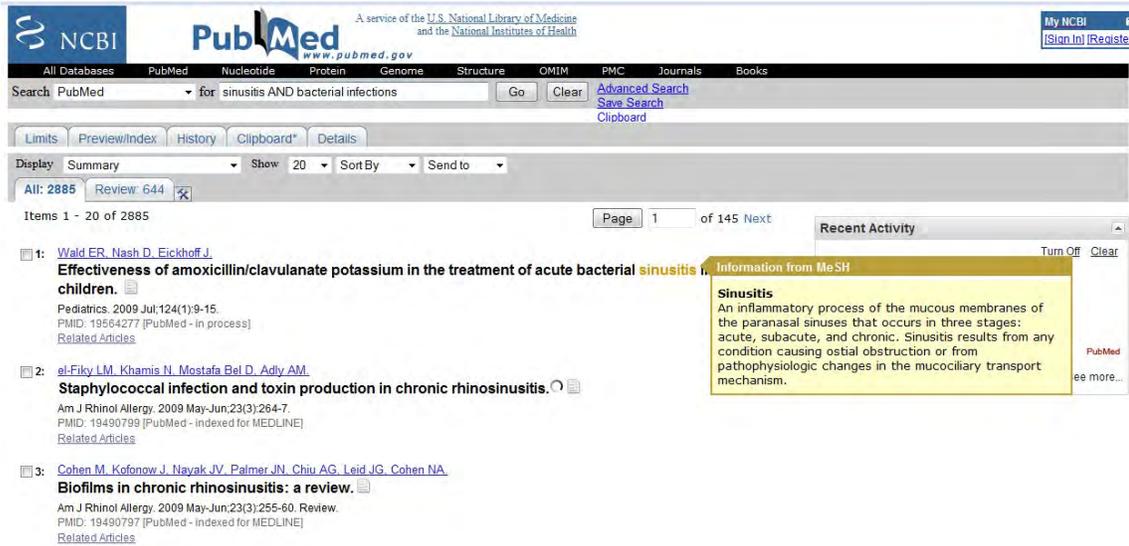
In 2011, Lu reviewed 28 web tools for searching PubMed. He divided them into four groups and provided examples of each category:³³

1. Enriching Results with Semantics and Visualization:

Tools in this group analyze search results and identify biomedical terms from the text, or employ other recognition features to enrich searching language. PubMed Ex is an example of this type of tool:

PubMed EX: PubMed EX is a browser extension for Mozilla Firefox and Internet Explorer that marks up PubMed search results with additional information derived from data mining. PubMed EX provides background information that enables searchers to focus on key concepts in the retrieved abstracts. (See Figure 13.12)³⁴

Figure 13.12: PubMed search on sinusitis and bacterial infections using a browser with the PubMed EX add-on



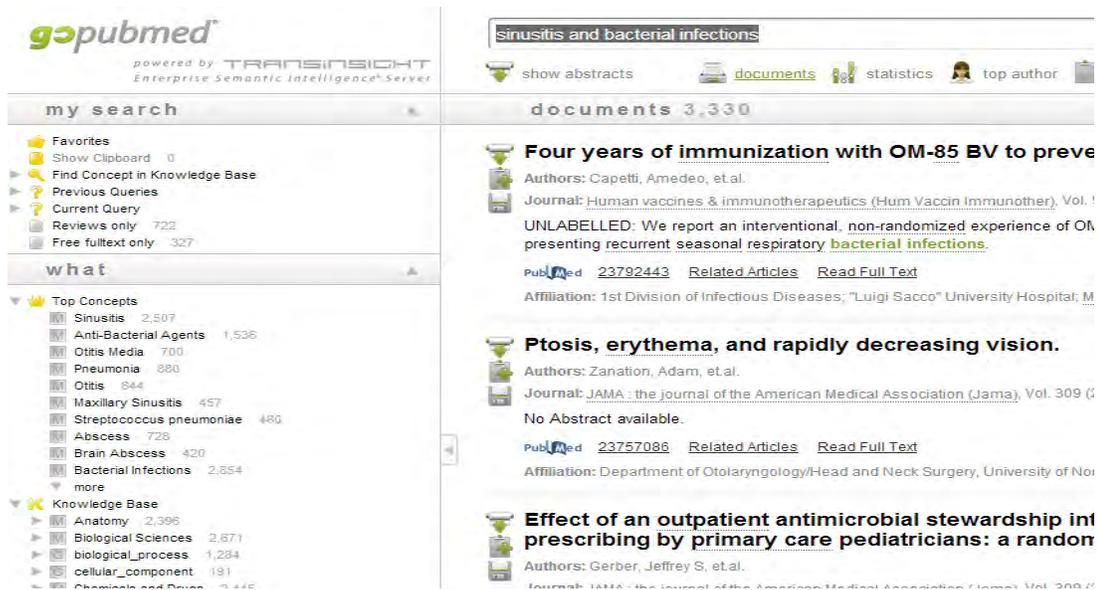
2. Clustering Results into Topics:

Categorizing results is a common approach employed by web tools. GOPubMed is an example of a clustering tool:

GOPubMed is a knowledge-based semantic browsing tool for searching PubMed. Simply

enter keywords or MeSH headings into the search box and the search engine will display the frequency of relevant terms with which to formulate the search. In Figure 13.13 the types of sinusitis as defined by MeSH are displayed on the left of the GOPubMed screen.³⁵

Figure 13.13: GOPubMed Basic Search on sinusitis and bacterial infection



3. Ranking Search Results:

PubMed displays results in reverse chronological order, whereas several web tools use relevance or other ranking systems to find and sort documents. One example of a ranking system is Quertle.

Quertle: Quertle is a semantic search engine that helps users find more relevant results by employing power terms that relate to biomedicine and by focusing on relationships between terms. Quertle offers filters by date, publication type, and key concept. (See Figure 13.14)³⁶

4. Improving Search Retrieval and Experience:

By providing alternative interfaces to PubMed searchers, tools in this group offer new web capabilities. iPubMed is an example of this type of tool.

iPubMed: This search interface has an interactive search feature. Spelling errors are automatically corrected and it links out to full text articles, citation managers, and Google Scholar. (See Figure 13.15)³⁷

Figure 13.14: Quertle Search on sinusitis and bacterial infections in adults

The screenshot displays the Quertle search engine interface. At the top, the Quertle logo is on the left, and a search bar contains the query "sinusitis and bacterial infection". To the right of the search bar is a "SEARCH" button. Below the search bar, there are input fields for "Authors" and "Journals", along with "Clear All" and "Help" links. The main content area shows search results for "sinusitis and bacterial infection". The results are organized into "Focused Results (46)" and "Broader Results (1,231)". The first three results are listed, each with a checkbox, a title, and a snippet of text. The titles are: "Indications, Efficacy, and Safety of Intranasal Corticosteroids in Rhinosinusitis", "Indications, efficacy, and safety of intranasal corticosteroids in rhinosinusitis.", and "Indications, efficacy, and safety of intranasal corticosteroids in rhinosinusitis.". The snippets mention "Rhinosinusitis can be acute or chronic, acute often due to viral or bacterial infections and chronic which is cl: chronic with nasal polyposids or chronic rhinosinusitis without nasal polyposis." The interface also includes a sidebar with "Applied Filters" (None), "Filters" (Also Containing, Published Within, Publication Type), and "Key Concepts" (General Concepts, chronic).

NLM Mobile: NLM Mobile is a resource listing mobile apps and websites including HazMap Mobile, PubMed Mobile, WISER (Wireless

System for First Responders and PubMed for Handhelds. (See Figure 13.16)³⁸

Figure 13.15: iPubMed Search

The screenshot shows the iPubMed Search interface. At the top, there is a search bar containing the text "sinusitis bacterial infections". Below the search bar, it indicates that there are 22,803,444 MEDLINE publications found as of June 29, 2013. There are two tabs: "exact match" (selected) and "fuzzy match".

The first search result is titled "Moxifloxacin: a review of its use in the management of bacterial infections." by Gillian M Keating, Lesley J Scott. The abstract preview states: "...pneumonia (CAP), acute bacterial sinusitis and uncomplicated skin and sk...with AECB, CAP, acute bacterial sinusitis and uncomplicated skin and sk...important option in the treatment of bacterial infections." It is from Adis International Limited, Auckland, New Zealand, dated 64 20 2004. Links for "Full text", "Google Scholar", "BibTex", and "Endnote" are provided.

The second search result is titled "New guidelines for sinusitis target prescribing practices." The abstract preview states: "...the prescriptions written for sinusitis each year are totally unneces...distinguish between viral and bacterial infections, as well as guidance on new therapeutic options when an antibiotic is warranted." It is from "Disease management advisor" dated 10 3 Mar, 2004. Links for "Full text", "Google Scholar", "BibTex", and "Endnote" are provided. An "Abstract:" section on the right side of this result reads: "Experts suggest as many as half of a each year are totally unnecessary. Th are millions being wasted on drugs tt of antibiotics is causing organisms to most common bugs. New guidelines distinguish between viral and bacteri new therapeutic options when an anti".

The third search result is titled "Bacteriological findings and antimicrobial resistance in odontogenic and non odontogenic chronic maxillary sinusitis." by Salvatore Puplisi, Salvatore Privitera, Luigi Maiolino, Agostino Serra, Matteo Garotta, Giovanna Blandino, Annamaria Speciale. The abstract preview states: "...frequency of chronic maxillary sinusitis of dental origin, and to eval...odontogenic chronic maxillary sinusitis. Aspirates from 59 patients with chronic maxillary sinusitis (47 non odontogenic, 12 odont...study, 20% of chronic maxillary sinusitis cases were associated with a ...specimens from chronic maxillary sinusitis were polymicrobial. Sixty aer...the 47 cases of non odontogenic sinusitis (2.9 bacteria per specimen); ... 12 patients with odontogenic sinusitis (3.3 bacteria per specimen). ...Moraxella catarrhali..." It is from the Department of Bio medical Sciences, Section of Microbiology, University of Catania, Catania, Italy, dated 60 Pt 9 Sep, 2011. Links for "Full text", "Google Scholar", "BibTex", and "Endnote" are provided.

Figure 13.16: NLM Mobile (Courtesy National Library of Medicine)

The screenshot shows the NLM Mobile website. The header includes the NLM logo, "U.S. National Library of Medicine", and "National Institutes of Health". There are navigation tabs for "Databases", "Find, Read, Learn", "Explore NLM", "Research at NLM", and "NLM for You". A search bar is visible in the top right.

The main content area is titled "NLM Mobile" and "Home". Below this is a "Gallery of Mobile Apps and Sites" with four featured items:

- NLM Mobile:** A screenshot of the NLM Mobile app interface. Description: "Use this authoritative guide to NLM mobile resources to locate sites and apps from NLM. Browse by Type, Device or Tags." Type: HTML5 Web Application. Device: Smartphones. Button: "Launch".
- Guide to NLM Mobile:** A screenshot of the guide's interface. Description: "Use this authoritative guide to NLM mobile resources to locate sites and apps from NLM. Browse by Type, Device or Tags." Type: Application. Device: Apple iOS. Button: "Install".
- HazMap Mobile:** A screenshot of the HazMap Mobile app interface. Description: "HazMap is an occupational health database for health and safety professionals and consumers seeking information about the adverse effects of workplace exposures to chemical and biological agents." Type: Website. Button: "Launch".
- MyMedList:** A screenshot of the MyMedList app interface. Description: "MyMedList (MML) allows user manage their medication list(can be e-mailed or printed, c reminder for taking medicatio as reference information in di hospitals." Type: Application. Device: Apple iOS. Button: "Install".
- NLM Native V:** A screenshot of the NLM Native V app interface. Description: "Explore video interviews from exhibition at the National Libr (iPad Only)". Type: Application. Device: Apple iOS. Button: "Install".

Recommended Reading

- *Safe Infant Sleep Recommendations On The Internet: Let's Google It.* Individuals rely heavily on the Internet for health information. This led Chung, a pediatric physician, to test and report the accuracy of results retrieved in Google by searching for information on safe infant sleep recommendations. He concluded that web sites often contain inaccurate information and he recommended that physicians provide their patients with reliable URLs.³⁹
- *Pubmed Searches: Overview And Strategies For Clinicians.* This article provides a thorough introduction to the premier biomedical resource PubMed. Examples of effective search strategies and an analysis of the database's structure help clinicians familiarize themselves with this comprehensive source.⁴⁰
- *Pubmed And Beyond: A Survey Of Web Tools For Searching Biomedical Literature.* PubMed is the primary biomedical databases and, as a product of a governmental agency (National Library of Medicine), its content is open access. Web based products offering searching innovations to PubMed's data have been developed and 28 of them are reviewed in this article. These systems enhance retrieval from the PubMed

database, especially in regards to searching, relevancy, and usability.⁴¹

- *Using Internet Search Engines to Obtain Medical Information: A Comparative Study.* Health professionals among others often use internet search engines to find medical information. The authors of this article compared and evaluated four popular browsers. They concluded that search engines are an effective means of obtaining useful health information but maintain that there is room for improvement.⁴²

Future Trends

It is difficult to conceive of a search engine more powerful or successful than Google but if past practice is any indication, innovations will occur at a fast pace. PubMed will continue to refine MESH and the filtering process. All search engines will improve as the Internet evolves with more intelligent searches. Search engines will be part of most software programs and the search process will be faster and more focused due to artificial intelligence, faster networks and the Semantic Web. Computational knowledge search engines such as Wolfram Alpha will provide standalone answers to complex questions or be integrated with other programs.⁴³

Key Points

- Search engines exist that can provide rapid high quality medical information
- Google has become a *defacto* initial medical search engine for many
- PubMed searches are important for formal searches of the medical literature
- New search engines and meta-search engines continue to appear
- All searches benefit from appropriate filters
- PubMed searching is enhanced by third party PubMed tools

Conclusion

At this time, Google is the premier search engine for non-medical and perhaps medical

searches. With proper filtering and experience, Google and Google Scholar can be used with significant success. This enables the average

person to search for answers to a variety of medical questions. Although this may produce some “cyber - hypochondria” in a minority of searchers, it is likely to produce better informed patients in the majority. Familiarity with PubMed and its new features

is important for healthcare workers who need to conduct formal searches of the medical literature. With training and experience a PubMed search can retrieve relevant results in a timely fashion.

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Chapter 14

Evidence Based Medicine and Clinical Practice Guidelines

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Learning Objectives

After reading this chapter the reader should be able to:

- State the definition and origin of evidence based medicine
- Define the benefits and limitations of evidence based medicine
- Describe the evidence pyramid and levels of evidence
- State the process of using evidence based medicine to answer a medical question
- Compare and contrast the most important online and smartphone evidence based medicine resources
- Describe the interrelationship between clinical practice guidelines, evidence based medicine, and electronic health records
- Define the processes required to create and implement a clinical practice guideline

“The great tragedy of Science - the slaying of a beautiful hypothesis by an ugly fact”

Thomas Huxley (1825-1875)

Introduction

Some might ask why Evidence Based Medicine (EBM) is included in a textbook on health informatics. The reason is that medical decisions and actions should be based on the best available evidence. Clearly, information technology has the potential to improve decision making through online medical resources, electronic clinical practice guidelines, electronic health records (EHRs) with decision support, online literature searches, digital statistical analysis and

online continuing medical education (CME). This chapter is devoted to finding the best available evidence and discussing one of its end products, clinical practice guidelines. Although one could argue that EBM is a buzz word like quality, in reality it means that clinicians should seek and apply the highest level of evidence available through a critical appraisal process. According to the Center for EvidenceBased Medicine, EBM can be defined as:

“the conscientious, explicit and judicious use of current best

evidence in making decisions about the care of individual patient”¹

Furthermore, in *Crossing the Quality Chasm*, the Institute of Medicine (IOM) states:

“Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place”²

What the IOM is saying is that every effort should be made to find the best answers and that these answers should be standardized and shared among clinicians. Such standardization implies that clinical practice should be consistent with the best available evidence that would apply to the majority of patients. This is easier said than done because clinicians are independent practitioners and interpret patient findings and research results differently. It is true that many questions cannot be answered by current evidence so clinicians may have to turn to subject matter experts. In addition, clinicians lack the time and the tools to seek the best evidence. Furthermore, greater than 1,800 citations are added to MEDLINE every day, making it impossible for a practicing clinician to stay up-to-date with the medical literature. Likewise, interpreting this evidence requires expertise and knowledge that not every clinician has. One does not have to look very far to see how evidence changes recommendations, e.g. bed rest is no longer recommended for low back pain³ or following a spinal tap (lumbar puncture); routine activity is recommended instead.⁴

Until these older recommendations were challenged with high-quality randomized controlled trials (RCTs) the medical profession had to rely on expert opinion, best guess or limited research studies.

Three pioneers are closely linked to the development of EBM. Gordon Guyatt coined the term EBM in 1991 in the American College of Physician (ACP) Journal Club.⁵ The initial focus of EBM was on clinical epidemiology,

methodology and detection of bias. This created the first fundamental principle of EBM: not all evidence is equal; there is a hierarchy of evidence that exists. In the mid-1990s, it was realized that patients’ values and preferences are essential in the process of decision making, and addressing these values has become the second fundamental principle of EBM, after the hierarchy of evidence. Archie Cochrane, a British epidemiologist, was another early proponent of EBM. The Cochrane Collaboration was named after him as a tribute to his early work. The Cochrane Collaboration consists of review groups, centers, fields, methods groups and a consumer network. Review groups, located in 13 countries, perform systematic reviews based on randomized controlled trials. As of 2013 the Cochrane Collaboration has completed over 5000 systematic reviews, even though there have been 300,000 randomized controlled trials published.^{6,7} The rigorous reviews are performed by volunteers, so efforts are slow. David Sackett is another EBM pioneer who has been hugely influential at The Centre for Evidence Based Medicine in Oxford, England and at McMaster University, Ontario, Canada. EBM has also been fostered at McMaster University by Dr. Brian Haynes who is the Chairman of the Department of Clinical Epidemiology and Biostatistics and the editor of the American College of Physician’s (ACP) Journal Club. Although EBM is popular in the United Kingdom and Canada it has received mixed reviews in the United States. The primary criticisms are that EBM tends to be a very labor intensive process and in spite of the effort, frequently no answer is found.

The first randomized controlled trial was published in 1948.⁸ For the first time subjects who received a drug were compared with similar subjects who would receive another drug or placebo and the outcomes were evaluated. Subsequently, studies became “double blinded” meaning that both the investigators and the subjects did not know whether they received an active medication or a placebo. Until the 1980s evidence was summarized in review articles written by experts. However, in the early 1990s, systematic reviews and meta-analyses became

known as a more focused, objective, and rigorous way to summarize the evidence and the preferred way to present the best available evidence to clinicians and policy makers. Since the late 1980s more emphasis has been placed on improved study design and true patient outcomes research. It is no longer adequate to show that a drug reduces blood pressure or cholesterol; it should demonstrate an improvement in patient-important outcomes such as reduced strokes or heart attacks.⁹

In spite of some reluctance by the US to embrace EBM universally, the US federal government has established multiple Evidence Based Practice Centers to conduct systematic reviews of topics in clinical medicine, social and behavioral science and economics.¹⁰ More recently, nine US medical societies participated in a new 2012 initiative known as Choosing Wisely that lists 45 dubious medical tests and therapies that are strongly discouraged, based on best evidence.¹¹

Importance of EBM

Learning EBM is like climbing a mountain to gain a better view. One might not make it to the top and find the perfect answer but individuals will undoubtedly have a better vantage point than those who choose to stay at sea level. Reasons for studying EBM resources and tools include:

- Current methods of keeping medically or educationally up-to-date do not work
- Translation of research into practice is often very slow
- Lack of time and the volume of published material results in information overload
- The pharmaceutical industry bombards clinicians and patients every day; often with misleading or biased information
- Much of what is considered the “standard of care” in every day practice has yet to be challenged and could be wrong

Without proper EBM training clinicians will not be able to appraise the best information

resulting in poor clinical guidelines and wasted resources.

Traditional Methods for Gaining Medical Knowledge

- Continuing Medical Education (CME). Traditional CME is desired by many clinicians but the evidence shows it to be highly ineffective and does not lead to changes in practice. In general, busy clinicians are looking for a non-stressful evening away from their practice or hospital with food and drink provided.¹²⁻¹³ Much CME is provided free by pharmaceutical companies with their inherent biases. Better educational methods must be developed. A recent study demonstrated that online CME was at least comparable, if not superior to traditional CME.¹⁴
- Clinical Practice Guidelines (CPGs). This will be covered in more detail, later in this chapter. Unfortunately, just publishing CPGs does not in and of itself change how medicine is practiced and the quality of CPGs is often variable and inconsistent.
- Expert Advice. Experts often approach a patient in a significantly different way compared to primary care clinicians because they deal with a highly selective patient population. Patients are often referred to specialists because they are not doing well and have failed treatment. For that reason, expert opinion needs to be evaluated with the knowledge that their recommendations may not be relevant to a primary care population. Expert opinion therefore should complement and not replace EBM.
- Reading. It is clear that most clinicians are unable to keep up with medical journals published in their specialty. Most clinicians can only devote a few hours each week to reading. All too often information comes from pharmaceutical representatives visiting the office. Moreover, recent studies may contradict similar prior studies, leaving clinicians confused as to the best course.

EBM Steps to Answering Clinical Questions

The following are the typical steps a clinician might take to answer a patient-related question:

- The physician sees a patient and generate a clinical well-constructed question. Here is the PICO method, developed by the National Library of Medicine:
 - **Patient or problem:** what is the patient group of interest? Elderly? Gender? Diabetic?
 - **Intervention:** what is being introduced, a new drug or test?
 - **Comparison:** with another drug or placebo?
 - **Outcome:** what needs to be measured? Mortality? Hospitalizations? A web-based PICO tool has been created by the National Library of Medicine to search Medline. This tool can be placed as a short cut on any computer.¹⁵
 - It has been recently suggested to add a T and S to PICO (i.e., PICOTS) to indicate the Type of study that would best answer the PICO question and the setting where it would take place.
- Seek the best evidence for that question via an EBM resource or PubMed.
- Critically appraise that evidence using tools mentioned in this chapter. Examine internal and external validity and impact of an intervention
- Apply the evidence to your patient considering patient's values, preferences and circumstances¹⁴

There are many more detailed treatises of EBM; probably the best and oldest is the textbook *Evidence-Based Medicine How to practice and teach it*, by Straus, Glasziou, Richardson and Haynes, now in its fourth edition.¹⁶

Terminology Used in Answering Clinical Questions

- **Evidence appraisal:** When evaluating evidence, one needs to assess its validity, results and applicability.

- **Validity:** Validity means is the study believable? If apparent biases or errors in selecting patients, measuring outcomes, conducting the study, or analysis are present, then the study is less valid.
- **Results:** Results should be assessed in terms of the magnitude of treatment effect and precision (narrower confidence intervals or statistically significant results indicate higher precision).
- **Applicability:** Also called external validity, applicability indicates that the results reported in the study can be generalized to the patients of interest.¹⁷

Most Common Types of Clinical Questions

- **Therapy question.** This is the most common area for medical questions and the primary one discussed in this chapter
- **Prognosis question**
- **Diagnosis question**
- **Harm question**
- **Cost question**

The Evidence Pyramid

The pyramid in Figure 14.1 represents the different types of medical studies and their relative ranking. The starting point for research is often animal studies and the pinnacle of evidence is the meta-analysis of randomized trials. With each step up the pyramid our evidence is of higher quality associated with fewer articles published.¹⁸ Although systematic reviews and meta-analyses are the most rigorous means to evaluate a medical question, they are expensive, labor intensive, and their inferences are limited by the quality of the evidence of the original studies.

- **Case reports/case series.** Consist of collections of reports on the treatment of individual patients without control groups; therefore they have much less scientific significance.
- **Case control studies.** Study patients with a specific condition (retrospective or after the

fact) and compare with people who do not. These types of studies are often less reliable than randomized controlled trials and cohort studies because showing a statistical relationship does not mean that one factor necessarily caused the other.

- Cohort studies. Evaluate (prospectively or followed over time) and follow patients who have a specific exposure or receive a particular treatment over time and compare them with another group that is similar but has not been affected by the exposure being studied. Cohort studies are not as reliable as randomized controlled studies, since the two groups may differ in ways other than the variable under study.
- Randomized controlled trials (RCTs). Subjects are randomly assigned to a treatment or a control group that received placebo or no treatment. The randomization assures to a great extent that patients in the two groups are balanced in both known and unknown prognostic factors, and that the only difference between the two groups is the intervention being studied. RCTs are often “double blinded” meaning that both the investigators and the subjects do not know whether they received an active medication or a placebo. This assures that patients and clinicians are less likely to become biased during the conduct of a trial, and the randomization effect remains protected throughout the trial. RCTs are considered the gold standard design to test therapeutic interventions.
- Systematic reviews. Defined as protocol-driven comprehensive reproducible searches that aim at answering a focused question; thus, multiple RCTs are evaluated to answer a specific question. Extensive literature searches are conducted (usually by several different researchers to reduce selection bias of references) to identify studies with sound methodology; a very time-consuming process. The benefit is that multiple RCTs are analyzed, not just one study. Standardized systematic review instruments, such as the Jadad scale can be used to evaluate the quality of individual RCTs.¹⁹
- Meta-analyses. Defined as the quantitative summary of systematic reviews that take the systematic review a step further by using statistical techniques to combine the results of several studies as if they were one large single study.¹⁵ Meta-analyses offer two advantages compared to individual studies. First, they include a larger number of events, leading to more precise (i.e., statistically significant) findings. Second, their results apply to a wider range of patients because the inclusion criteria of systematic reviews are inclusive of criteria of all the included studies.¹⁷

Figure 14.1: The Evidence Pyramid

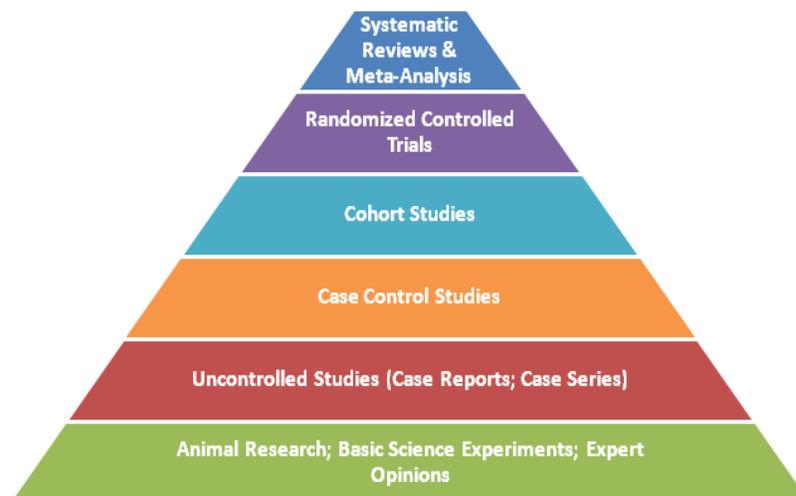


Table 14.1: Suggested studies for questions asked

Type of Question	Suggested Best Type of Study
Therapy	RCT > cohort > case control > case series
Diagnosis	Prospective, blind comparison to a gold standard
Harm	RCT + cohort > case control > case series
Prognosis	Cohort study > case control > case series
Cost	Economic analysis and modeling

This chapter will deal primarily with therapy questions so note that RCTs are the suggested study of choice.²⁰ Studies that don't randomize patients or introduce a therapy along with a control group are referred to as observational studies (case control, case series and cohort) and are usually retrospective in nature.

Evidence of harm should be derived from both RCTs and cohort study designs. Cohort studies have certain advantages over RCTs when it comes to assessing harm: larger sample size, longer follow up duration, and more permissive inclusion criteria that allow a wide range of patients representing a real world utilization of the intervention to be included in the study.

Levels of Evidence (LOE)

Several methods have been suggested to grade the quality of evidence, which on occasion, can be confusing. The most up-to-date and acceptable framework is the GRADE (Grading of Recommendations, Assessment, Development and Evaluation).²¹ The following is a description of the levels of evidence in this framework:

- Level 1: High quality evidence (usually derived from consistent and methodologically sound RCTs)
- Level 2: Moderate quality evidence (usually derived from inconsistent or less methodologically sound RCTs; or exceptionally strong observational evidence)

- Level 3: Low quality evidence (usually derived from observational studies)
- Level 4: Very low quality evidence (usually derived from flawed observational studies, indirect evidence or expert opinion)

In this framework, RCTs start with a level 1 and observational studies start with a level 3. The rationale for this rating reflects the rigor of the RCTs and the strong inference they provide. For example, a recent systematic review and meta-analysis reported that seven observational (non-randomized) studies demonstrated a beneficial association between chocolate consumption and the risk of cardiometabolic disorders.²² The highest levels of chocolate consumption were associated with significant reduction in cardiovascular disease and stroke compared with the lowest levels. Although these results seem impressive at face value, it is implausible that the effect of chocolate consumption is that profound (37% and 29% reduction in the risk of cardiovascular disease and stroke). This magnitude of effect rivals the best available drugs and interventions used to prevent these diseases. Observational studies like these, have likely exaggerated the magnitude of benefit due to many factors (i.e., bias and confounding). It is possible that chocolate users are healthier, wealthier, more educated or have other characteristics that make them have lower incidence of disease. The opposite is also possible. Therefore, our confidence in estimates of effects generated from observational studies is lower than that of randomized trials. Hence, one derives evidence with different quality rating. Furthermore, it is important to recognize that the quality of evidence can be upgraded or downgraded if additional criteria based on study methodology and applicability is available.

Risk Measures and Terminologies

Overall, therapy trials are the most common area of research and ask questions such as, is drug A better than drug B or placebo? In order to determine what the true effect of a study is, it is important to understand the concept of risk

reduction and the number needed to treat. These concepts are used in studies that have dichotomous outcomes (i.e., only two possible answers such as dead or alive, improved or not improved); which are more commonly utilized outcomes. The chapter will define these concepts and then present an example for illustration.

Risk is defined as the rate of events during a specific period of time. It is calculated by dividing the number of patients suffering events by the total number of patients at risk for events. Odds are defined as the ratio of the number of patients with events to the number of patients without events.

Notice that $Odds = 1 / (1 + risk)$

Example

Amazingstatin is a drug that lowers cholesterol. If a physician treats a 100 patients with this drug and five of them suffer a heart attack over a period of 12 months, the risk of having a heart attack in the treated group would be $5/100 = 0.050$ (or 5%). The odds of having a heart attack would be $5/95 = 0.052$. In the control group, if he or she treats 100 patients with placebo and seven suffer heart attacks, the risk in this group is $7/100 = 0.070$ or 7% and the odds are $7/93 = 0.075$.

Notice that the risk in the experimental group is called experimental event rate (EER) and the risk in the control group is called control event rate (CER). To compare risk in two groups, the following terms are used:

- Relative Risk (RR) is the ratio of two risks as defined above. Thus, it is the ratio of the event rate of the outcome in the experimental group (EER) to the event rate in the control group (CER).
 - $RR = EER / CER$
- Relative Risk Reduction (RRR) is the difference between the experimental event rate (EER) and the control event rate (CER), expressed as a percentage of the control event rate.
 - $RRR = (EER - CER) / CER$

- Absolute Risk Reduction (ARR) is the difference between the EER and the CER.
 - $ARR = EER - CER$
 - (Note that “difference” is not the same as subtracting CER from EER. For example if the EER is 1.5 and the CER is 2.0, the difference is .5, not -.5)
- Number Needed to Treat (NNT) is the number of patients who have to receive the intervention to prevent one adverse outcome.²³
 - $NNT = 1 / ARR$
 - (or $100 / ARR$, if ARR is expressed as a percentage instead of a fraction)
- Odds Ratio (OR) is the ratio of odds (instead of risk) of the outcome occurring in the intervention group to the odds of the outcome in the control group.

On Amazingstatin, 5% (EER) of patients have a heart attack after 12 months of treatment. On placebo 7% (CER) of patients have a heart attack over 12 months

$$RR = 5\% / 7\% = 0.71$$

$$RRR = (7\% - 5\%) / 7\% = 29\%$$

$$ARR = 7\% - 5\% = 2\%$$

$$NNT = 100 / 2 = 50$$

In summary, on average, 50 patients must be treated with Amazingstatin over 12 months to prevent one heart attack. As calculated above, the odds for the intervention and control group respectively are 0.052 and 0.075; the odds ratio (OR) = $0.052 / 0.075 = 0.69$.

Comments

RR and OR are very similar concepts and as long as the event rate is low, their results are almost identical. These results show that this drug cuts the risk of heart attacks by 29% (almost by a third), which seems like an impressive effect. However, the absolute reduction in risk is only 2% and therefore 50 patients need to be treated to prevent one adverse event. Although this NNT may be acceptable, using RRR seems to exaggerate our impression of risk reduction compared with ARR. Most of what is written in

the medical literature and the lay press will quote the RRR. Unfortunately, very few studies offer NNT data, but it is very easy to calculate if the ARR specific to your patient is known. Nuovo et al. noted that NNT data was infrequently reported by five of the top medical journals in spite of being recommended.²⁴ In

another interesting article, Lacy and co-authors studied the willingness of US and UK physicians to treat a medical condition based on the way data was presented. Ironically, the data was actually the same but presented in three different ways. Table 14.2 suggests that US physicians may need more training in EBM.²⁵

Table 14.2: Physician’s Likelihood of Prescribing Medication Based on How Research Data is Presented

Physicians From	Relative Risk Reduction (RRR)	Absolute Risk Reduction (ARR)	Number Needed To Treat (NNT)
United States	54%	4%	10%
United Kingdom	24%	11%	22%

Examples of Using RRR, ARR and NNT

A full page article appeared in a December 2005 Washington Post newspaper touting the almost 50% reduction of strokes by a cholesterol lowering drug. This presented an opportunity to take a look at how drug companies usually advertise the benefits of their drugs. Firstly, in small print, the reader notes that patients have to be diabetic with one other risk factor for heart disease to see benefit. Secondly, there are no references. The statistics are derived from the CARDS Study published in the Lancet in Aug 2004.²⁶ Stroke was reported to occur in 2.8% in patients on a placebo and 1.5% in patients taking the drug Lipitor. The NNT is therefore $100/1.3$ or 77. So, a physicians would have to treat 77 patients for an average of 3.9 years (the average length of the trial) to prevent one stroke. This doesn’t sound as good as “cuts the risk by nearly half.” Now armed with these EBM tools, look further the next time a miraculous drug effect is advertised.

Number Needed to Harm (NNH) is calculated similarly to the NNT. If, for example, Amazingstatin was associated with intestinal bleeding in 6% of patients compared to 3% on placebo, the NNH is calculated by dividing the ARR (%) into 100. For our example the calculation is $100/.03 = 33$. In other words, the treatment of 33 patients with Amazingstatin for

one year resulted, on average, in one case of intestinal bleeding as a result of the treatment. Unlike NNT, the higher the NNH, the better.

The Case of Continuous Variables and effect size. The results of studies (effect measures) described so far (i.e., RR, OR, ARR) are used when outcomes are dichotomous (such as dead or alive, having a heart attack or not, etc.). However, outcomes can also be continuous (e.g., blood cholesterol level). These outcomes are usually reported as a difference in the means of two study groups. This difference has a unit, which in the cholesterol example, is mg/dL. In addition to the mean difference, results would also include some measure that describes the spread or dispersion of measurements around the mean (i.e., standard deviation, range, interquartile range or a confidence interval).

If the metrics of continuous variables do not have intuitive intrinsic meaning (e.g., a score on a test or a scale), the *effect size* can be standardized (i.e., difference in means is divided by the standard deviation; which makes the data measured in standard deviation units). This process allows the comparison of students taking different tests, or tests taken in different years, or comparing the results of studies that used different scales as their outcomes. This is possible because all these measurements are

standardized (have the same unit, which is standard deviation unit). A commonly used effect size is Cohen's *d*, which is a standardized difference in means. It is interpreted arbitrarily as a small, moderate or large effect, if *d* was 0.2, 0.5 or 0.7; respectively. In addition to knowing that a result is statistically significant, calculating the effect size gives one an idea of how big the difference actually is.

Confidence Intervals. Most results published in journals will include confidence intervals that give the reader an idea of the precision of the results. In other words, if the result of interest is a mean of 5.4 kilograms and the 95% confidence intervals are 3.9-6.9, then this means there is a 95% chance the true result lies somewhere between 3.9 and 6.9 (and 5% would fall outside this range). Be leary of results with wide confidence intervals as this frequently means the sample size was too small. Also, if the confidence intervals includes zero (example -3.0 to 30) one can't be sure an intervention had a positive or negative effect.²⁷

Cost of Preventing an Event (COPE). Many people reviewing a medical article would want to know what the cost of the intervention is. A simple formula exists that sheds some light on the cost: $COPE = NNT \times \text{number of years treated} \times 365 \text{ days} \times \text{the daily cost of the treatment}$. Using our example of Amazingstatin = $50 \times 1 \times 365 \times \2 or \$36,500 to treat 50 patients for one year to prevent one heart attack. COPE scores can be compared with other similar treatments.²⁸

Limitations of the Medical Literature and EBM

Because evidence is based on information published in the medical literature, it is important to point out some of the limitations researchers and clinicians must deal with on a regular basis:

- There is a low yield of clinically useful articles in general.²⁹

- Conclusions from randomized drug trials tend to be more positive if they are from for-profit organizations.³⁰
- Up to 16% of well publicized articles are contradicted in subsequent studies.³¹ A more recent review of articles published from 2001 to 2010 in just the New England Journal of Medicine concluded that 40% represented reversal of prior recommendations.³²
- Even systematic reviews have their limitations. An evaluation of over one thousand reviews in the Cochrane Library revealed that 44% of treatments were likely to be beneficial but in only 1% was no further research recommended. Similarly, they found that 49% of interventions were not determined to be either helpful or harmful and only in 1% of cases was no further research recommended.³³
- Peer reviewers are "unpaid, anonymous and unaccountable" so it is often not known who reviewed an article and how rigorous the review was.³⁴
- Many medical studies are poorly designed:³⁵
 - The recruitment process was not described.³⁶
 - Inadequate power (size) to make accurate conclusions. In other words, not enough subjects were studied.³⁷
 - Studies published in high-impact journals attract a lot of attention but are often small randomized trials with results that may not be duplicated in future studies. This may be positive publication bias.³⁸
 - Studies with negative results (i.e., results that are not statistically significant) are not always published or take more time to be published, resulting in "publication bias." In an effort to prevent this type of bias the American Medical Association advocates mandatory registration of all clinical trials in public registries. Also, the International Committee of Medical Journal Editors requires registration as a condition to publish in one of their journals. However, they do not require

publishing the results in the registry at this time. Registries could be a data warehouse for future mining and some of the well-known registries include:

- ClinicalTrials.gov
- WHO International Clinical Trials Registry
- Global Trial Bank of the American Medical Informatics Association
- Trial Bank Project of the University of California, San Francisco³⁹

In spite of the fact that EBM is considered a highly academic process towards gaining medical truth, numerous challenges exist:

- Different evidence rating systems by various medical organizations
- Different conclusions by experts evaluating the same study
- Time intensive exercise to evaluate existing evidence
- Systematic reviews are limited in the topics reviewed (over 5,000 in the Cochrane Library in 2013) and are time intensive to complete (6 to 24 months). Often, the conclusion is that current evidence is weak and further high quality studies are necessary
- Randomized controlled trials are expensive. Drug companies tend to fund only studies that help a current non-generic drug they would like to promote
- Results may not be applicable to every patient population; i.e. external validity or generalizability
- Some view EBM as “cookbook medicine”⁴⁰
- There is not good evidence that teaching EBM changes behavior⁴¹

Other Approaches

EBM has had both strong advocates and skeptics since its inception. One of its strongest proponents Dr. David Sackett published his experience with an “Evidence Cart” on inpatient rounds in 1998. The cart contained numerous EBM references but was so bulky that it could not be taken into patient rooms.⁴² Since that article, multiple, more convenient EBM

solutions exist. While there are those EBM advocates who would suggest the sole use of EBM resources, many others feel that EBM “may have set standards that are untenable for practicing physicians.”⁴³⁻⁴⁴

Dr. Frank Davidoff believes that most clinicians are too busy to perform literature searches for the best evidence. He believes that healthcare needs “Informationists” who are experts at retrieving information.⁴⁵ To date, only clinical medical librarians (CMLs) have the formal training to take on this role. At large academic centers CMLs join the medical team on inpatient rounds and attach pertinent and filtered articles to the chart. As an example, Vanderbilt’s Eskin Library has a Clinical Informatics Consult Service.⁴⁶⁻⁴⁷ The obvious drawback is that CMLs are only available at large medical centers and are unlikely to research outpatient questions.

According to Slawson and Shaughnessy clinicians must become an “information master” to sort through the “information jungle.” They define the usefulness of medical information as:

$$\text{Usefulness} = \frac{\text{Validity} \times \text{Relevance}}{\text{Work}}$$

Only the clinician can determine if the article is relevant to his/her patient population and if the work to retrieve the information is worthwhile. Slawson and Shaughnessy also developed the notion of looking for “patient oriented evidence that matters” (POEM) and not “disease oriented evidence that matters” (DOEM). POEMs look at mortality, morbidity and quality of life whereas DOEMs tend to look at laboratory or experimental results. They point out that it is more important to know that a drug reduces heart attacks or deaths (POEM), rather than just reducing cholesterol levels (DOEM).⁴⁸ This school of thought also recommends that clinicians not read medical articles blindly each week but should instead learn how to search for patient-specific answers using EBM resources.⁴⁹ This also implies that physicians are highly motivated to pursue an answer, have adequate time and have the appropriate training. See case study below for example of EBM being applied to a clinical scenario.

Case Study

People with blockage of the carotid artery are at risk of stroke and death. They can be treated via surgery (called endarterectomy) or a less invasive procedure (putting a stent in the blocked area by going through the arteries, i.e., without surgery). The choice of procedure is controversial.

The evidence

A systematic review and meta-analysis appraised the quality of the totality of existing evidence in this area. They found 13 randomized controlled trials that enrolled a total of 7,484 patients. The methodological quality of the trials was moderate to high. Compared with carotid endarterectomy, stenting was associated with increased risk of stroke (relative risk [RR], 1.45; 95% confidence interval [CI], 1.06-1.99) and decreased risk of myocardial infarction (MI) caused by surgery (RR, 0.43; 95% CI, 0.26- 0.71). For every 1,000 patients opting for stenting rather than endarterectomy, 19 more patients would have strokes and 10 fewer would have MIs.

Patients values, preferences and context

Patients vary in their values such as aversion (fear) of stroke vs death and their fear of surgery and surgical complications such as scars in the neck and anesthesia. Patients also vary in their surgical risk (e.g., those with history of heart disease may prefer less invasive procedure to avoid prolonged anesthesia).

Guidelines

Due to the different impact of these procedures on the different outcomes, the guidelines were nuanced and stratified and allowed patients values and preferences, age, surgical and anatomical risk factors to be used in decision making. This example highlights the importance of patients' values and preferences as the second principle of EBM

References

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Ricotta JJ, Aburahma A, Ascher E, et al. Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease: executive summary. J Vasc Surg. 2011 Sep;54(3):832-6.

Evidence Based Health Informatics (EBHI)

EBHI is not a separate field, it represents the application of EBM tools to the field of health informatics. Dr. Elske Ammenwerth, a major proponent of EBHI defined this approach in

2006 as the “conscientious, explicit and judicious use of current best evidence when making decisions about information technology in healthcare.”⁵⁰ While the quality of health informatics research has improved in the past

decade, the overall report card for most studies is mixed, regardless of which technology is being studied.⁵¹ There are at least three reasons why published research studies in health informatics have not been optimally evidence based:

- **Early Hype.** In multiple other chapters the overly optimistic predictions regarding the impact of HIT on healthcare quality, safety, proficiency and cost reduction is pointed out. Many of these predictions were based on expert opinions or modeling and not high quality research. The hype was not isolated to HIT vendors and techno-enthusiasts; it was shared by academia and the federal government. It was aggravated by “technology pressure” or the natural tendency to try to fit new technologies into healthcare, even when the benefits have not been proven. This tends to raise expectations and may cause governments to introduce technology friendly policies, prior to having all of the facts. Early success stories were widely broadcast, even though many of the early innovations came from several medical centers with a track record for home grown successful technology.⁵²⁻⁵³
- **Methodological challenges.** Early research studies frequently suffered from internal validity (quality of study design and execution) and external validity (whether results are generalizable to other locations and patients) issues. Most studies reported on health information technology (HIT) are observational and retrospective in nature. Many are before/after studies. This distinction is important because cause and effect are difficult to prove with observational studies, compared to prospective RCTs. Randomization and blinding are difficult with health information technology. As an example, randomizing physicians to electronic prescribing (vs. paper prescribing) is difficult to implement and often impractical. In an observational study, physicians who volunteer to try electronic prescribing are likely “early adopters” and not representative of average

physicians, which could skew the results. Alternate methods of randomization are feasible and desired. For example, “cluster randomization” would be a practical methodology in this situation. With this method, several clinics or hospitals can be randomized as a whole practice to electronic prescribing whereas other clinics or hospitals can be randomized to paper prescribing. HIT interventions are complicated in nature and one could argue represent a technosocio-economic experience. Early studies tended to have small sample sizes, short term outcomes, inadequate endpoints, inadequate cost data and few comments about negative effects.

Clearly, there are HIT innovations that are popular and save time such as drug look-up apps for mobile technology, patient portals and voice recognition but they have been poorly studied so there is a lack of good qualitative and quantitative data about their overall effect.

There are several articles that focus on the methodological challenges of HIT research along with recommendations.⁵⁴⁻⁵⁶

Dr. Ammenwerth has been instrumental in developing guidelines for *evaluating* health informatics (GEP-HI) and *reporting* health informatics studies (STARE-HI).⁵⁷⁻⁵⁸

- **The failure to anticipate unintended consequences** related to HIT adoption. Weiner coined the term “e-iatrogenesis” in 2007 to describe adverse events related to technology.⁵⁹ Sittig and Singh divided unintended consequences into: technology unavailable; technology malfunctions and technology functions but there is human error (e.g. e-prescribing works properly but clinician entered wrong drug dose).⁶⁰ Additional aspects of unintended consequences that include patient safety issues are as follows:
 - The Joint Commission issued a Sentinel Event alert in 2008 to alert healthcare

workers that 25% of medication errors were related to a technology issue.⁶¹

- Alert fatigue may cause drug and lab test alerts to be ignored.⁶²
- Alarm fatigue is as big an issue as alert fatigue. This is discussed in more detail in the chapter on patient safety and HIT.⁶³
- Distraction while using mobile devices and social media and issue while on the job ⁶³
- Upcoding with EHR use could increase healthcare costs and raise thorny ethical/legal issues.⁶⁴
- HIT may raise, not lower long term healthcare costs.⁶⁵
- Privacy and security issues are on the increase due to widespread HIT adoption. This is addressed in the chapter on Healthcare Privacy and Security.

The end result of this convergence of factors could be widespread negativism towards HIT, increased medical errors and cost and decreased governmental and payer-based funding. Hopefully, with better research over time one will have fewer questions and more answers. Dr. Ammenwerth has been instrumental in promoting EBHI and creating a web based repository (EVALDB) of over 1500 health informatics interventions archived.⁶⁶

EBM Resources

There are many first-rate online medical resources that provide EBM type answers. They are all well referenced, current and written by subject matter experts. Several include the level of evidence (LOE). These resources can be classified as **filtered** (an expert has appraised and selected the best evidence, e.g., up-to-date or **unfiltered** (non-selected evidence, e.g., PubMed). For the EBM purist, the following are considered traditional or classic EBM resources:

- Clinical Evidence⁶⁷

- British Medical Journal product with two issues per year
- Sections on EBM tools, links, training and articles
- Evidence is oriented towards patient outcomes (POEMS)
- Very evidence based with single page summaries and links to national guidelines
- Available in paperback (Concise), CD-ROM, online or PDA format
- Cochrane Library⁶⁸
 - Database of systematic reviews. Each review answers a clinical question
 - Database of review abstracts of effectiveness (DARE)
 - Controlled Trials Register
 - Methodology reviews and register
 - Fee-based
- Cochrane Summaries⁶⁹
 - Part of the Cochrane Collaboration
 - Reviews can be accessed for a fee but abstracts are free. A search for low back pain in 2011, as an example, returned 393 reviews (abstracts)
- EvidenceUpdates⁷⁰
 - Since 2002 BMJ Updates has been filtering all of the major medical literature. Articles are not posted until they have been reviewed for newsworthiness and relevance; not strict EBM guidelines
 - Users can go to their site and do a search or choose to have article abstracts e-mailed on a regular basis
 - These same updates are available through www.Medscape.com
- ACP Journal Club⁷¹
 - Bimonthly journal that can be accessed from OVID or free if a member of the American College of Physicians (ACP)
 - Over 100 journals are screened but very few articles end up being reviewed
 - They have a searchable database and email alerting system
- Practical Pointers for Primary Care⁷²
 - Free online review of articles from the New England Journal of Medicine, Journal of the American Medical

- Journal, British Medical Journal, the Lancet, the Annals of Internal Medicine and the Archives of Internal Medicine
 - Program can be accessed via the web or monthly reports e-mailed to those who subscribe
 - Editor dissects the study and makes summary comments that are very helpful to the average reader
- Essential Evidence Plus⁷³
 - Physician oriented content that is fee-based
 - Offers daily patient oriented evidence that matters (POEMS) (easy to read synopses) emailed to subscribers
 - Essential evidence plus search tool researches EBM topics, EBM guidelines (CPGs), POEMS, Cochrane Systematic Reviews, National Guideline Clearinghouse CPGs, and decision and diagnostic calculators
- Evidence Based On-Call⁷⁴
 - User friendly site intended for quick look-ups for clinicians on call
 - Has multiple critically appraised topics (CATs) that point out the most important clinical pearls, with level of evidence
- TRIP Database has a search engine that using three different strategies to determine a search score⁷⁵
- OVID has the ability to search the Cochrane Database of Systematic Reviews, DARE, ACP Journal Club and Cochrane Controlled Trials Register at the same time. Also includes Evidence Based Medicine Reviews.⁷⁶
- SUMSearch. Free site that searches Medline, National Guideline Clearing House and DARE⁷⁷
- Bandolier. Free online EBM journal; used mainly by primary care doctors in England. Provides simple summaries with NNTs. Resource also includes multiple monographs and books on EBM that are easy to read and understand.⁷⁸
- Centre for Evidence Based Medicine is a comprehensive EBM site presented by Oxford University.⁷⁹

- Best Bets (best evidence topics) lists topics of interest to primary care and emergency department clinicians. Hosted by the Emergency Department at the Manchester Royal Infirmary, UK.⁸⁰
- Evidence Based Health Care is a very good EBM resource repository from the Health Sciences Library at the University of Colorado.⁸¹
- Google. Inserting “evidence based” with any search question will yield multiple results.⁸²
- The NNT web site provides NNT and NNH for multiple medical conditions. In addition to therapy reviews they provide probabilities for diagnosis related conditions.⁸³
- MDCalc is a web based calculator site based on EBM. Helpful for those looking for examples of common clinical calculations.⁸⁴
- EBM for Mobile Technology:
 - MedCalc 3000 calculators are both web based and available for smartphones. EBM Stats includes approximately 50 EBM calculators to include NNT, NNH, etc. Fee-based app for iPhone and Android operating systems.⁸⁵

Clinical Practice Guidelines

The Institute of Medicine in 1990 defined clinical practice guidelines (CPGs) as:

“systematically developed statements to assist practitioner and patient decisions about health care for specific clinical circumstances”⁸⁶

CPGs take the very best evidence based medical information and formulate an approach to treat a specific disease or condition. If one considers evidence as a continuum that starts by data generated from a single study, appraised and synthesized in a systematic review, CPGs would represent the next logical step in which evidence is transformed into a recommendation. Many medical organizations use CPGs with the intent to improve quality of care, patient safety and/or reduce costs. Information technology assists CPGs by expediting the search for the best evidence and linking the results to EHRs and

smartphones for easy access. Two areas in which CPGs may be potentially beneficial include disease management and quality improvement strategies, covered in other chapters. As 83% of Medicare beneficiaries have at least one chronic condition and 68% of Medicare's budget is devoted to the 23% who have five or more chronic conditions, CPGs can play an important role in improving care and lowering costs.⁸⁷ There is some evidence that guidelines that address *multiple comorbidities* (concurrent chronic diseases) actually do work. As an example, in one study of diabetics, there was a 50% decrease in cardiovascular and microvascular complications with intensive treatment of multiple risk factors.⁸⁸

In spite of evidence to suggest benefit, several studies have shown poor CPG compliance by patients and physicians. The well publicized 2003 RAND study in the *New England Journal of Medicine* demonstrated that “overall, patients received 54% of recommended care.”⁸⁹⁻⁹⁰ In another study of guidelines at a major teaching hospital there was overuse of statin therapy (cholesterol lowering drugs). Overuse occurred in 69% of primary prevention (to prevent a disease) and 47% of secondary prevention (to prevent disease recurrence or progression), compared to national recommendations.⁹¹

It should be emphasized that creating or importing a guideline is the easy part because hundreds have already been created by a variety of national and international organizations. Implementing CPGs and achieving buy-in by all healthcare workers, particularly physicians, is the hard part.

Developing Clinical Practice Guidelines

Ideally, the process starts with a panel of content and methodology experts commissioned by a professional organization. As an example, if the guideline is about preventing venous thrombosis and pulmonary embolism, multi-disciplinary content experts would be pulmonologists, hematologists, pharmacists and hospitalists.

Methodology experts are experts in evidence based medicine, epidemiology, statistics, cost analysis, etc. The panel refines the questions, usually in PICO format, that was discussed in the previous chapter. A systematic literature search and evidence synthesis takes place. Evidence is graded and recommendations are negotiated. Panel members have their own biases and conflicts of interest that should be declared to CPG users. Voting is often needed to build consensus since disagreement is a natural phenomenon in this context.

The Strength of Recommendations

Guideline panels usually associate their recommendations by a grading that describes how confident they are in their statement. Ideally, panels should separately describe their confidence in the evidence (the quality of evidence, described in previous chapter) from the strength of the recommendation. The reason for this separation is that there are factors other than evidence that may affect the strength of recommendation. These factors are: (1) how closely balanced are the benefits and harms of the recommended intervention, (2) patients' values and preferences, and (3) resource allocation.

For example, even if there is very high quality evidence from randomized trials showing that warfarin (a blood thinner) decreases the risk of stroke in some patients, the panel may issue a weak recommendation considering that the harms associated with this medicine are substantial. Similarly, if high quality evidence suggests that a treatment is very beneficial, but this treatment is very expensive and only available in very few large academic centers in the US, the panel may issue a weak recommendation because this treatment is not easily available or accessible.

Application to Individuals

A physician should consider a strong recommendation to be applicable to all patients who are able to receive it. Therefore, physicians should spend his/her time and effort on

explaining to patients how to use the recommended intervention and integrate it in their daily routine.

On the other hand, a weak recommendation may only apply to certain patients. Physicians should spend more time discussing pros and cons of the intervention with patients, use risk calculators and tools designed to stratify patients' risk to better determine the balance of harms and benefit for the individual. Weak recommendations are the optimal condition to use decision aids, which are available in written, videographic and electronic formats and may help in the decisionmaking process by increasing knowledge acquisition by patients and reduce their anxiety and decisional conflicts.

Appraisal and Validity of Guidelines

There are several tools suggested to appraise CPGs and determine their validity. These tools assess the process of conducting CPGs, the quality and rigor of the recommendations and the clarity of their presentation. The following list includes some of the attributes that guidelines users (clinicians, patients, policy makers) should seek to determine if a particular CPG is valid and has acceptable quality:

- Evidence based, preferably linked to systematic reviews of the literature
- Considers all relevant patients groups and management options
- Considers patient-important outcomes (as opposed to surrogate outcomes)
- Updated frequently
- Clarity and transparency in describing the process of CPGs development (e.g., voting, etc.)
- Clarity and transparency in describing the conflicts of interests of the guideline panel
- Addresses patients' values and preferences
- Level of evidence and strength of recommendation are given
- Simple summary or algorithm that is easy to understand
- Available in multiple formats (print, online, PDA, etc.) and in multiple locations
- Compatibility with existing practices

- Simplifies, not complicates decision making⁹²

Barriers to Clinical Practice Guidelines

Attempts to standardize medicine by applying evidence based medicine and clinical practice guidelines have been surprisingly difficult due to multiple barriers:

- Practice setting: inadequate incentives, inadequate time and fear of liability. A 2003 study estimated that it would require 7.4 hours/working day just to comply with all of the US Preventive Services Task Force recommendations for the average clinician's practice!⁹³
- Contrary opinions: local experts do not always agree with CPG or clinicians hear different messages from drug detail representatives
- Sparse data: there are several medical areas in which the evidence is of lower quality or sparse. Guideline panels in these areas would heavily depend on their expertise and should issue weak recommendations (e.g. suggestions) or no recommendations if they did not reach a consensus. These areas are problematic to patients and physicians and are clearly not ready for quality improvement projects or pay-for-performance incentives. For years, diabetologists advocated tight glycemic control of patients with type 2 diabetes; however, it turned out from results of recent large randomized trials that this strategy does not result in improved outcomes.⁹⁴
- More information is needed why clinicians don't follow CPGs. Persell et al. reported in a 2010 study that 94% of the time when clinicians chose an exception to the CPG it was appropriate. Three percent were inappropriate and 3% were unclear.⁹⁵
- Knowledge and attitudes: there is a lack of confidence to either not perform a test (malpractice concern) or to order a new treatment (don't know enough yet).

Information overload is always a problem.⁹⁶⁻⁹⁷

- CPGs can be too long, impractical or confusing. One study of Family Physicians stated CPGs should be no longer than two pages.⁹⁸⁻¹⁰⁰ Most national CPGs are 50 to 150 pages long and don't always include a summary of recommendations or flow diagram
- Where and how should CPGs be posted? What should be the format? Should the format be standardized?
- Less buy-in if data reported is not local since physicians tend to respond to data reported from their hospital or clinic.
- No uniform level of evidence (LOE) rating system
- Too many CPGs posted on the National Guideline Clearinghouse. For instance, a non-filtered search in June 2013 by one author for "type 2 diabetes" yielded 608 CPGs. The detailed search option helps filter the search significantly.¹⁰⁰
- Lack of available local champions to promote CPGs
- Excessive influence by drug companies: A survey of 192 authors of 44 CPGs in the 1991 to 1999 time frame showed:
 - 87% had some tie to drug companies
 - 58% received financial support
 - 59% represented drugs mentioned in the CPG
 - 55% of respondents with ties to drug companies said they did not believe they had to disclose involvement¹⁰¹
- Quality of national guidelines: National guidelines are not necessarily of high quality. A 2009 review of CPGs from the American Heart Association and the American College of Cardiology (1984 to Sept 2008) concluded that many of the recommendations were based on a lower level of evidence or expert opinion, not high quality studies.¹⁰²
- No patient input. At this point patients are not normally involved in any aspect of CPGs, even though they receive recommendations based on CPGs. In an interesting 2008 study, patients who received an electronic

message about guidelines experienced a 12.8% increase in compliance. This study utilized claims data as well as a robust rules engine to analyze patient data. Patients received alerts (usually mail) about the need for screening, diagnostic and monitoring tests. The most common alerts were for adding a cholesterol lowering drug, screening women over age 65 for osteoporosis, doing eye exams in diabetics, adding an ACE inhibitor drug for diabetes and testing diabetics for urine microalbumin.¹⁰³ It makes good sense that patients should be knowledgeable about national recommendations and should have these guidelines written in plain language and available in multiple formats. Also, because many patients are highly "connected" they could receive text messages via cell phones, social networking software, etc., to improve monitoring and treatment.

Initiating Clinical Practice Guidelines

Examples of Starting Points:

- High cost conditions: heart failure
- High volume conditions: diabetes
- Preventable admissions: asthma
- There is variation in care compared to national recommendations: deep vein thrombophlebitis (DVT) prevention
- High litigation areas: failure to diagnose or treat
- Patient safety areas: intravenous (IV) drug monitoring

The Strategy

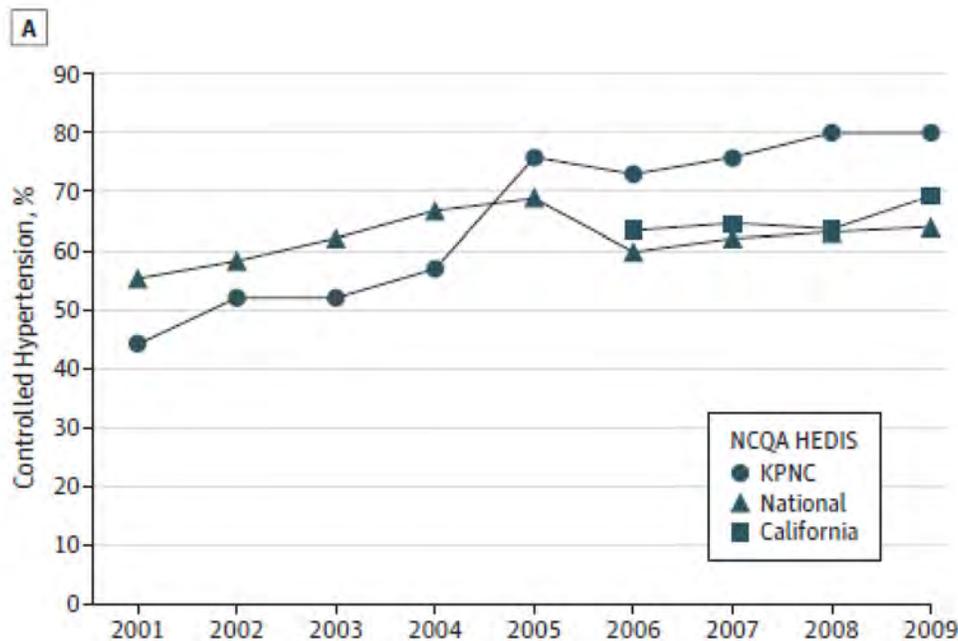
- Leadership support is crucial
- Use process improvement tools such as the Plan-Do-Study-Act (PDSA) model
- Identify gaps in knowledge between national recommendations and local practice

- Locate a guideline champion who is a well-respected clinical expert.¹⁰⁴ A champion acts as an advocate for implementation based on his/her support of a new guideline
- Other potential team members:
 - Clinician selection based on the nature of the CPG
 - Administrative or support staff
 - Quality Management staff
- Develop action plans
- Educate all staff involved with CPGs, not just clinicians
- Pilot implementation
- Provide frequent feedback to clinicians and other staff regarding results
- Consider using the checklist for reporting clinical practice guidelines developed by the 2002 Conference on Guideline Standardization (COGS).¹⁰⁵

Clinical Practice Guideline Example

There have been thousands of CPGs created and disseminated but far fewer have been studied, in terms of impact and even fewer have been significantly successful. Figure 14.2 represents a 2013 study reported from Kaiser Permanente Northern California (KPNC) for hypertensive control. Note that control of hypertension increased from a baseline of 43% in 2001 to 80% in 2009. The national averages are also presented. It is important to realize that Kaiser has had a system wide EHR since 2005 and that they have developed multiple evidence based CPGs. Furthermore, because everyone has the same leadership and information technology system, it is easier to get everyone on the team on the same page. This study is presented later in this chapter under “current knowledge.”¹⁰⁶

Figure 14.2: Results from 2013 Study using hypertension CPG



Electronic Clinical Practice Guidelines

CPGs have been traditionally paper-based and often accompanied by a flow diagram or

algorithm. With time, more are being created in an electronic format and posted on the internet or Intranet for easy access. Zielstorff outlined the issues, obstacles and future prospects of online practice guidelines in an early review.¹⁰⁷

What has changed since then is the ability to integrate CPGs with smartphones and electronic health records.

CPGs on smartphones: These mobile platforms function well in this area as each step in an algorithm is simply a tap or touch of the screen. In Figures 14.3 and 14.4 programs are shown that are based on national guidelines for cardiac risk and cardiac clearance. Figure 14.3 depicts a calculator that determines the 10 year risk of heart disease based on serum cholesterol and other risk factors. A cardiac clearance program determines whether a patient needs further cardiac testing prior to an operation (Figure 14.4).¹⁰⁸ Many excellent guidelines for the smartphone exist that will be listed later in this chapter.

Figure 14.3: 10 Year Risk of Heart Disease

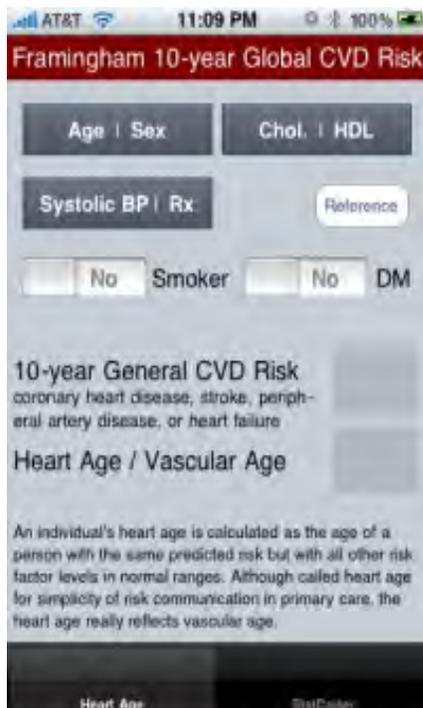
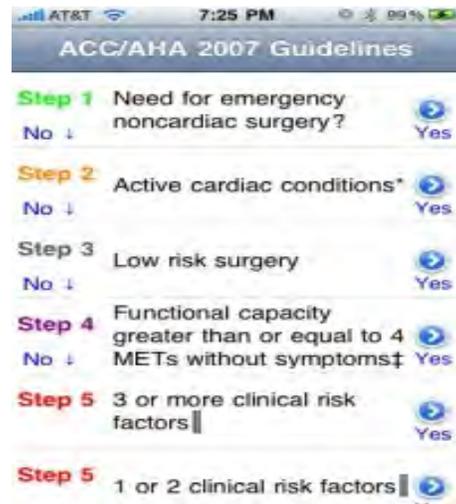


Figure 14.4: Cardiac Clearance



Web-Based Risk Calculators: Many of these are available on a mobile platform and are also available online. While these are not CPGs exactly, they are based on population studies and are felt to be part of EBM and can give direction to the clinician. As an example, some experts feel that aspirin has little benefit in preventing a heart attack unless your 10 year risk of one exceeds 20%. The following is a short list of some of the more popular online calculators:

- ATP III Cardiac risk calculator: estimates the 10 year risk of a heart attack or death based on your cholesterol, age, gender, etc.¹⁰⁹
- FRAX fracture risk calculator: estimates the 10 year risk of a hip or other fracture based on all of the common risk factors for osteoporosis. Takes into account a patient's bone mineral density score, gender and ethnicity.¹¹⁰
- GAIL breast cancer risk assessment tool: estimates a patient's risk of breast cancer, again, based on known and accepted risk factors.¹¹¹
- Stroke risk calculator: based on the Framingham study it predicts 10 year risk of a stroke based on known risk factors.¹¹²

- Risk of stroke or death for new onset atrial fibrillation: also based on the Framingham study, it calculates five year risk of stroke or death.¹¹³

Electronic Health Record CPGs

Although not all electronic health records have embedded CPGs, there is definite interest in providing local or national CPGs at the point of care. CPGs embedded in the EHR are clearly a form of decision support. They can be linked to the diagnosis or the order entry process. In addition, they can be standalone resources available by clicking, for example, an “info-button.” Clinical decision support provides treatment reminders for disease states that may include the use of more cost effective drugs. Institutions such as Vanderbilt University have integrated more than 750 CPGs into their EHR by linking the CPGs to ICD-9 codes.¹¹⁴ The results of embedded CPGs appears to be mixed. In a study by Durieux using computerized decision support reminders, orthopedic surgeons showed improved compliance to guidelines to prevent deep vein thrombophlebitis.¹¹⁵ On the other hand, three studies by Tierney, failed to demonstrate improved compliance to guidelines using computer reminders for hypertension, heart disease and asthma.¹¹⁶⁻¹¹⁸ Clinical decision support, to include order sets is discussed in more detail in the chapters on electronic health records and patient safety.

There are other ways to use electronic tools to promulgate CPGs. In an interesting paper by Javitt, primary care clinicians were sent reminders on outpatient treatment guidelines based only on claims data. Outliers were located by using a rules engine (Care Engine) to compare a patient’s care with national guidelines. They were able to show a decrease in hospitalizations and cost as a result of alerts that notified physicians by phone, fax or letter. This demonstrates one additional means of changing physician behavior using CPGs and information technology not linked to the electronic health record.¹¹⁹ Critics might argue that claims data are

not as accurate, robust or current as actual clinical results.

Software is now available (EBM Connect) that can compute compliance with guidelines automatically using administrative data. The program translates guidelines from text to algorithms for 20 disease conditions and therefore would be much more efficient than chart reviews. Keep in mind it will tell users if, for example, LDL cholesterol was ordered, not the actual results.¹²⁰

Clinical Practice Guideline Resources

Web-based CPGs

- **National Guideline Clearinghouse.** This program is an initiative of the Department of Health and Human Services and is the largest and most comprehensive of all CPG resources. Features offered:
 - Includes about 2664 guidelines
 - There is extensive search engine filtering i.e. one can search by year, language, gender, specialty, level of evidence, etc.
 - Abstracts are available as well as links to full text guidelines where available
 - CPG comparison tool
 - Forum for discussion of guidelines
 - Annotated bibliography
 - They link to 17 international CPG resource sites¹⁰⁰
- **National Institute for Health and Clinical Excellence (NICE)**
 - Service of the British National Health Service
 - Approximately 100 CPGs are posted and dated
 - A user-friendly short summary is available as well as a lengthy guideline, both in downloadable pdf format
 - Podcasts are available¹²¹
- **Agency for Health Care Research and Quality (AHRQ)**
 - 1 of 12 agencies within the Department of Health and Human Services (HHS)

- AHRQ supports health services research initiatives that seek to improve the quality of health care in America
- AHRQ's funds evidence practice centers that conduct evidence appraisal and reviews to support the development of clinical practice guidelines¹²²
- **Health Team Works (formerly Colorado Clinical Guidelines Collaborative)**
 - Free downloads available for Colorado physicians and members of CCGC
 - As of October 2011 they have 14 CPGs available
 - Guidelines are in easy to read tables, written in a pdf format
 - References, resources and patient handouts are available¹²³
- **Institute for Clinical Systems Improvement (ICSI)**
 - Collaboration of three major health plans in Minnesota to improve healthcare quality
 - Their web site includes about 40 CPGs with adoption by 180 countries
 - Each CPG has a main algorithm with hyperlinked steps
 - They also have order sets and patient resources. Some are for members only
 - Evidence based and rated CPGs
 - Executive summary with date of publication¹²⁴
 - Smartphone-based CPGs

Most CPGs can be downloaded for the iPhone or iPad through the iTunes Store or the Android Market. For further information about medical apps, readers are referred to the chapter on mobile technology. The following are a sample of CPGs available for smartphones:

- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) are available for iPhone and Android.
- Skyscape has multiple free CPGs available for download and also has 150+ fee-based CPGs. For example, Pediatric Clinical Practice Guidelines & Policies provides access to more than 30 clinical practice guidelines and more than 380 policy

statements, clinical reports and technical reports.¹²⁵

- mTBI Pocket Guide provides evidence based information about traumatic brain injury (TBI) and is available on the Android Market.
- ePSS is an app available for all operating systems, developed by the US Preventive Services Task Force. Preventive medicine guidelines are presented based on age, gender, smoking status, etc.¹²⁶

Recommended Reading

Several recent articles are posted that address EBM and CPGs

- *Improving Adherence To Otitis Media Guidelines With Clinical Decision Support And Physician Feedback* is a 2013 cluster-randomized study of adherence to CPGs for acute otitis media (AOM) and otitis media with effusion (OME), using EHR-CDS and monthly physician feedback. Researchers found that clinical decision support (CDS) and feedback both improved CPG compliance but they were not additive.¹²⁷
- *Childhood Obesity: Can Electronic Medical Records Customized With Clinical Practice Guidelines Improve Screening And Diagnosis?* Researchers wanted to know if CPGs that are part of an EHR improve recording of BMI, growth chart completion, risk score questionnaire completion and coding for obesity. In this before/after study there was an increase in all parameters, but the number of children reported with obesity was still below the known rates of obesity for this community.¹²⁸
- *Use Of Health IT For Higher-Value Critical Care.* Authors advocated using CPGs in EHRs to risk stratify patients, particularly with non-cardiac illnesses, for admission to the critical care unit.¹²⁹
- *A "Smart Heart Failure Sheet: Using Electronic Medical Records To Guide Clinical Decision Making.* The authors

report their experience with an embedded CPG Developed at the Beth Israel Deaconess Medical Center. The resource is highly educational for both the physician and patient. The smart sheet automatically uploads lab and imaging pertinent to heart failure diagnosis and treatment. It appears in the EHR after adding heart failure to the problem summary list or demonstrating a low ejection fraction by echocardiography. The program also allows a clinician to see all of his/her patients with heart failure, along with flow charts, etc. No outcome data has been published.¹³⁰

- *Improved Blood Pressure Control Associated with a Large Scale Hypertension Program.* This Kaiser-Permanente Northern California (KPNC) study looked at blood pressure control based on reported HEDIS measures from 2001-2009 in California. After implementing a hypertension CPG and creating a hypertension registry for the entire region they also instituted a polypill (single pill containing several blood pressure medications). Follow-up visits were by medical assistants. The end result was to see control rise from 43% to 80%; a percentage considerably higher than the national average (55% in 2001, 64% in 2009). Also, see Figure 14.2.¹⁰⁶
- *Why Randomized Controlled Trials are Needed to Accept New Practices: 2 World Views and The Necessity for Clinical Reasoning in the Era of Evidence Based Medicine.* Both of these articles appeared in a late 2013 issue of the Mayo Clinic Proceedings. They highlight the healthy controversy between those who believe clinicians must have evidence before they proceed and those who accept that the evidence is lacking or mixed so one must employ a good clinical reasoning.¹³¹⁻¹³²

Future Trends

The field of EBM continues to evolve. Methodologists continue to identify opportunities to improve our understanding and interpretation of research findings. It is anticipated that more standardization of reporting and more transparency. The Appraisal of Guidelines for Research & Evaluation (AGREE II) is a web based tool that rates the quality of CPGs with 23 items covering 6 quality domains. Two studies published in 2010 help refine our knowledge base:

- Trials are often stopped early when extreme benefits are noted in the intervention group. The rationale for stopping enrollments of participants is that it is “unethical” to continue randomizing patients to the placebo arm because researchers are depriving them from the benefits of the intervention. However, it was found that stopping trials early for benefit exaggerates treatment effect by more than 30%; simply because the trial is stopped at a point of extreme benefit that is clearly made extreme by chance. Such exaggeration leads to the wrong conclusions by patients and physicians embarking on comparing the pros and cons of a treatment and also leads to the wrong decisions by policymakers. In fact, stopping early may be unethical from a societal and individual point of view.¹³³
- The second recent advancement in methodology relates to the finding that authors who have financial affiliation with the industry are three times more likely to make statements that are favorable to the sponsored interventions. It is very plausible that this bias is subconscious and unintentional; nevertheless, as readers of the literature, one should recognize the potential and implications of this bias.¹³⁴

Advances with CPGs will be related to better integration with a variety of HIT and more research into those factors that improve CPG compliance. It is not known if embedded CPGs will become part of stage 3 meaningful use.

Key Points

- Evidence Based Medicine (EBM) is the academic pursuit of the best available answer to a clinical question
- The two fundamental principles of EBM are: (1) a hierarchy of evidence exists (i.e., not all evidence is equal) and (2) evidence alone is insufficient for medical decision making. It should rather be complemented by patient's values, preferences and circumstances.
- Health information technology will hopefully improve medical quality, which is primarily based on EBM.
- There are multiple limitations of both EBM and the medical literature.
- The average clinician should have a basic understanding of EBM and know how to find answers using EBM resources.
- Clinical Practice Guidelines (CPGs), based on evidence based medicine, are the roadmap to standardize medical care.
- CPGs are valuable for chronic disease management or as a means to measure quality of care.

Conclusion

Knowledge of EBM is important for those involved with patient care, quality of care issues or research. Rapid access to a variety of online EBM resources has changed how clinicians practice medicine. In spite of its shortcomings, an evidence based approach helps healthcare workers find the best possible answers. Busy clinicians are likely to choose commercial high quality resources, while academic clinicians are likely to select true EBM resources. Ultimately, EBM tools and resources will be integrated with electronic health records as part of clinical decision support.

The jury is out regarding the impact of CPGs on physician behavior or patient outcomes. Busy clinicians are slow to accept new information, including CPGs. Whether embedding CPGs into

EHRs will result in significant changes in behavior that will consistently result in improved quality, patient safety or cost savings remains to be seen. It is also unknown if linking CPGs to better reimbursement (pay-for-performance) will result in a higher level of acceptance. While it is being determined how to optimally improve healthcare with CPGs, most authorities agree that CPGs need to be concise, practical and accessible at the point of care. Every attempt should be made to make them electronic and integrated into the workflow of clinicians.

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Chapter 15

Disease Management and Disease Registries

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Learning Objectives

After reading this chapter the reader should be able to:

- Define the role of disease management in chronic disease
- Describe the need for rapid retrieval of patient and population statistics to manage patients with chronic diseases
- Compare and contrast the various disease registry formats including those that integrate with electronic health records
- Elaborate on how Meaningful Use objectives impact disease management and electronic health records
- Describe the interrelationships between disease registries, evidence based medicine and quality improvement programs

Introduction

Disease Management (DM) Programs are important for several reasons that will be pointed out in this chapter. First, an enterprise-level approach is needed to disease management in order to evaluate, track and treat chronic diseases. The Institute of Medicine has stated that the existing strategy has been insufficient because “the current delivery system responds primarily to acute and urgent health care problems. Those with chronic conditions are better served by a systematic approach that emphasizes self-management, care planning with a multidisciplinary team and ongoing assessment and follow up.”¹ A systematic approach implies the means to coordinate care

and share information which requires information technology. Second, there is both a national and international rise in chronic diseases which is of great concern to governments trying to deal with rising healthcare costs. For this reason, disease management programs now exist in most developed countries. In the United States disease management is part of Meaningful Use (HITECH Act) and Accountable Care Organizations (Affordable Care Act) discussed in this and multiple other chapters.

In the next section key terms will be defined that are important in understanding disease management, population health and public health.

Definitions

- **Public Health:** "the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals."² Public health focuses on surveillance that includes tracking infectious disease epidemics, chronic diseases, bioterrorism and other events. For a more detailed discussion readers are referred to the chapter on public health informatics.
- **Population Health:** "the health outcomes of a group of individuals, including the distribution of such outcomes within the group."³ Some authorities include disease, lifestyle, demand and condition management programs under population health.
- **Disease Management (DM):** "a systematic population based approach to identify persons at risk, intervene with a specific program of care and measure clinical and other outcomes."⁴ DM focuses on specific diseases, e.g. diabetes.
- **Lifestyle Management:** focuses on personal risk factors (e.g. smoking)
- **Demand Management:** focuses on improved utilization (e.g. emergency room usage)
- **Condition Management:** focuses on temporary conditions (e.g. pregnancy)
- **Patient Registry:** "is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes"⁵

Disease Management Programs (DMPs)

The goal of all DMPs is to improve multiple patient outcomes: clinical, behavioral, financial, functional and quality of life outcomes.

Historically, DMPs were created in part because health maintenance organizations (HMOs) wanted to control the rising cost of chronic diseases. DMPs were established in the 1980s at Group Health of Puget Sound and Lovelace Health System in New Mexico and now are part of many large health care organizations. As an example, in a survey of over 1,000 healthcare organizations, disease registries were established with the following frequencies: diabetes (40.3%), asthma (31.2 %), heart failure (34.8 %) and depression (15.7 %).⁶

Chronic diseases affect about 20% of the general population yet account for 75% of health care spending. By the year 2030, 20% of the US population will be 65 or older. Chronic diseases are more likely to affect lower income populations who have limited access to medical care, health illiteracy and limited insurance coverage. Figure 15.1 shows the predicted prevalence of chronic disease by year.⁷

The most common chronic diseases to be managed are heart failure, diabetes and asthma due to high prevalence and cost. Following close behind are obesity, hypertension, chronic renal failure and chronic obstructive lung disease (COPD).

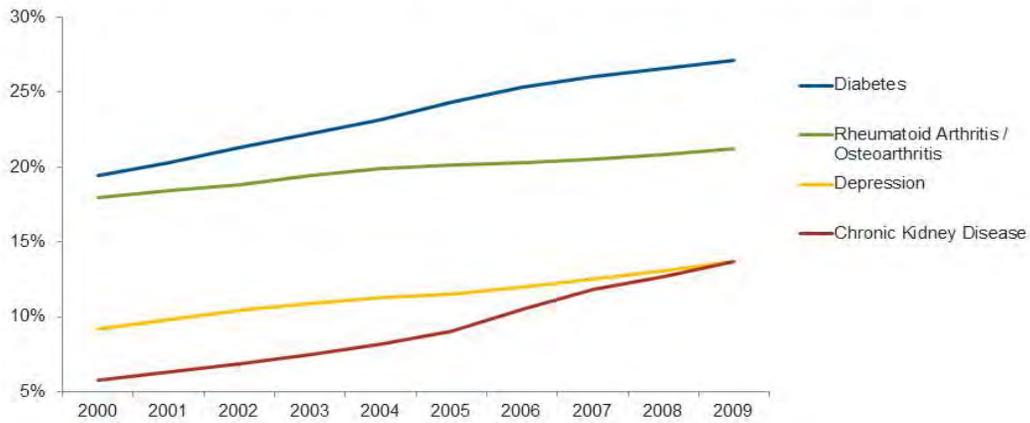
Disease Management Program Participants

DMPs require a team approach as well as multiple internal and external partners interested in managing chronic diseases. The integration of multiple players is best demonstrated by the classic Chronic Care Model created by Dr. E. Wagner and the Macoll Institute for Healthcare Innovation. His model incorporates community resources, healthcare systems, information technology, patient participation and a disease management team and is demonstrated in Figure 15.2.⁸

Figure 15.1: Predicted chronic disease prevalence (millions) (Courtesy AHA)

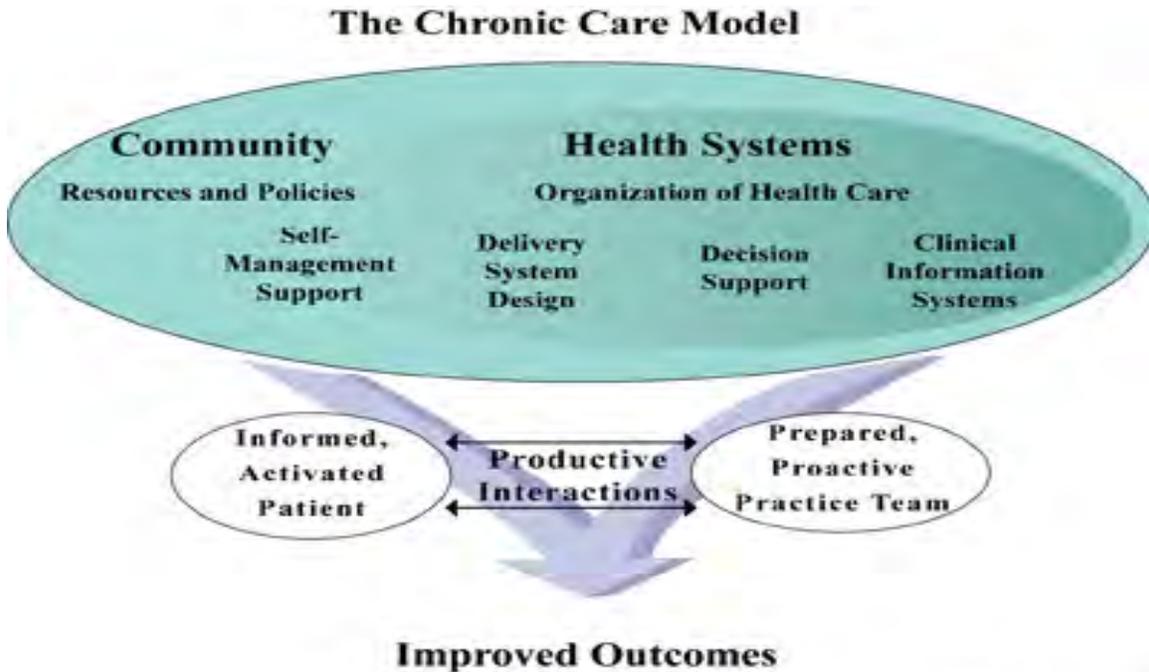
Chronic disease rates are rising in the Medicare population.

Chart 2: Rates of Chronic Conditions Among Medicare Beneficiaries,* 2000 – 2009



*Includes random 5% sample of Medicare beneficiaries.
 Source: CMS Chronic Condition Data Warehouse Medicare 5% Sample, Medicare Beneficiary Prevalence for Chronic Conditions for 2000 Through 2009.
http://www.cdwdata.org/cs/groups/public/documents/document/wls_ucm1-000774.pdf
 American Hospital Association. Research and analysis by Avalere Health

Figure 15.2: Chronic Care Model (Courtesy MaColl Institute)



Developed by The MacColl Institute
 © ACP-ASEM Journals and Books

The following are common DMP participants:

- Quality Improvement Organizations (QIOs)
- State and Federal Governments (Medicaid and Medicare)
- Healthcare systems including newer delivery models such as the patient centered medical home and accountable care organizations
- Physicians
- Employers
- Insurers
- Health Information Organizations (HIOs)

The Disease Management Approach

Establishment of a DM program usually involves the following questions and steps:

- Identifying a disease or condition and a target population e.g. type 2 diabetes in the uninsured.
- Determining if the problem is common enough or expensive enough to warrant a DM team. Is the disease or condition a high volume problem, a high cost problem or both?
- Defining the goal, e.g. decrease diabetic complications, decrease trips to the emergency room by asthmatics, etc.
- Determining if information systems already exist for the program. Data retrieval is easier if systems are already in place.
- Comparing local to national data, e.g. a local hospital has an annual readmission rate for heart failure of 55%; the national average is 40%.
- Reviewing existing clinical practice guidelines to see if they can be used or modified. In other words, don't re-invent the wheel.
- Determining if outcomes are clearly defined, measurable and meaningful.

- Evaluating patient self-management education; a very important aspect of disease management. Do web-based or mobile applications exist?
- Evaluating process and outcome measurements with eventual feedback to clinicians. One of the most effective ways to get buy-in by busy physicians is to show them how they are doing, compared to other similar physicians. The hospital management team also needs feedback.
- Emphasizing systems and populations, not individuals.
- Planning the necessary coordination among multiple services and agencies.⁹

For an example of how a university medical center improved compliance with discharge instructions for heart failure patients see the following case study on the next page. It should be obvious to readers that disease management programs are highly dependent on reliable data and the need for informaticians and data analytics experts.

The Role of Health Information Technology and DMPs

Health Information Technology (HIT) can assist DMPs in a variety of ways to include:

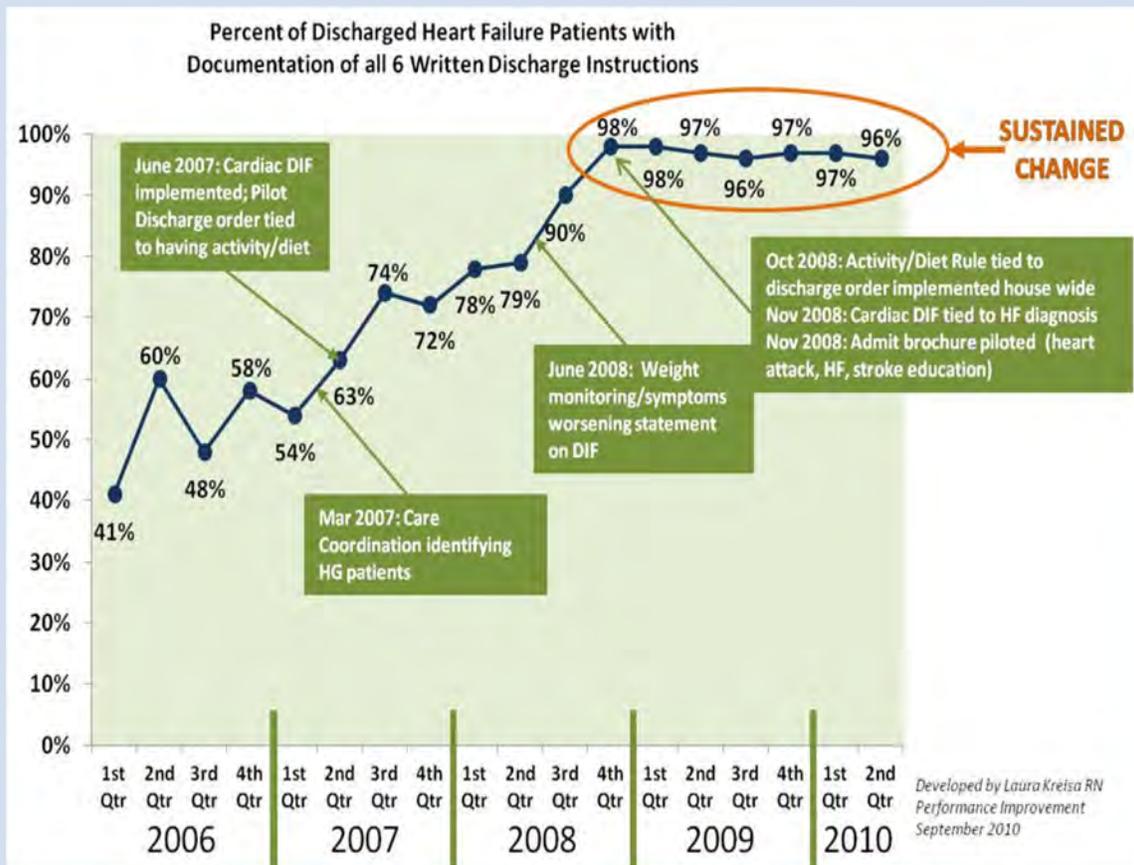
- Automated data collection and analysis, e.g. using a clinical data warehouse (CDW).
- Clinical practice guidelines (CPGs) that are web-based or embedded into the electronic health records (EHRs).
- Disease registries that are part of EHRs. Patient tracking using a registry to track e.g. all type 2 diabetes or all patients with pacemakers.
- Telemonitoring of patients at home (telehomecare), e.g. recording weight, blood sugar and blood pressure and then forwarding it to a disease registry, an EHR or dedicated server.
- Using mobile technology so that patients can upload personal health data to a personal health record or patient portal using their smartphones.

- Using disease specific web sites so data can be uploaded and educational information acquired.
- Using health information exchanges to connect multiple healthcare workers on the

DM team. This also permits aggregating data from an entire region or state and submitting quality reports.

Case Study

Virginia Commonwealth University (VCU) Health System recognized that in order to reduce readmissions for heart failure (HF), the most common Medicare diagnosis-related group, it would need to improve compliance with six evidence based recommended discharge instructions. The instructions were in the areas of activity, diet, follow-up, medications, symptoms and weight monitoring. The challenge was to standardize and document compliance across the multiple hospital locations where HF patients might be discharged. They set the goal of 95% compliance with providing written HF instructions that included the six areas of patient education. The strategy was to embed clinical decision support (rules and alerts) as part of their enterprise electronic health record's (EHR) computerized physician order entry (CPOE). This required a multi-disciplinary approach that included clinicians, IT and the Office of Clinical Transformation. This effort complemented the existing 300 evidence based EHR order sets already in existence. The success rate from January 2006 to June 2010 is demonstrated in the graph below.¹⁰



Disease Management and US Federal Government

According to the Centers for Medicare and Medicaid (CMS) their costs account for about one-third of national health expenditures so those programs are constantly looking for ways to improve quality and reduce costs. A quote from the CMS web site: “About 14% of Medicare beneficiaries have congestive heart failure but they account for 43% of Medicare spending. About 18% of Medicare beneficiaries have diabetes, yet they account for 32% of Medicare spending. By better managing and coordinating the care of these beneficiaries, the new Medicare initiatives will help reduce health risks, improve quality of life, and provide savings to the program and the beneficiaries.”¹¹

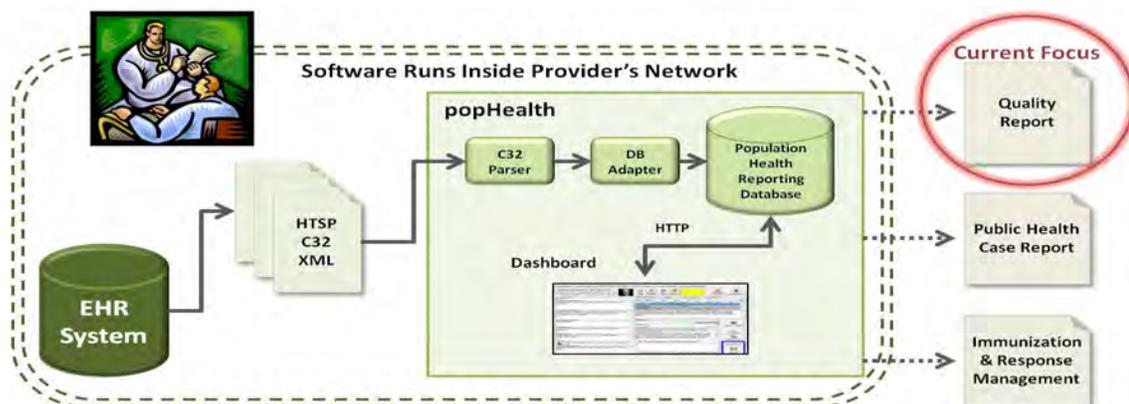
CMS has created 10 pilot programs to see if disease management can save the government money over a three year period (phase I). The Chronic Care Improvement Program (part of the Medicare Modernization Act of 2003) is now known as the Medical Health Support Program. Companies involved would not get paid for disease management unless they showed a total savings of 5% compared to a control group. Companies that can demonstrate improved outcomes were asked to participate in phase II. This “commercial” DMP was based less on physician support and more on nurse call centers and health coaches.

Eight large healthcare companies participated in this randomized controlled trial of more than 200,000 patients.¹² They reported their progress in late 2011 and showed little success in slowing the growth in hospital or emergency department admissions or any of the 10 outpatient diseases they were tracking. Importantly, they were not able to bend the cost curve for Medicare patients.¹³

The Affordable Care Act addressed the issue of chronic disease management by establishing several initiatives e.g., the accountable care organization model that is discussed in detail in the chapter on quality improvement strategies.

There is the expectation by the federal government that health IT, in particular EHRs, will result in better management and reporting of chronic diseases. For that reason, disease management reporting is part of Meaningful Use. There is a concern that that many EHRs are not capable of sending robust reports and government organizations such as Medicare/Medicaid are not ready to receive an avalanche of quality reports. To improve population health/disease management reporting, the Office of the National Coordinator released a free open source (Apache 2.0 license) population health reporting tool (popHealth) in early 2010. The popHealth application runs on JRuby or the Ruby programming language atop the Java Virtual Machine (JVM). Figure 15.3 shows how this application would run within the network of the user and generate quality reports.

Figure 15.3: popHealth Application (Courtesy Project popHealth)



The goal of this tool is to allow for easier submission of quality reports to public health organizations. In addition, it will allow clinicians to create new ad hoc reports and perform their own population health analyses. Importantly, this tool integrates with EHRs because it complies with multiple data standards (CCD and CCR) and integrates with open source CONNECT, discussed in the chapters on health information exchange and data standards. The program was certified as a module for Meaningful Use. Figure 15.4 shows a screenshot of a typical quality report. On the left is a disease and condition menu demonstrating overall patient compliance with goals such as LDL cholesterol under 100. On the right the user can select gender or age to analyze the data further.¹⁴

As mentioned in multiple chapters, the US government has made healthcare data more transparent and available for research and IT developers in an effort to develop better data analytics and eventually improve patient

outcomes. In mid-2013 CMS partnered with Archimedes a healthcare modeling and analytics company, founded by the well known David Eddy MD, PhD. The tool utilized is ARCHEs Population Explorer and it can be used to analyze a variety of healthcare data, to include synthetic de-identified Medicare claims data. These files are free to download and include inpatient and outpatient demographic, clinical and cost data. The vendor has a free version of ARCHEs PE for any user on their web site and they offer four data sets: CMS (DE-synPUF) from 2008-2010 claims dataset, NHANES III mortality dataset, Archimedes simulation dataset and China Health and Nutrition Survey dataset. Figure 15.5 shows a sub-population created from the simulation dataset consisting of adults > age 65 who have a Hemoglobin A1c level less than six (not in the diabetic range). The figure shows that this sub-population is at much lower risk of type 2 diabetes than the population at large. This software demonstrates the importance of data analytics for population and public health.¹⁵

Figure 15.4: Patient Dashboard (Courtesy Project popHealth)

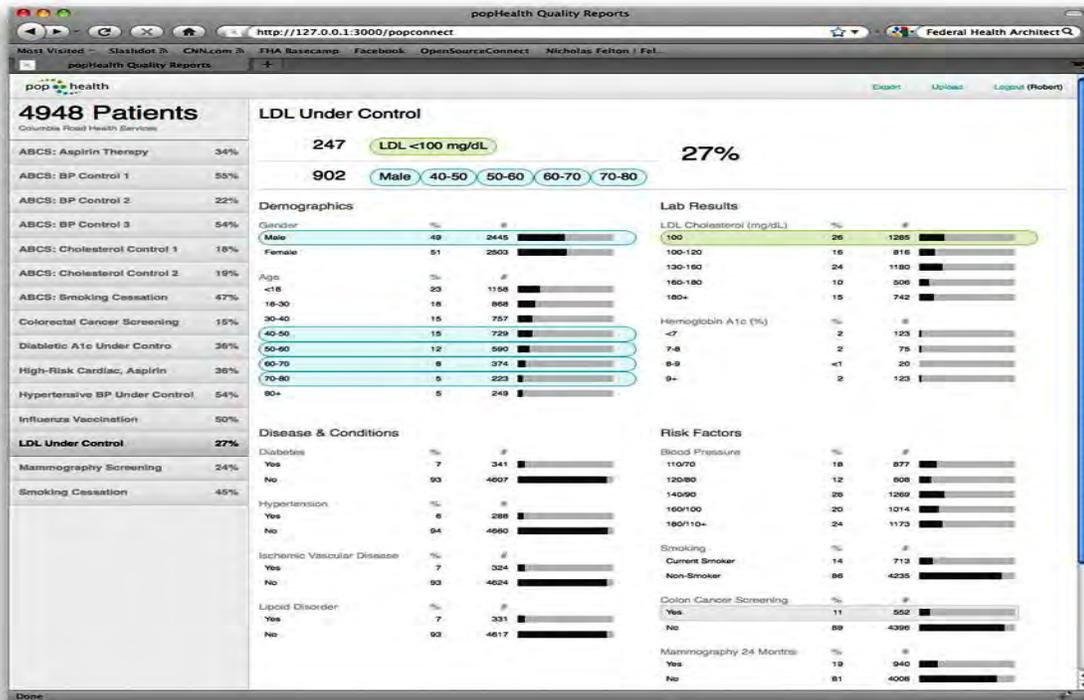


Figure 15.5: Data analytics with Archimedes

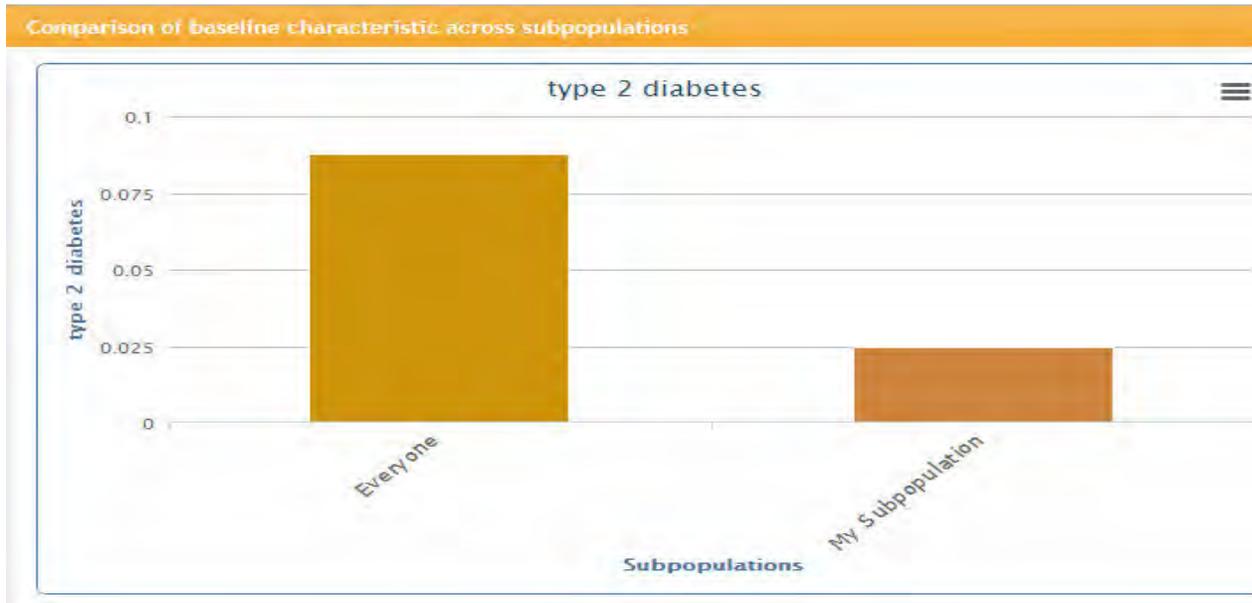
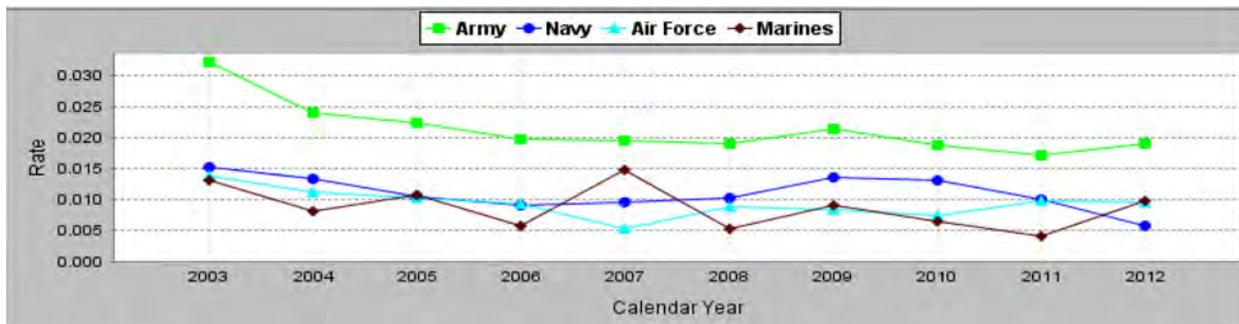


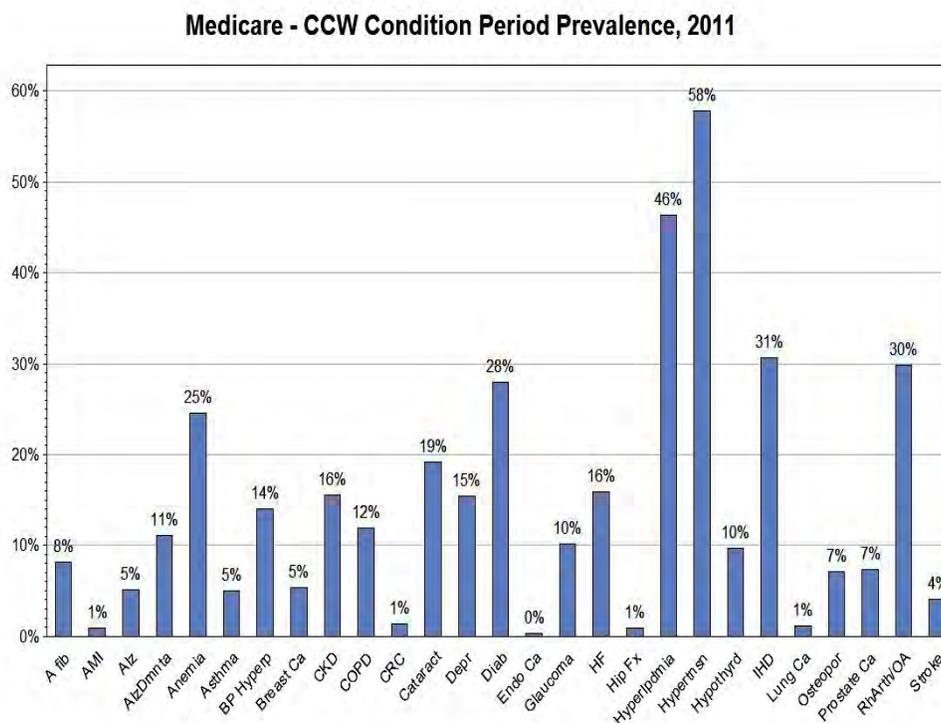
Figure 15.6: DMED Asthma Statistics



Another federal initiative to study population health and chronic disease is the Defense Medical Epidemiology Database (DMED) that provides access to de-identified data on all active duty service members. They report inpatient and outpatient data based on ICD-9 codes. If the Department of Defense wanted to know if asthma was on the rise as a result of multiple deployments to harsh environments, they could query all active duty, ages, ranks and both genders from 2003-2012 and they would see data that would suggest asthma is stable in active duty military members (Figure 15.6).¹⁶

The Chronic Condition Data Warehouse was launched in 2013 by CMS with the goal of helping healthcare researchers study chronic diseases based on Medicare and Medicaid data. CCW files are available on request from CMS and they are stored in an Oracle relational database. Data includes basic demographics, data from fee-for-service Medicare part A + B and part D drug claims. Figure 15.7 shows the prevalence of Medicare common chronic diseases in 2011 generated from the CCW.¹⁷

Figure 15.7: Medicare Conditions Report From Chronic Condition Data Warehouse



Recommended Reading

The following are recent articles from the medical literature evaluating the impact of disease management:

- Improving Primary Care for Patients With Chronic Illness: The Chronic Care Model.** This study demonstrated that 32 of 39 interventions showed improvement in at least one process or outcome measurement for diabetic patients; 18 of 27 studies involving three chronic conditions also demonstrated lower health care costs and/or lower utilization of services.¹⁸
- Effectiveness Of A Comprehensive Diabetes Lower Extremity Amputation Prevention Program In A Predominately Low Income African-American Population.** A comprehensive DM program for African-American diabetics showed large reductions
- in amputations, hospitalizations, emergency room visits and missed work days with an aggressive foot care program.¹⁹
- HealthPartners Optimal Diabetes Care Impact.** Healthcare organization program noted 400 fewer cases of retinopathy (eye damage) each year; 120 fewer amputations each year and 40 to 80 fewer myocardial infarctions (heart attacks) per year.²⁰
- The Effectiveness Of Disease Management Programmes In Reducing Hospital Admissions In Older Patients With Heart Failure: A Systematic Review And Meta-Analysis Of Published Reports.** A systematic review/meta-analysis of DM programs for heart failure concluded that programs are effective in reducing admissions in elderly patients.²¹

- *A Disease Management Program Reduced Hospital Readmission Days After Myocardial Infarction.* A DMP for myocardial infarctions reduced readmissions, emergency room visits and insurance claims.²²
- *Virtually Healthy: Chronic Disease Management in the Home.* A study of almost 800 chronically ill veterans using a web-based interactive disease dialogue telemedicine strategy at home was able to show a reduction in emergency room visits (40%), a reduction in hospital admissions (63%), a reduction in hospital bed days (60%), a reduction in nursing home admissions (64%) and a reduction in nursing home bed days (88%). Medication compliance improved as did compliance with national guidelines.²³
- *Practice-Linked Online Personal Health Records for Type 2 Diabetes Mellitus.* Authors studied the effect of a specific diabetic web portal/personal health record that was integrated with an EHR. Although participants were more likely to have medications changed, their diabetic, blood pressure and cholesterol control was not better than a similar group of patients who had access to a standard web portal. One of the lessons learned was that patient participation in this trial was only 5% of their diabetic population. Also, poorly controlled diabetics were less likely to enroll in such a study.²⁴
- *Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries.* Researchers reviewed 15 disease management programs (Medicare Coordinated Care Demonstration) funded by Medicare. They studied 18,000 patients to determine if care coordination by nurses would improve chronic disease care or decrease costs. Only two of the 12 largest programs showed any statistically significant effects on hospital admissions. Expenditures were 8% to 41% higher in the intervention groups compared to controls.
 - None of the programs generated net savings. They subsequently terminated all but two of the programs. They concluded that care coordinators (nurses) must interact with patients in person and not rely on telephones and technology. Also, coordinators must collaborate with the primary care clinicians to be successful.²⁵
 - *The Role Of Specialists In Managing The Health Of Populations With Chronic Illness: The Example Of Chronic Kidney Disease.* Nephrologists (kidney specialists) working for Kaiser Permanente in Hawaii wanted to improve the number of referrals from generalists so they could intervene earlier for chronic kidney disease. Because they all used the same electronic health record, they were able to monitor kidney function in the entire population of 214,000 patients. Access to lab results, clinical notes and secure messaging allowed the specialists to contact the generalists with advice and schedule consultations with themselves rather than waiting for the generalists. The end result was the decrease in late referrals from 32% to 12%. This was a good example of using a disease registry to improve population health. Rather than rely on a computerized clinical decision support, the specialists provided the decision support. Actual patient outcomes such as whether kidney dialysis was delayed due to the specialists intervening early were not included. They outlined the key features of the EHR-based electronic population management database:
 - Access to comprehensive, current patient information
 - Database permitted risk stratification
 - Ability to annotate records to improve communication
 - Seamless integration of new data into the longitudinal record
 - Electronic messaging between specialists and generalists
 - Electronic alerts for deteriorating lab results

- Generation of population level statistics
- Ability to flag patient records by status²⁶
- *Osteoporosis Disease Management: What Every Orthopedic Surgeon Should Know.* In another study from Kaiser Permanente they used their EHR to collect information on 650,000 individuals from 2002 to 2007. The EHR allowed them to easily note who had had a bone mineral density test (DEXA), who had a fracture and what meds the patients were on. Armed with this information they were able to show that hip fractures decreased 38%, DEXA testing increased 263% over the five years and the number of people on anti-osteoporosis drugs increased 153%. Again, population health is much easier with computable information obtained from robust EHR systems.²⁷
- *Allocating Scarce Resources In Real-Time To Reduce Heart Failure Readmissions: A Prospective, Controlled Study.* The authors used an electronic risk prediction model that extracted 29 predictive values real time from the EHR in a large academic medical center. Those at highest risk were given a team disease management approach. Only a part time case manager was added to the usual support. This was not a randomized controlled trial and no cost data was published. Using this model the readmission rate for heart failure (HF) dropped from 26.2% to 21.2% ($p = .01$, $OR = .73$ and $NNT = 20$). No cost data were reported.²⁸
- *Impact Of A Chronic Kidney Disease Registry And Provider Education On Guideline Adherence—A Cluster Randomized Controlled Trial.* This VA study looked at whether a clinic that had the advantage of specific education and access to a kidney disease registry would be more likely to adhere to clinical guidelines. The authors found marginal improvement and importantly only 5 of 37 clinicians actually accessed the registry.²⁹
- *Effects of a Web-Based Patient Activation To Overcome Clinical Inertia on Blood*

Pressure Control: Cluster Randomized Controlled Trial. The study was conducted by Hersey Medical Center to determine if a web based intervention would improve blood pressure (BP) control. Many experts feel that only about 50% of patients have optimal BP control. The web tool encouraged patients to ask their primary care physicians questions about BP control. After 12 months there was no difference in BP control between the group with the web-based tool and those who lacked the tool.³⁰

- *Improved Blood Pressure Control Associated with a Large-Scale Hypertension Program.* Kaiser Permanente Northern California created clinical practice guidelines, a hypertension registry as part of a DMP and studied BP control from 2001 to 2009. They used combined meds into one pill (polypill) to help compliance and used medical assistants to track hypertension at a lower cost. Their compliance increased from 43% to 80% over this 8 year period, exceeding the national average for control.³¹

In spite of some encouraging reports, there are problems with the quality of the studies published thus far, such as lack of randomization or lack of a control group. In addition, many studies do not convincingly prove a reasonable return on investment. It is unlikely that healthcare organizations will implement HIT without conclusive proof of benefit (improving quality and/or reducing cost). Large healthcare organizations with forward thinking leadership, a track record of successful HIT implementation and compliant physicians and patients will achieve the most success. In addition, the patients who have poorly controlled chronic diseases are not traditionally the same patients who embrace mobile and web-based technologies. It is unclear if the medically underserved will derive significant benefit from HIT. Indigent populations are at increased risk of chronic diseases but they also face a myriad of challenges that compete with healthcare priorities.³²

Disease Registries

In the beginning of this chapter a patient registry is defined. Patient registries can track a variety of diseases and conditions so disease registries should be considered a type of patient registry. Patient registries serve several purposes: (1) Describing the natural history of disease, (2) Determining the clinical impact or cost effectiveness of a program, (3) Assessing the safety or harm of a treatment or approach, (4) Measuring or improving the quality of care, (5) Augmenting public health surveillance, and (6) Promoting disease control.⁵

Patient Registry Categories

Patient registries can be categorized as follows:

Health Services Registries: used to track services such as hospitalizations, office visits, surgeries and infectious diseases.

Disease/Condition Registries: used to track chronic diseases such as diabetes, cancer, heart failure and conditions such as pregnancy. Registries can also track rare diseases, e.g. alopecia areata or track resource intensive conditions, e.g. heart transplants.

Product Registries: used to track patient safety-related concerns such as toxin exposure, certain medications, adverse drug events and devices, e.g. pacemakers.

Combination Registries: quite possibly a patient might be in more than one registry such as coronary artery disease and coronary stent registries.⁵

An electronic disease registry is defined as “ a software application for capturing, managing and providing access to condition specific information for a list of patients to support organized clinical care”.³³ Stated another way; registries are tools that disease management programs use to track patients with chronic diseases or conditions, such as diabetes or smoking. As a result of this data DM programs can remind clinicians, nurses and patients to get lab work done and keep appointments. In addition, they can aggregate data to show, for

example, the average hemoglobin A1c levels (blood test to measure blood sugar control) of a single patient or an entire clinic that could be useful for pay-for-performance (next chapter) programs (see Figure 15.8).

Figure 15.8: EHR-Disease registry that generates quality reports for reimbursement



Disease registries can be populated through several mechanisms:

Manual: data manually inputted onto paper or a computer database or spreadsheet or into a web-based program.

Automatic: data automatically inputted into standalone software or web-based site using client-server software and integrated with, for example, a laboratory result program using LOINC and HL7 standards.

Automated and integrated: data input, retrieval, tracking and graphing are all automatic and part of an electronic health record (EHR) or health information organization (HIO). This model is increasingly being adopted and is felt to have the greatest potential in DMP and pay-for-performance programs.

Large integrated delivery networks were the first healthcare organizations to develop sophisticated registries to measure and track diseases and other conditions. In the information box below the Kaiser Permanente total joint registry is presented.³⁴ The Cleveland

Clinic has a disease registry linked to their EHR, designed to collate, track and study patients who have chronic kidney disease (CKD). As of 2010 they had more than 50,000 patients enrolled.³⁵



Total Joint Replacement Registry (TJRR)

In 2001 Kaiser-Permanente created a registry just for total joint replacement surgery, given the fact that Kaiser-Permanente surgeons perform 17,000 joint replacements each year. Electronic forms were created for data input that were integrated with the EHR. The registry is used for possible implant recalls and advisories, patient safety/quality improvement initiatives, to identify best practices and to conduct research. In addition to the TJRR, they have created four more orthopedic registries to monitor e.g. spine surgery.³⁴

The ultimate solution will be to have universal adoption of EHRs that have robust disease registries. In this manner all fields are automatically populated with patient data, to include lab results, etc. As discussed in the chapter on EHRs, stage I and 2 Meaningful Use criteria included the requirement to generate patient lists for specific conditions to use for quality improvement, reduction of disparities and outreach. It also required outpatient quality reports and the ability to send reminders to patients for preventive care. EHRs therefore should be able to generate a list of diabetic patients but the registry may not allow customization of data fields, exportation of data or user-friendly notification of patients or embedded clinical decision support. An EHR disease registry must be more than just a list of patients with a condition. For example, in the case of diabetes, the registry must include all pertinent labs dealing with diabetes, to include related labs for cholesterol, kidney function, etc. The registry data fields should closely match the national CPG recommendations so that users can see how closely the clinicians and patients are adhering and provide notifications to the patients.³⁶

Disease registries are not unique to the United States. A 2011 article reported on the status of registries in Sweden, Australia, Denmark, United States and the United Kingdom. They identified many areas where improved patient care was associated with disease registries but causality can't be proven with the study design. It was clear that the registry was a valuable clinical tool but data transparency needed to take place as well as education of clinicians and patients, i.e. disease management. In the case of Sweden they had almost 90 government-supported registries established by medical subspecialties so buy-in was not an issue. Importantly, it was the belief of the authors that disease registries are associated with significant cost savings globally.³⁷

Disease Registry Limitations

Potential disease registry limitations were summarized in a monograph by the Robert Wood Johnson Foundation: (1) Standardizing data elements among disparate disease registries, (2) Uniform method for patient identification, (3) Assistance in linking registries with EHRs, (4) Standardizing methodologies for statistical analysis, (5) Ensuring high clinician participation, (6) Guaranteeing registry sustainability, (7) Clinical and administrative (claims) data should be combined in a registry, (8) The need to manually input data for some registries, (9) The need for accurate coding, (10) The need for frequent updating, and (11) The need for additional staff to maintain a registry.³⁸

Disease Registry Cost

Approximately 50 standalone disease registries exist that are free or fee-based. Cost is usually \$500 to \$600 annually per user for commercial registries. In general, free public registries have less functionality than commercial registries.

Disease Registry Resources

For an excellent in-depth review of 16 standalone registries see *Chronic Disease Registries: A Product Review* by the California HealthCare Foundation.³⁹ They also review the

IT tools used for chronic disease management. Five California foundations have combined resources to support a \$4.5 million project known as “Tools for Quality” to test disease registries for the low income and underserved populations in their state. They have recruited 33 clinics thus far that will be paid on average about \$40,000 to acquire and maintain disease registries.⁴⁰ The California HealthCare Foundation also has a monograph that compares electronic health records with disease management systems but does not offer specific examples or vendors.⁴¹ A paper by Khan et al. discusses the current and future status of diabetic registries that has implications for other diseases.⁴²

Disease Registry Examples

Chronic Disease Electronic Management Systems (CDEMS): This popular program is Microsoft Access-based and tracks diabetes and adult preventive health. The program is customizable and includes lab reminders for clinicians. The reports generated are also customizable and users have access to a web forum to discuss issues. A free add-on program inputs data automatically from several laboratory information systems (Quest, Labcorp, Dynacare and PAML). Shortcomings include the need to manually input data and access is limited to ten concurrent users.⁴³

Remedy MD: This web-based site has more than 100 disease registries for clinicians and researchers. Application can capture, aggregate and analyze data from administrative, clinical and genetic information from EHRs as well as imaging applications and portals. The built-in OntologyManager™ supports all of the major standards such as LOINC, CPT, ICD, SnoMed, and UMLS. Registries are customizable.⁴⁴

Patient Electronic Care System (PECYS): This is a disease registry based on Wagner’s Chronic Disease Model. It is used frequently by community health centers to manage chronic diseases. Clinical practice guidelines are embedded for decision support.⁴⁵

The preceding section was an overview of the topic of patient registries. Several disease registry vendors have gone out of business, most likely due to the fact that the vast majority of EHRs will have registries as part of disease management and meaningful use requirements. For an example of an electronic disease registry see Figure 15.9. For additional reading, an extensive 2010 monograph by AHRQ is recommended.⁵

Future Trends

Developed and developing nations are faced with escalating chronic diseases that are associated with high healthcare expenditures. Not only will there have to be healthcare reform to change the payment strategy, there will need to be more disease management programs. Health information technology will support coordinated care, patient tracking, data retrieval and outcome analysis. A myriad of technologies will need to be interoperable such as electronic health records, patient portals, health information exchanges, home telemedicine devices and mobile devices to provide coordinated disease management programs.

As larger organizations develop comprehensive disease management programs with their own data warehouses one can expect higher quality outcome studies. The goal which will be better data generating better medical practices, resulting in better patient outcomes.

Newer programs such as the Hospital Readmission Reduction Program will begin financially penalizing hospitals with higher than normal readmission rates for heart attacks, heart failure and pneumonia in FY 2013. Look for both a carrot and stick approach to disease management by the federal government.⁴⁶

Future Meaningful Use requirements may force EHR vendors to have comprehensive and interoperable disease registries that include automated reporting.

Figure 15.9 Electronic Disease Registry (Courtesy HealthWV)

Registry	Measure	Value	Date	Registry Goal	Patient Goal	Due
Diabetes Registry	LDL	69 mg/dL	23 Apr 2009	< 100; Every 180 days		23 Apr 2010
Diabetes Registry	A1c	10.2 %	01 Oct 2009	< 7.0; Every 90 days		30 Dec 2009
Diabetes Registry	Assessed for Nephropathy	MICROALBUMIN/CREATININE, URINE: normal	21 Jul 2009	Every 365 days		21 Jul 2010
Diabetes Registry	BP	110/72	17 Feb 2010	< 130/80; Every 180 days		16 Aug 2010
Diabetes Registry	Dilated Fundus Exam	Dilated Fundus Exam: Normal	01 Sep 2009	Every 365 days		01 Sep 2010
Diabetes Registry	Foot Exam	Foot Exam: Normal	01 Sep 2009	Every 365 days		01 Sep 2010
Diabetes Registry	Diabetes Education	Diabetes Education with Nutrition Counseling	01 Sep 2009	Every 365 days		01 Sep 2010
Diabetes Registry	Diabetes Self-Mgmt Goal	Check Blood Sugars	01 Oct 2009	Every 365 days		01 Oct 2010
Diabetes Registry	Exercise	>=3x per wk 20 minutes	23 Feb 2010	in (>=3x per wk 20 minutes); Every 365 days	Not applicable	
Diabetes Registry	Current Tobacco Use	No	18 Feb 2010	in (No; Former); Every 365 days		18 Feb 2011
Diabetes Registry	Glucose	130 mg/dL	13 Nov 2007			

Key Points

- Chronic diseases are on the rise in the USA and worldwide
- Chronic diseases are costly so disease management programs are commonplace, but benefits are controversial
- Disease management programs benefit from information technology by creating electronic disease registries
- Most EHRs have electronic disease management programs in order to meet Meaningful Use

Conclusion

For Disease Management programs to succeed there needs to be a mandate to improve the treatment of chronic disease coupled with financial support. Due to the rising costs of chronic diseases, CMS and managed care organizations are interested in new pilot programs. What must be shown is that DM programs improve patient outcomes and save money. It is much easier to show that programs improve processes such as lab tests drawn than improved patient outcomes, such as fewer heart attacks or strokes. The Congressional Budget Office in 2004 concluded that there was

inadequate evidence that DM programs reduced healthcare spending and little has changed since then.⁴⁷ Bringing in more patients for preventive care will clearly increase medical costs, at least in the short run. The hope is that the costs will fall long term with preventive care.

Ultimately, all electronic health records will have comprehensive disease management features that will be customizable for clinicians and administrators. Data will be easier to retrieve and analyze in a real time mode and will be linked to reimbursement. Until that happens, however, clinicians will rely on a variety of disease registries and disease management

systems. Even with ARRA reimbursement of EHRs that have disease registries, it will be many years before the true impact of electronic disease management and Meaningful Use reporting is understood.

At this time, models that integrate human (nurse, physician, pharmacist, etc.) involvement with technology seem to work better than purely technical solutions for disease management.

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Chapter 16

Quality Improvement Strategies

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Learning Objectives

After reading this chapter the reader should be able to:

- Define quality medical care and how it relates to patient safety
- State the goals of quality improvement (QI) programs
- List the components of the Quality Improvement Roadmap and National Quality Strategy
- Describe how health information technology (HIT) can support quality improvement
- List several quality improvement programs sponsored by the Centers for Medicare and Medicaid Services (CMS)
- Compare and contrast the patient centered medical home and accountable care organization models and how they are supported by HIT
- List the concerns and limitations of current QI programs for the average clinician

“The United States is among the wealthiest nations in the world, but it is far from the healthiest. Although life expectancy and survival rates in the United States have improved dramatically over the past century, Americans live shorter lives and experience more injuries and illnesses than people in other high-income countries”¹

U.S. Health in International Perspective: Shorter Lives, Poorer Health. 2013

Introduction

When compared to other developed countries medical care in the United States is expensive, accounting for about 16% of gross national product (GNP), and is not associated with improved longevity.² A 2011 study by Nolte and McKee looked at preventable mortality in 16 developed countries and found that there was improvement in all countries, but the least improvement occurred in the United States.³

Another study comparing medical quality in developed countries noted that the United States physicians reported: the highest percent (58%) of patients claiming difficulty affording medication, the lowest after-hours support (29%) for patients, last place in use of electronic health records (EHRs) and one of the lowest rates in use of teams to treat chronic diseases.⁴ However, as result of reimbursement for

Meaningful Use of electronic health records by Medicare/Medicaid, EHR adoption is catching up (see chapter on EHRs).

Interestingly, some of the most common words in medicine are the most difficult to define and “quality” is one of those hard to describe terms. One approach to quality is to say that it is the standard of care for the society in which the physician practices. In other words, poor quality care is care that does not meet the current standard of care. Clearly, this definition relies on our knowing the current standard of care. One can say that the current standard of care is the practice of evidence-based medicine and, in the situation where there is little reliable evidence, the care provided by most experienced physicians.

While it is beyond the scope of this book to discuss all the factors that impact the quality of healthcare in the United States, but some of the more important factors will be outlined:

- The U.S. health care system is fragmented and poorly organized for improvement. Unlike an integrated delivery network such as Kaiser Permanente, most of the country is based on small independent medical practices that receive reimbursement based on fee-for-service.
- According to the Institute of Medicine (IOM), health care in the U.S. has experienced the growing complexity of science and technology yet has not been able to fully exploit the revolution in health information technology.⁵
- There has been an increase in chronic conditions, e.g. obesity, diabetes and heart failure, and health care has poorly designed delivery systems that are not organized around quality and patient safety.⁶
- The Agency for Healthcare Research and Quality (AHRQ) has demonstrated that there is too much variation in health care when comparing states, e.g. coronary angiography rates.⁷
- A well publicized 2003 Rand study suggested that only 55% of Americans received recommended care.⁸ It should be pointed out, however, that the methodological approach for the study has been challenged and according to a follow-on study it would take, on average, 7.4 hours daily for the average physician to comply with all recommendations for preventive care.⁹

The bottom line is the federal agencies involved with health care have been extremely concerned about the high cost of health care, the less than optimal health care delivered, and sub-optimal patient safety. As a result, agencies seek new non-traditional health care delivery and reimbursement models aimed at incentivizing quality and reducing variation in outcomes. Select strategies will be addressed in the remainder of the chapter. An example is the Centers for Medicare and Medicaid Services’ (CMS) *Quality Improvement Roadmap* where the agency espouses a simple vision “The right care for every person every time.” The Roadmap lists six criteria of the right health care, adopted from the Institute of Medicine’s *Crossing the Quality Chasm*:

- Safe: care does not harm patients
- Effective: care prevents disease and complications and minimizes suffering, disability and death
- Efficient: patients receive care without waste
- Patient centered: care is coordinated and continuous; patients are informed and educated and involved in decision making
- Timely: patients and staff do not experience unwanted delay
- Equitable: care is equal, regardless of race, language, personal resources, diagnosis or condition

The core strategies of the Quality Improvement Roadmap can be summarized as follows:

- Publish quality measurements and information: Use the same performance measures among all health care

organizations and select those that are the most evidence based

- Pay-for-performance: Principles are explained later in this chapter
- Promote health information technology: Includes the adoption of electronic health records, e-prescribing and health information exchanges
- Work through partnerships: Select national, federal, and civilian quality-oriented partners (e.g. Agency for Healthcare Research and Quality, National Quality Forum, American Health Quality Association and National Committee on Quality Assurance)
- Improve access to better treatments: Accelerate the availability and effective use of the best treatments ¹⁰

Although this vision derives from the Institute of Medicine (IOM), it has been incorporated by most federal, state and civilian healthcare organizations. To accomplish this vision organizations have developed multiple quality improvement strategies (e.g. pay-for-performance, care coordination, patient safety initiatives, e-prescribing, electronic health records, quality performance reporting and clinical practice guidelines). All of these are discussed in detail in other chapters.

In early 2011, the Department of Health and Human Services announced the National Strategy for Quality Improvement in Health Care (National Quality Strategy) that was mandated by the Affordable Care Act. Private and public partners (e.g. AHRQ) will carry out the strategy. More than 300 organizations provided input into the creation of the Strategy. Further Strategy details such as pilot initiatives are available. The three major goals of the National Quality Strategy:

- Better care by improving quality and making healthcare more patient-centered, reliable, accessible and safe
- Healthy people and communities by improving interventions that address

behavioral, social and environmental health determinants

- Affordable care by reducing the cost of healthcare for individuals, families, employers and government

Six priorities will help achieve these aims:

- Making care safer by reducing harm
- Ensuring that individuals and families are engaged in their care
- Promoting effective communication and coordination of care
- Promoting effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
- Working with communities to promote wide use of best practices to enable healthy living
- Making quality care more affordable by spreading new health care deliver models ¹¹

Several of these priorities will be facilitated by health information technologies such as electronic health records, clinical decision support, personal health records, health information exchanges, disease registries; all discussed in detail in other chapters.

Quality Improvement Strategies

Pay-for-Performance

Healthcare is in the process of seeing newer payment and delivery models but there is little data to analyze at this point. One strategy known as pay-for-performance (P4P) has captured attention and funding. The Centers for Medicare and Medicaid Services define P4P as a “quality improvement and reimbursement methodology aimed at changing current payment structure which primarily reimburses based on the number of services provided regardless of outcome. P4P attempts to introduce market forces and competition to

promote payment for quality, access, efficiency and successful outcomes.”¹⁰

There have been numerous studies since the IOM classic *Crossing the Quality Chasm* report that confirm the United States is not getting our money’s worth from the American healthcare system. As an example, a study by the Commonwealth Fund demonstrated that the quality of care delivered to Medicare recipients was not related to the amount of money spent.¹² The IOM has been consistently critical of the variation in care delivery and outcomes as well as serious patient safety issues (see patient safety chapter). As a result, they have repeatedly called for an increase in payments to clinicians who offer higher quality care. These concerns about “value-based care” are further aggravated by the fact that the United States has an annual \$2.3 trillion dollar health care price tag that continues to rise each year. The IOM released *Rewarding Provider Performance: Aligning Incentives in Medicare* report in 2006 that called for a change in reimbursement that would result in higher quality of care delivered.¹³

Statements by organizations such as the IOM have helped support the notion that major changes in the field of medicine, to include how one determines reimbursement for care are needed. P4P (also known as value-based purchasing) has gained traction in the United States in a surprisingly short period of time. The

momentum may in part be due to the 2004 statement made by Mark McClellan, administrator for the Centers for Medicare and Medicaid Services in the Wall Street Journal:

“In the next five to ten years, pay-for-performance based compensation could account for 20-30% of what the federal programs pay providers.”¹⁴

As a further example of the rise of P4P programs, Rosenthal et al. in a 2006 article examined the incidence of P4P programs in 252 Health Maintenance Organizations (HMOs). They determined that over half had P4P programs; 90% of programs were for physicians and 38% were for hospitals.¹⁵

There are three types of outcomes: administrative, for example, equipment use and system utilization; surrogate clinical outcomes, for example, mammograms; and true clinical outcomes, for example, breast cancer. Presently, most tracked outcomes are administrative and surrogate outcomes because true outcomes are complex, need relatively large populations, and require statistical adjustments. Process measures can include administrative and surrogate outcomes.

Table 16.1 shows the types of data, clinical scenarios and examples of information technology used in P4P programs.

Table 16.1: Types of data, clinical scenarios and IT support for P4P programs (EHR = Electronic health record, HIE = health information exchange)

Types of data	Clinical Scenarios	IT Support
Utilization data	Emergency room visits	Data repositories, EHRs, HIE
Clinical quality	Women who have had mammograms	Patient lists, disease registries, EHRs, HIE
Patient satisfaction	Percent of patients who would recommend their primary care manager	Online surveys
Patient safety	Percent of patients questioned about allergic reactions	EHRs, e-prescribing module

In spite of the potential of information technology to improve quality, numerous issues exist. Most EHRs are not ready for generating P4P type reports. Ideally, data would be automatically generated from the EHR if the data were inputted into data fields via structured templates rather than free text. Unfortunately, most clinical notes are not written using structured templates and problem summary lists are not updated often enough to be a reliable data source. Perhaps natural language processing (NLP) will eventually be able to scan a dictated patient encounter and automatically submit a P4P report as well as a coding level. Lab results are often easier to report because they are coded by data standards such as Logical Observation Identifiers Names and Codes (LOINC). Similarly, the federal government is not yet ready to receive voluminous quality reports from EHRs as part of Meaningful Use requirements. A 2007 article by Baker on automated review of quality measures for heart failure using an EHR concluded that the current system was insufficient, e.g. it lacked the ability to tell why a drug was not started or why it was stopped. Chart reviews were the only way to tell why recommended medications were not used or were discontinued.¹⁶ Furthermore, there is a need to identify acute versus chronic problems and active versus inactive problems in EHRs. Until EHRs are universal, organizations must consider a transitional plan like disease registries and disease flow sheets. Health care systems may benefit from health information exchange that includes a central data repository (CDR) or data warehouse with a rules engine.¹⁷ Data could be pushed or pulled from the CDR for monthly reports. Further information about the role of HIT in quality improvement can be found in the chapters on EHRs, medical data, disease management and health information exchange (HIE).

In order for P4P to be well received there needed to be a set of outpatient clinical performance measures that would be accepted by clinicians.¹⁸⁻¹⁹ Many of the early P4P projects were actually pay-for-reporting that looked at processes and not pay-for-performance that focused on clinical outcomes. Process measurements check to see if

a test was done and not the actual result. This typically allows for easy retrieval of data using administrative or insurance claims data. Organizations such as the National Quality Forum (NQF) are developing medical quality measures that will be used in all quality improvement programs and are now part of Meaningful Use reporting.

CMS has a game plan over the next three to five years to transition from a passive fee-for-service reimbursement plan to a proactive value-based purchasing model. Much of the innovation in health care delivery will likely be realized through the new CMS Innovation initiative. The Innovation Center was created under the Affordable Care Act (ACA), in order to “test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care” for those who get Medicare, Medicaid or CHIP benefits. The Center received \$10 billion in direct funding in fiscal years 2011 through 2019 to support this mission. Through the Innovation Center, CMS is working to transform from a claims payer in a fragmented care system into a partner that helps achieve better value for our health care dollars.²⁰

Finally, pay-for-performance is a massive data initiative. The programs that implement P4P will have to be very large and very sophisticated. Currently, there are few public systems of this magnitude in existence

Meaningful Use (MU)

MU was discussed in detail in the chapter on EHRs with the core and menu objectives for stages 1 and 2 posted in the appendix at the end of the chapter. MU is mentioned in this section because EHR adoption is pivotal to health care reform and quality improvement in many areas. Health care data must be digital and discrete in order to be shared and analyzed so this is impossible with paper records. In order to be reimbursed for using a certified EHR, an eligible physician would have to demonstrate (and prove) MU. Three out of five of the overarching goals of MU have these implications: (1)

improve quality, safety, efficiency and reduce health disparities, (2) improve care coordination, and (3) improve population and public health. These goals are achieved through EHR tools such as e-prescribing, disease registries, CPOE, clinical decision support, quality reports, HIE and electronic patient summaries.

In 2014 eligible professionals will need to report nine out of sixty four quality measures electronically to CMS. Eligible hospitals will need to report 16 out of 29 quality measures for reimbursement under stage 2 meaningful use. The domains of quality measures are: patient and family engagement, patient safety, care coordination, population/public health, efficient use of healthcare resources and clinical processes/effectiveness.²¹

Integrated Delivery Networks

Before some of the newer healthcare models are presented it is important to mention that some healthcare systems have been highly successful and part of their success has been the early adoption and integration of electronic health records and other technologies into their corporate fabric. At the top of this list would be organizations such as the Veterans Administration, Kaiser-Permanente, Geisinger Clinic and the Mayo Clinic.

Kaiser-Permanente will be highlighted as one organization in this section that represents a successful example of a healthcare delivery model with many reported successes. It must be emphasized that their success is multifactorial: excellent leadership and vision, adequate resources (people and money), early adoption of cutting edge technologies and emphasis on medical quality. Kaiser has a large patient enrollment of approximately 8 million patients. In the past decade at a cost of about \$4 billion

dollars they implemented KP Health Connect, their comprehensive electronic health record. The following is a summary of some of the accomplishments achieved by this organization:

- Medical Care excellence
 - Reduced rates of sepsis mortality, overall hospital mortality, HIV mortality, hospital acquired pressure ulcers, reduced obesity
 - Improved mammography, chlamydia detection rates, stroke mortality rates, hip fracture rates, flu shot compliance, early intervention of kidney disease, hypertension control and cholesterol control
- Research Excellence with approximately 1000 research projects yearly
 - Collection of 400,000 DNA samples for future research and integration with current medical information
 - Publication of several hundred medical articles annually
- Technology excellence
 - Total joint registry
 - MyChart the patient portal
 - Smartphone apps
 - Online clinical library
 - Health information exchange with the VA
 - Data mining with “big data”
- Philanthropy ²²

The ACA initiative is causing the consolidation of local and regional healthcare delivery systems. This is creating integrated delivery networks in almost all the major metropolitan areas and healthcare monopolies in smaller communities.

BCBS of Michigan Patient Centered Medical Home Model

The Michigan PCMH is the largest in the US with 3600 primary care physicians, representing more than 1,243 primary care practices. From 2012-2013 the number of PCMH model practices grew by 25%. BCBS claims a 19 percent lower hospital admission rate, lower emergency room usage rates, lower radiology use and higher use of generic drugs, compared to non-PCMH practices. They estimate that roughly \$155 million was saved in the first three years due to lower emergency room and hospital admissions.²⁹

The Patient-Centered Medical Home (PCMH) Model

This model is intended to be an improved model for health care quality and delivery, payment reform, chronic disease management and practice innovation. It is based on the relationship between the patient and their primary care physician (PCP). It is up to the PCP and his/her team to improve access and manage chronic diseases with the goal of keeping the patient healthy and at home. The team sets individual goals, encourages patients to be more proactive and coordinates their care across the continuum. Patient education and preventive care are major goals of this medical model. Although the concept has been around since 1967, in pediatrics, it was promoted by major medical associations in 2007. Since then the concept has been embraced by private insurers,²³ Medicare,²⁴ and the Department of Defense.²⁵ Most medical practices that desire the designation PCMH will need to be certified by NCQA, discussed in a section later in the chapter. Standard goals include: enhance access and continuity; identify and manage patient populations; plan and manage care; provide self-care support and community resources; track and coordinate care and measure and improve performance. Part of the concept for PCMH is technology support using disease registries, EHRs, personal health records, e-prescribing, patient portals, secure messaging, e-visits, HIEs and telehome care. In this model, practices would have to handle more walk-ins and same-day appointments. CMS has demonstration projects in eight states and early evidence suggests a positive effect on cost and quality.

Projects will eventually include Federally Qualified Health Centers (FQHCs).²⁶

Bates and Bitton maintain that EHRs are pivotal for this model but frequently lack the desired functionality.²⁷ Rittenhouse et al. suggest that small to medium sized medical practices (the majority of US primary care) use very few PCMH processes, most likely due to limited IT support.²⁸

Preliminary information is beginning to appear that the PCMH model may be associated with cost savings. In 2013 the Blue Cross Blue Shield of Michigan PCMH, the largest in the US, published some of their results. (see Infobox)²⁹ More research is needed to know if the PCMH will consistently improve medical care, access and care coordination.

For a review of the topic and more detail readers are referred to several recent articles.³⁰⁻³²

Accountable Care Organizations (ACOs)

An accountable care organization (ACO) is a healthcare delivery organization that assumes the clinical and financial responsibility for the care of a defined group of patients. ACOs were created in 2010 by the passage of the Patient Protection and Affordable Care Act (PPACA, aka ACA). The rationale of the legislation is that the quality of care can be improved and the cost of care can be lowered by bringing together the many components of the healthcare delivery system into a functional unit that increases the efficacy of care, reduces system waste, and increases patient safety.

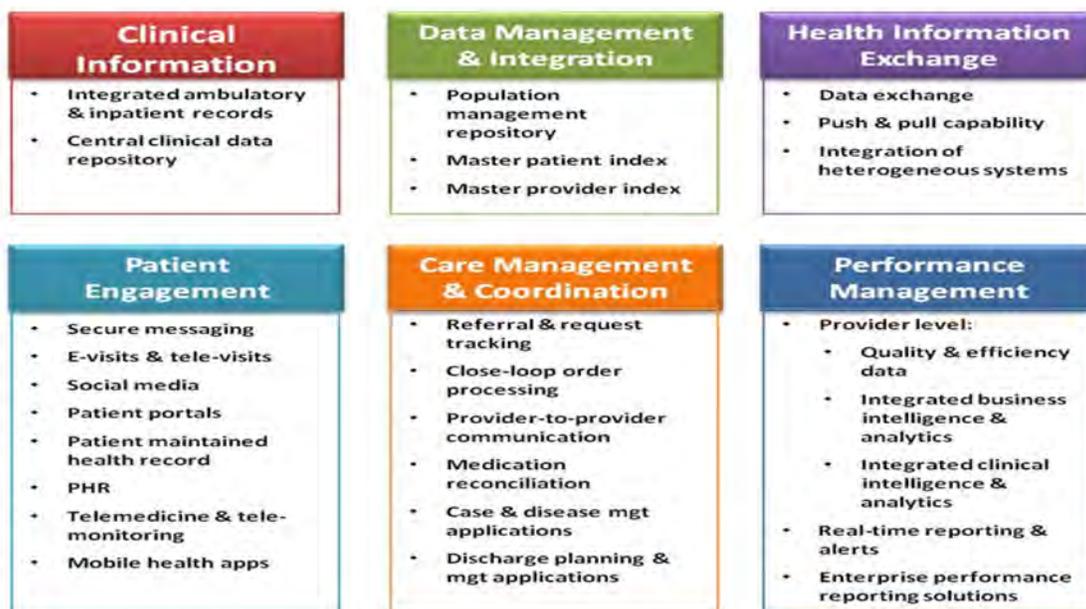
Participants will need to report on 33 quality measures in four domains: (1) patient experience domain with seven measures, (2) care coordination/patient safety domain with six measures, (3) preventive medicine domain with eight measures, and (4) at risk populations domain measuring care for diabetes, heart failure, hypertension and coronary disease with 12 measures. EHR use is voluntary but counts double as a quality measure. Year one will be pay-for-reporting and by year three pay-for-performance. These measures are aligned with other CMS quality programs. ACOs will have baseline performance recorded July 2011 to March 2012, measuring all Medicare part A&B payments as the economic benchmark. A scoring system has been developed that will substantiate payment for achievement or improvement in performance, compared to baseline. Practices will need to be innovative, evidence based, patient centric and care coordination will be essential. Additionally, ACOs must be more of a team effort and exchange data more readily to succeed. A variety of ACO pilot projects are underway in the United States by civilian insurers and Medicaid.³³ As of early 2013 more than 400 ACOs have been created. Of the CMS-related ACOs about half are physician-lead, rather than

hospital-lead organizations. With the first 32 Medicare ACOs (known as Pioneer ACOs) there have been many successes and failures.³⁴ In at least one instance, financial success was due to data analytics which fostered a comprehensive game plan for high risk patients.³⁵

The electronic health record (EHR) is a critical element of the ACA because without it the components of the healthcare delivery system cannot be integrated into a functional unit. The impact of the EHR on medicine is, as yet, unclear. For example, its projected cost savings may have been overestimated and its clinical impact in terms of improving medical care has yet to be clearly demonstrated.³⁶

HIT will be an integral part of ACOs to promote evidence based medicine (EHR order sets and clinical practice guidelines) and patient engagement (patient portals, PHRs and secure messaging), quality and cost reports (EHR generated), and care coordination (HIE, continuity of care documents, telehealth and remote patient monitoring). The Certification Commission for HIT (CCHIT) developed a framework for understanding what technologies are necessary for the infrastructure of most ACOs.³⁷ Figure 16.1 demonstrates how HIT is integral to ACOs.

Figure 16.1: ACO technology infrastructure (adapted from Battani)³⁸



Quality Improvement Projects

It is estimated that more than 100 organizations have P4P programs in place, in spite of the paucity of studies to prove efficacy or return on investment. Many of the programs are really pay-for-reporting programs, in that, clinicians are being reimbursed for submitting evidence that they checked on an important test, not that the test was optimal or met national recommendations. Presented in the following section are newer quality improvement initiatives.

Physician Quality Reporting System (PQRS)

PQRS (formerly known as the Physician Quality Reporting Initiative or PQRI) is a Medicare program that began in 2007 for the purpose of reimbursing for reporting quality measures. It is a pay-for-reporting initiative where participants can report individual quality measures, disease/condition-specific measures or reports through disease registries (that could be part of an EHR). The program applies to individuals or group practices. In 2013 there were four methods to report in the PQRS: 1. To CMS on their Medicare Part B claims, 2. To a qualified Physician Quality Reporting registry, 3. To CMS via a qualified electronic health record (EHR) product, 4. To a qualified Physician Quality Reporting EHR data submission vendor. Specific reporting details, such as qualified EHR vendors and data submission vendors are included on their web site. Each eligible professional (EP) must satisfactorily report on a minimum of 80 percent of eligible instances, on at least three measures or report on a 20-patient sample (on measures groups) to qualify for payment under the 2013 PQRS. If eligible physicians (EPs) successfully report quality measures they can expect to receive an incentive payment equal to 0.5% of Medicare Part B allowable charges. Starting in 2015 there will be adjustments to payments for those physicians who do not meet the guidelines.³⁹ For details regarding alignment issues with PQRS and

Meaningful Use payments, readers are referred to the chapter on EHRs.

Clinicians are paid bonuses the following year and physician survey data suggests that this time-based delay has not been well received. In addition, clinicians have been slow to receive feedback on their progress from CMS.⁴⁰ For example, for 2013 reporting clinicians can expect to receive feedback via a web portal in the Fall of 2014.

CMS Premier Hospital Quality Incentive Demonstration Project

The project began in 2003 with 270 hospitals participating in a three year demonstration period. Hospitals were paid based on compliance with 34 quality indicators in five common areas (heart attack, heart failure, pneumonia, coronary artery bypass surgery and hip/knee disease). The program leverages the Premier Perspective database which is the largest of its kind in the nation. After review of first year data, hospitals scoring in the top 10% received a 2% bonus in Medicare payments. Hospitals scoring in the second 10% received 1% and those below received no bonus. It was therefore possible for hospitals to have a 1% to 2% decrease in Medicare payments if at year three of participation they had not improved beyond the baseline.

An annual report for years 2003 to 2009 on the 5 common medical disorders is available on the Premier web site.⁴¹⁻⁴² Results from this initiative helped provide input for the Affordable Care Act.

Surgical Care Improvement Project (SCIP)

The SCIP, a partnership of 10 national organizations, is a similar CMS P4P project for surgical care in hospitals. The overarching goal at the onset was to reduce surgical infections by 25% by 2010. Each of the SCIP target areas are advised by a technical expert panel (TEP). Beginning in July 2005, the project explored post-surgery complications such as: site infections, adverse cardiac events, deep vein thrombosis (blood clots in the legs) and pneumonia.⁴³ The current surgical quality measures are part of the National Hospital

Inpatient Quality Measures.⁴⁴ Participation is voluntary and results are eventually posted on the Hospital Compare web site.⁴⁵ A 2010 JAMA article reported adherence with individual SCIP measures, that are publicly reported, was not associated with a significantly lower probability of infection.⁴⁶ A compendium of other medical articles resulting from SCIP is available on the AHRQ web site.⁴⁷

Hospital Value-Based Purchasing Program

The Hospital Value-based Purchasing Program, authorized through the Affordable Care Act, began in October 2012 (FY 2013) and may impact 3500 hospitals in the U.S. A primary program goal is to improve care and reduce costs and inpatient care; the largest part of Medicare payments. Reimbursement will be linked to quality improvement and patient satisfaction. Examples include (1) how fast hospitals provide balloon angioplasty to those needing it, (2) how often patients receive blood thinners to prevent blood clots, and (3) how often do patients with heart failure receive appropriate discharge instructions. Program quality measures were endorsed by the NQF and measures are posted on the Hospital Compare web site.⁴⁵ By 2015 hospitals will receive reduced payments if they are not using appropriate HIT to improve delivery of coordinated care. Baseline, performance periods and domains are listed on the Quality Net site.⁴⁸

Comprehensive Primary Care Initiative

The Comprehensive Primary Care Initiative, launched in 2011 reimburses physicians a monthly care-management fee in addition to the usual Medicare fee-for-service. This initiative is part of the patient centered medical home model previously discussed. Primary care physicians will be reimbursed for care coordination, prevention and improved communication with care givers. The monthly care-management fee will decrease in year three and four. CMS is inviting private payers to join the program with the goal of providing better reimbursement so clinicians can hire more staff and health information technology to deliver better care. As

of September 2013, there were 497 practices participating (2347 clinicians), located in eight states.⁴⁹

A track record of projects conducted by purchasers, payers, QI organizations, Medicaid and other countries now exists from which to draw conclusions.⁵⁰⁻⁶²

Quality Improvement Dashboards

Historically, medical information was numeric and it was presented as printouts and reports. Dashboards are visual displays of information. The underlying idea is that information needs to be simplified in order for it to be useful to clinicians and patients. Clearly, there are important issues related to data presentation, including variable selection, time spans, summary measures, confidence intervals, statistical adjustments, and dealing with unmeasured covariates and missing data. A critical issue is what should be compared and how to make the comparisons.

Federal Government

- **Hospital Compare.** This web site has been in existence since 2005; created for the purpose of consumers comparing voluntarily submitted data from more than 3000 US hospitals. It lists compliance with clinical practice guidelines for common medical disorders causing hospital admission. The site also lists patient experience scores, readmission rates, mortality and complication rates. In 2013 the dashboard was enhanced to allow for searching data from all hospitals within a certain zip code; whether the hospital's outpatient practices can receive lab results into their EHRs; whether outcome data is submitted to professional society registries or National Surgical Quality Improvement Program and emergency department wait times. Consumers can also compare performance with state and national results. Table 16.2 outlines categories in Hospital Compare as of late 2013.⁴⁵

Table 16.2 Hospital Compare Categories and Details

Category	Details
General	Category of hospital Provide emergency care? Ability to receive electronic lab data? Ability to track lab between visits?
Patient Surveys	Communication skill of doctors and nurses Pain management Bathroom cleanliness Quietness at night Discharge instructions
Timely and Effective Care	Heart attack care Heart failure care Pneumonia care Surgical care (SCIP) Emergency department care Preventive care Children’s asthma care
Readmissions, Complications and deaths	30 day death and readmission rates Hospital complications Hospital acquired conditions Hospital related infections
Medical Imaging	Imaging appropriateness
Medicare Payments	Spending per hospitalized Medicare patient
Medicare Patients Treated	Number of Medicare patients treated

- **Physician Compare.** The search engine locates clinicians who participate in Medicare. In 2014 quality of care comparisons will be included.⁶³
- **Nursing Home Compare.** Search engine locates nursing home based on name or zip code. Each entry is rated with a 1-5 star system. Categories include overall

ranking, health inspections, staffing and quality rankings. Searchers can compare up to three nursing homes at same time and drill down into the categories: general information; inspection results, staffing numbers, quality measures and penalties.⁶⁴

- **Home Health Compare.** Public can select several home health companies and

compare services offered/available. In addition the search drills down to a general category for services, quality of care using actual patient outcomes and patient survey results.⁶⁵

- **Dialysis Facility Compare.** Public can search for facilities near them and then compare up to three at the same time based on these categories: general (hemodialysis stations, peritoneal dialysis availability, home dialysis training; best treatment; hospitalizations and deaths.⁶⁶

Civilian

- **ProPublica Prescriber Check Up.** This 2013 initiative permits the public to look at prescriber's habits based on Medicare Part D data from 2007-2010; to compare prescriber's habits in their area and see who the leading prescribers are for the 500 most prescribed drugs. Moreover, reviewers can see the average prescriptions per beneficiary and average retail price of a prescription. Additionally, the public can see if drugs considered risky or inappropriate for the elderly were prescribed.⁶⁷
- **The Commonwealth Fund Health System Data Center.** The Fund developed a new search engine based on initial input of state, zip code or hospital referral region. Rankings and quartiles are provided based on access, prevention and treatment, potentially avoidable hospital use and cost and healthy lives. The general demographics of a region are provided and the anticipated benefits if this region improved to the level of the best region.⁶⁸
- **The Association of Health Care Journalists** is hosting a new web site to list hospital deficiencies they have in the past been paper based. The data is not complete at this time but CMS will be working with AHCJ to improve data availability. Viewers can search by topic or

by state. Details of the inspection report are available.⁶⁹

- **National Committee for Quality Assurance (NCQA)** is a civilian organization that develops quality and performance measures primarily for commercial insurance plans, Medicare and Medicaid. While it is not a quality dashboard it is an important quality organization. NCQA accredits healthcare plans, PCMH models and develops healthcare effectiveness data information set (HEDIS) measures that 90% of healthcare plans use as quality yardsticks. The HEDIS measures are broad encompassing eight domains. They are in the process of developing quality measures for ACOs as a pilot project.⁷⁰

Recommended Reading

The following articles are several important articles in the medical literature concerning HIT and medical quality

- *Systematic Review: The Impact of Health Information Technology on Quality, Efficiency and Cost of Medical Care.* One of the most quoted reviews of HIT and medical quality. There is evidence that HIT increases adherence to guidelines, enhances disease surveillance and decreases medication errors but most of the studies come from four institutions and therefore generalizability may be limited.⁷¹
- *The Impact Of Health Information Technology On The Quality Of Medical And Health Care: A Systematic Review.* Twenty three articles were included in their review. Of the 17 articles relevant to quality, 14 showed a positive influence of HIT on guideline compliance. Studies that looked at actual patient outcomes, however showed insufficient evidence of impact.⁷²
- *Small Physician Practices In New York Needed Sustained Help To Realize Gains In Quality From Use Of Electronic Health*

Records. Participants in the Primary Care Information Project for nine or more months experienced improved quality, but only for a limited group of quality measures and only for physicians receiving extensive technical assistance.⁷³

- *Accuracy Of Electronically Reported “Meaningful Use” Clinical Quality Measures.* Researchers compared accuracy of quality reported by EHRs versus paper and concluded that there was a wide variance of accuracy with EHR-generated reports.⁷⁴
- *Hospital Implementation Of Health Information Technology And Quality Of Care: Are They Related?* This was a survey of 470 hospital-based quality managers and clinicians. They compared results with scores from Hospital Compare, MEDPAR and HCAHPS survey. Their results indicated that hospitals with high levels of HIT engaged in more quality improvement practices with better performance on mortality rates and patient satisfaction. This association is important, but does not prove cause and effect.⁷⁵
- *American Hospital Quality Outcomes 2014.* In late 2013 HealthGrades released a report based on data from 4500 hospitals looking at 31 inpatient procedures. They concluded that there was still too much inter-hospital variability in quality; complications drive up costs 1.8 times; mortality drives up costs 3 fold and minimally invasive surgery, where appropriate, is associated with fewer complications and lower costs. In this monograph they post the differences in mortality between the highest and lowest rated hospitals for quality on six medical conditions. Their conclusion is that higher quality is associated with fewer complications and mortality and lower cost.⁷⁶

Quality Improvement Concerns and Limitations

The following are some of the concerns about quality improvement programs expressed primarily by physicians and their organizations:

- Do QI programs discriminate against practices without EHRs?
- Are EHRs sophisticated enough to provide accurate measures of quality? There is some evidence that quality reporting from EHRs as a part of meaningful use is associated with several problems, noted in the “recommended reading” section
- Should data be public?
- Will QI programs cause clinicians to “dump” non-compliant or sicker patients?
- Will QI programs result in higher quality care or long term return on investment?
- Will QI programs adjust for sicker, poorer and more elderly patients?
- Much of the practice of medicine does not have identified quality measures, so improvement may be spotty.
- Will the motive behind change be financial and not really improving quality?
- Will the number of QI measurements for multiple government programs be excessive?
- Should bonuses be paid for improvement even if results do not meet national goals?
- At this time, the majority of QI reimbursement goes to primary care physicians and not specialists or hospitals. Is this likely to change with newer models?
- Waiting on performance “report cards” occasionally takes a long time and impedes next year’s improvement.⁷⁷⁻⁸³

Future Trends

Overall, the most important trend is the shift from paying for the volume of health care delivered to paying for the actual quality of care. The presumption by health care experts and the

federal government is that high quality evidence based health care in the long run will be less expensive and be associated with improved patient safety. Certainly, hospitals that are highly rated by organizations such as HealthGrades have confirmed this association. How to transition smaller, rural and poorer healthcare organizations to higher quality remains to be seen and is a future challenge. It is anticipated that extensive lessons learned will result from the PCMH and ACO models.

Much of what has been discussed in terms of quality is related to providing outcome feedback to administrative and clinical personnel. The assumption is that one can improve quality by intervening in the delivery of healthcare at the point of care (e.g., the clinician-patient

interaction) and effecting a change that improves true clinical outcomes. There is little empirical evidence to support this assumption because it has been very difficult to intervene at the point of care. The existence of computers at the point of care that are used by clinicians to provide and document care represents a new opportunity to improve care. Information delivery systems and clinical decision support systems have the potential to dramatically improve clinical outcomes.

Meaningful use stages 2 and 3 will set the bar higher for reporting of quality measures as well as feedback regarding which measures are feasible and which ones are more successful to implement.

Key Points

- U.S. health care is the most expensive in the world, yet many important quality outcomes demonstrate worse results than other countries who invest less in health care
- Civilian and federal insurers are looking at reimbursing for quality in lieu of just quantity of service
- Measuring quality is difficult and controversial but will likely benefit from new health information technology (particularly the electronic health record)
- Multiple new QI demonstration projects are underway
- It is unclear whether newer quality improvement strategies will really improve medical quality or reduce cost

Conclusion

The federal government, mandated and supported by the Affordable Care Act, developed a National Quality Strategy with the goals of improving quality and reducing cost. Newer quality improvement strategies such as the patient-centered medical home and accountable care organization models will require robust information technology to record and transmit quality measures. There is a legitimate concern that healthcare might not be ready to generate, receive and analyze an avalanche of new quality measures, even with widespread EHR adoption.

Organizations will likely benefit from pilot produce lessons learned and public-private collaborations that produce innovation.

Overall, the progress has been slow in the past 14 years since the first IOM report, *To Err is Human* was published. Chassin, the CEO of the Joint Commission discusses the slow progress and notes that newer quality tools are available, reporting must be more transparent and urges “cultures of safety” be established in every hospital and healthcare organization.⁸⁴

Healthgrades Inc., in their *American Hospital Quality Outcomes 2014: Healthgrades report*

to the Nation, found substantial differences in in-hospital mortality between the best performing and worst performing hospitals for selected conditions as noted in the recommended reading section of this chapter. They also found differences between the best performing and worst performing hospitals for the selected complications of hip replacement surgery, total knee replacement, carotid surgery, and gallbladder removal surgery. In addition, they determined that complications and deaths increased costs. It should be noted that the outcomes for most hospitals were very similar. A critical assumption of the analysis is that medical outcomes are completely deterministic, that there is no random variation in medicine. In reality, there is random variation due to the inherent complexity of medical care. In addition, there are differences between hospitals in terms of the types of hospitals, dissimilar catchment areas, patient volumes per condition, and other factors – many of these factors are as yet unmeasured and unadjusted for in the analysis. Therefore, comparing an unusually good outcome hospital with an unusually bad outcome hospital may not be the best way to assess quality. One has to take into account structural and one-time factors and there will certainly be regression to the mean. Further, the selected conditions' outcomes are themselves

subject to variance, within hospitals, across hospitals, and over time. In other words, it may not be possible to accurately pick in advance which hospital will be the best and the worst in the next year for a given outcome.

It is important to realize that better data collection is needed to adjust for differences between hospitals. Even then, it is not yet clear at the patient level what it means for two hospitals to have the same or different risk adjusted outcomes. Finally, a better way to assess quality is to improve variable collection, follow hospitals in terms of the all the relevant conditions over several years, and determine if the hospitals are significantly better or worse than comparable hospitals.

Healthcare is still in the infancy stage of optimally employing HIT to improve quality and reduce cost. Readers should be on the look out for interesting examples of quality improvement and lessons learned. AHRQ produced a 2010 monograph “Using Health IT: Eight Quality Improvement Stories that discusses real world examples of HIT implementations that lead to quality improvement.⁸⁵ In addition, AHRQ offers a free quality indicators toolkit to assist hospitals with quality improvement initiatives. The toolkit focuses on 28 inpatient quality indicators.⁸⁶

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Chapter 17

Patient Safety and Health Information Technology

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Learning Objectives

After reading this chapter the reader should be able to:

- Identify why patient safety is a national concern
- Define medical errors, adverse events and preventable adverse events
- Compare and contrast how information technology can potentially improve or worsen patient safety
- Compare and contrast the governmental and non-governmental patient safety programs
- List the various technologies that are likely to improve medication error rates
- Identify the obstacles to widespread implementation of patient safety initiatives

"When you look back after someone has been killed in a patient safety incident, you can often see that all the ingredients were in place for a disaster to happen. It was almost as if the person who died was a 'dead patient walking' as they stepped through the entrance of the hospital."

- Sir Liam Donaldson, David Skeggs Lecture at Royal College of Radiologists 18 November 2005

Introduction

In spite of expensive healthcare in the United States, medical errors continue to occur. Most often they are system failures with multiple breakdowns in protocol and communication. Technology has great potential to help reduce medical errors, but like most new interventions, it also has the potential to cause harm. This chapter will discuss the role of health informa-

tion in reducing medical errors, with multiple innovative applications. First, definitions related to patient safety will be discussed.

Patient Safety-Related Definitions

- Safety is the minimization of the risk and occurrence of patient harm events.

- Harm is defined as inappropriate or avoidable psychological or physical injury to the patient and/or the family.
- Adverse Events: “an injury resulting from a medical intervention”
- Preventable Adverse Events: “errors that result in an adverse event that are preventable”
- Overuse: “the delivery of care of little or no value” (e.g. widespread use of antibiotics for viral infections)
- Underuse: “the failure to deliver appropriate care” (e.g. vaccines and cancer screening)
- Misuse: “the use of certain services in situations where they are not clinically indicated” (e.g. magnetic resonance imaging for routine low back pain)¹⁻³

The terms inappropriate and avoidable must be defined in their clinical context. Although the proximate cause of a patient harm event is usually the actions or non-actions of an individual, significant patient harm events are rarely the result of a single failure. Rather, they are almost always due to a consecutive series of failures in the system of care. Patient harm is a type of low quality medical care. An important goal of a healthcare system is the elimination of the risk and occurrence of patient harm events. Health information technology has an important role to play in improving safety.

Although safety is usually discussed in terms of errors, not all safety risks or events are related to errors and not all errors create safety issues. Further, not all errors are preventable and it can be difficult to distinguish between preventable and non-preventable safety risks and events. In the classic report *To Err is Human* published in 2000, the Institute of Medicine (IOM) estimated that at least 98,000 inpatients die every year and 1,000,000 are injured due to preventable errors.¹ The mortality and morbidity rate may have been actually higher as many outpatient adverse events were not reported. While McDonald and others argue that the methodology used to report these statistics was

flawed, most agree that American medicine is not as safe as it should be.⁴ The 2001 Institute of Medicine report *Crossing the Quality Chasm* emphasized the importance of medical quality leading to improved patient safety.² The current medical system was described as an “era of Brownian motion in health care.”

The IOM has long been an advocate of using information technology to improve healthcare quality and patient safety. They clearly state that safety is the first domain of medical quality. The 2001 IOM report recommended that the US “improve access to clinical information and support clinical decision making” and “create a national information infrastructure to improve health care delivery and research.” Also, one of their goals was to eliminate handwritten notes in the following decade.²

Errors can involve different aspects of medical care such as diagnosis, treatment and preventive care. Furthermore, medical errors can be errors of commission or omission and fortunately not all errors result in an injury and not all medical errors are preventable. Until the past two decades, there was a paucity of articles written about patient safety and most articles dealt specifically with medication errors and not errors occurring in other areas of medical practice. A 2003 article ranked the most common types of medical errors made by American family physicians: prescribing medications, getting the correct laboratory test for the correct patient at the correct time, filing system errors, dispensing medications and responding to abnormal test results.⁵ As will be discussed in this chapter health information technology has the potential to improve these types of medical errors.

Researchers at Johns Hopkins University School of Medicine looked at 25 years of Medicare claims and determined that diagnostic errors accounted for the largest percentage of malpractice claims, surpassing treatment errors. Diagnostic errors can result from missed, wrong or delayed diagnoses and are more likely in the outpatient setting. This is somewhat surprising given the fact that US physicians tend to practice “defensive medicine”.⁶ According to some

experts ineffective communication between patient-physician and physician-physician is also a major cause of medical errors.⁷ Diagnostic errors will not be explored in any detail in this chapter but health information technology may improve communication, along with improved clinical decision support and contribute to a decrease in diagnostic errors.

Overdiagnosis is also a health concern but it receives far less publicity. Over testing of the healthy creates anxiety and greatly increases the cost of healthcare, not to mention adverse events.⁸ It would be an optimistic goal that widespread EHR adoption with embedded clinical practice guidelines might reduce overdiagnosis.

Most authorities believe that errors occur more often due to inadequate systems and not inadequate individuals. Most of these errors arise because our system of medical care including training, staffing, financial incentives, as well as local and federal policies, was not designed to prevent errors or mitigate their effects. Some authorities believe that about 50% of medical errors are preventable with better systems.⁹ Also, our fee-for-service system did not traditionally reimburse based on quality or patient safety. This has changed greatly in recent years and is discussed in more depth in the chapter on quality improvement strategies.

Other industries such as the airlines have dramatically reduced mishaps thru initiatives such as “crew resource management” (CRM).¹⁰ CRM training focuses on interpersonal communication, situational awareness, leadership and decision making. This technique has been so successful hospitals often incorporate CRM as part of management training. In particular, some operating rooms employ a CRM-based check list prior to initiating surgery. Interestingly, some medical specialties have done a better job than others tackling patient safety issues. The first specialty to experience dramatic advances in patient safety was anesthesiology, with less than one death in 200,000 patients undergoing anesthesia.¹¹

A 2012 report estimated that the annual cost of medical errors in the United States approached \$1 trillion dollars.¹² In addition to the obvious increased cost, mortality and morbidity that results from medical errors there is a resulting increase in litigation. It was estimated in a 2010 report that malpractice in the United States cost about \$55 billion per year, of which \$45 billion is spent practicing “defensive medicine.”¹³ In 2013, the LeapFrog Group developed a calculator for employers and purchasers to determine the surcharge they will likely pay as a result of medical errors.¹⁴

Meaningful Use

Stage 2 meaningful use that is expected to go into effect in 2014 will contain several objectives for *eligible hospitals* that impact patient safety:

- **“Objective:** Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines. **Measure:** More than 60 percent of medication, 30 percent of laboratory, and 30 percent of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.
- **Objective:** Use clinical decision support to improve performance on high-priority health conditions. **Measure:** 1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's patient population, the clinical decision support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency. 2. The

eligible hospital or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

- **Objective:** The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation. **Measure:** The eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department.
- **Objective:** Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR). **Measure:** More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period for which all doses are tracked using eMAR.
- **Objective:** The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral. **Measure:** 1: The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals. 2: The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is

consistent with the governance mechanism ONC establishes for the nationwide health information network. 3: The eligible hospital or CAH must satisfy one of the two following criteria: Conducts one or more successful electronic exchanges of a summary of care document, which is counted in "measure 2" (for eligible hospitals and CAHs).

- **Objective:** Generate and transmit permissible discharge prescriptions electronically (eRx). **Measure:** More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using certified EHR technology¹⁵.

The reality is that the United States has not shown much progress in decreasing medical errors over the past decade and has turned to health information technology as a possible solution.¹⁶ This chapter will discuss how health information technology (HIT) may improve patient safety, largely through improving the quality of care delivered. Medical quality is discussed in more detail in the chapter on quality improvement strategies. It is important to stress, however, that HIT can also create new types of medical errors as discussed in this chapter and the chapter on electronic health records. In the next section several well-known reports on patient safety and the quality of medical care in the United States are listed.

Patient Safety Reports

Institute of Medicine (IOM) Reports

Earlier in this chapter the important IOM patient safety reports *To Err is Human, Building a Safer Health System* (2000) and *Crossing the Quality Chasm, A New Health System for the 21st Century* (2001) were discussed. Their recommendations are listed in the executive summary:

- Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality
- A nationwide reporting system for medical errors should be established
- Volunteer reporting should be encouraged
- Congress should create legislation to protect internal peer review of medical errors
- Performance standards and expectations by healthcare organizations should include patient safety
- FDA should focus more attention on drug safety
- Healthcare organizations and providers should make patient safety a priority goal
- Healthcare organizations should implement known medication safety policies¹⁻²

The IOM's *Patient Safety: Achieving a New Standard for Care* (2003) expanded on the prior two sentinel monographs with the following statements and recommendations:¹⁷

- Patient safety must be linked to medical quality
- A new healthcare system must be developed that will prevent medical errors in the first place
- New methods must be developed to acquire, study and share error prevention among physicians, particularly at the point of care
- The IOM recommended specific data standards so patient safety-related information can be recorded, shared and analyzed

In 2011 the IOM released a report titled *Health IT and Patient Safety: Building Safer Systems for Better Care*. Unlike its previous reports, this report focused exclusively on health IT as it relates to patient safety and quality. Somewhat alarming was a primary finding that the evidence about the impact of health IT on patient safety, as opposed to quality, is mixed but shows the challenges involve people and

clinical implementation as much as the technology.¹⁸ While published evidence suggests improvement in patient safety have been realized with HIT, a finding of “no effect” or actual “associated harm” were also realized. The report cites a lack of health IT-related safety data and suggested contributing causes which include the absence of measures and a central repository for analysis as well as contractual barriers preventing sharing of information. The report issues 10 recommendations to encourage:

- HHS to publish an “action and surveillance plan” within 12 months
- HHS to push health IT vendors to support the free exchange of information about health IT experiences and issues
- ONC to work with public and private sectors to make comparative user experiences publicly available
- HHS should fund a Health IT Safety Council to assess and monitor the safe use of health IT and its use to enhance patient safety
- Health IT vendors to publicly register and list their products with ONC
- HHS to specify the quality and risk management processes that health IT vendors must adopt
- HHS should establish a mechanism for vendors and users of health IT-related deaths, serious injuries, or unsafe conditions
- HHS recommend to Congress establishing an independent federal entity to investigate patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT
- HHS should monitor and report progress of health IT safety annually and FDA begin developing framework for regulation
- HHS, in collaboration with others, should support cross-disciplinary research toward the use of health IT as part of a learning system¹⁸

HealthGrades 2013 Patient Safety Excellence Awards

The *Patient Safety Excellence Award* recognizes hospitals with the lowest occurrences of 14 preventable patient safety events, placing the hospitals in the top 10% in the nation for patient safety. This organization reviews the data from inpatient Medicare and Medicaid cases each year and rates hospitals, in terms of patient safety. Specifically, they rate risk-adjusted mortality and complications for hospital procedures. Ratings range from one star (lowest) to five star (highest). They estimate that the top ranking hospitals represent, on average, a 43% lower risk of a patient safety adverse event compared to the lowest ranking hospitals. The awardees are listed on their web site by state. Samantha Collier MD of HealthGrades believes that the hospitals that traditionally have excellent safety scores have a “culture of safety” and they are the ones that have all of the mechanisms including technology in place to prevent and track patient safety issues.¹⁹

Organizations such as AHRQ, National Quality Forum and Leapfrog Group support frequent assessment of hospital safety culture. AHRQ has developed a survey that can be used by others to measure and track the culture of safety.²⁰ The Info box gives an example of one organization with a culture of patient safety.

Governmental and Non-Governmental Organizations and Programs Supporting Patient Safety

US Federal Agencies

The Department of Health and Human Services, as authorized by legislation, plays a key leadership role in patient safety and quality in the United States, delivered via several of its agencies.

Agency for Healthcare Research and Quality (AHRQ): This agency is the designated lead federal agency for patient safety. The agency maintains an active patient safety research portfolio and numerous grant and contract funding mechanisms to deliver on its mission. The patient safety portfolio is broad in scope including the: Patient Safety Organizations Network (as authorized by Public Law 109-41), preventing medication error, reducing unavoidable inpatient readmissions, preventing healthcare-associated infections, TeamSTEPPS™ training and an associated Health IT portfolio. Relatively new to the health IT portfolio is their Ambulatory Safety & Quality Program. This program accentuates the role of health IT through funding opportunity



Patient Safety Culture

Virginia Mason is an integrated healthcare system located in Seattle WA. For the past decade they have reanalyzed multiple health care processes, based on the Toyota Production System. The result has been fewer inpatient falls, bed sores, etc. They post several independent quality reports on their web site that compares them to the state and national averages. They stress patient involvement in care, to include rapid response teams if a family member believes the patient is deteriorating. Their nurses work in teams so they can now spend 90% of their time with patients, instead of the national average of 35%.²¹

announcements (FOAs); specifically:

- Enabling quality measurement through health IT (includes patient safety focus)
- Improving quality through clinician use of health IT
- Enabling patient-centered care through health IT
- Improving management of individuals with complex health care needs through health IT

22

Centers for Medicare and Medicaid Services (CMS): In late 2008 Medicare stopped reimbursing hospitals for complications they deemed preventable, but the policy did not affect physician reimbursement. The list of non-reimbursable complications included:

- Objects left in a patient during surgery and blood incompatibility
- Catheter-associated urinary tract infections
- Pressure ulcers (bed sores)
- Vascular catheter-associated infections
- Surgical site infections
- Serious trauma while hospitalized
- Extreme blood sugar derangement
- Blood clots in legs or lungs

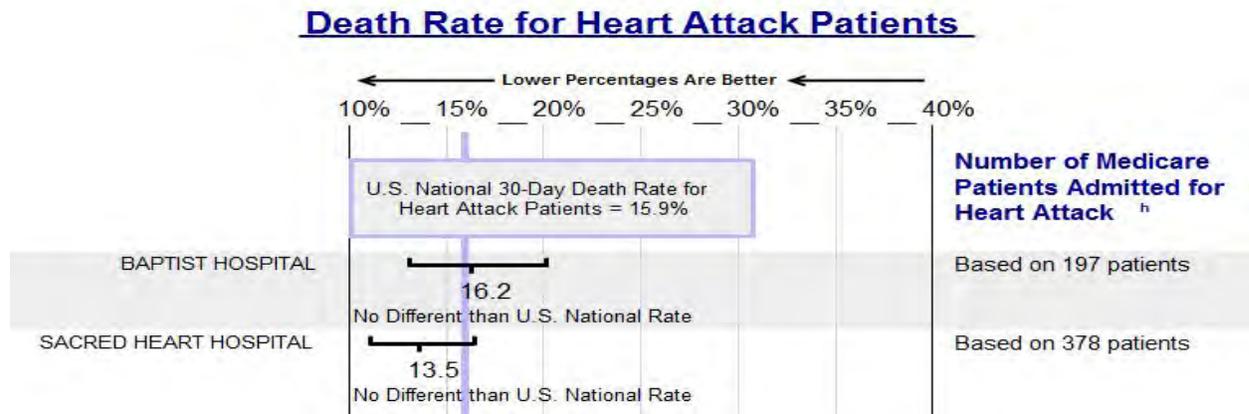
CMS launched its new *Partnership for Patients* initiative, funded by up to \$1 billion through the Patient Protection and Affordable Care Act in 2011 with two core goals of keeping patients from getting sicker or injured in the health care system and helping patients heal without complications by improving transitions in care from hospitals to alternative settings. As a result, hospitals with higher than anticipated 30 day readmission rates for heart attacks, heart failure and pneumonia will receive decreased reimbursement. This will occur in FY 2013 and the Secretary of HHS has the opportunity to increase the number of conditions in FY 2015. Specific program goals are to decrease hospital readmission rates by 20% and hospital-acquired conditions by 40% by 2013 (compared to 2010

baseline data). To date there are over 4,000 partners (including 3700 hospitals) nationally. There is a funding mechanism associated with hospital membership where the institution received financial incentives for participating and demonstrating improvement in 10 areas associated with harm.²³ They include:

- Adverse drug events
- Catheter-associated urinary tract infections
- Central line associated blood stream infections
- Injuries from falls and immobility
- Obstetrical adverse events
- Pressure ulcers
- Surgical site infections
- Venous thromboembolism
- Ventilator-associated pneumonia
- Other hospital-acquired conditions ²³

Noteworthy is an understanding of the key importance of health informatics and health IT in the Partnership for Patients initiative. Hospitals and other partners must have the ability to assemble, analyze and trend clinical and administrative data to capture baseline data and measure improvement over time. Health IT-based interventions, several mentioned below, are expected to assist the partners in realizing improvement.

As a component of their agency mission CMS manages the Quality Care Finder (www.hospitalcompare.hhs.gov) that allows consumers to review quality metrics e.g. morbidity (complications) and mortality (death), when making decisions about hospitals, physicians, nursing homes, home health, and dialysis centers in terms of their own care. Users can search by medical condition, surgical procedure or patient satisfaction measures. Figure 17.1 compares two large hospitals located in the same city, in terms of mortality rates from heart attacks. Several quality dashboards are discussed in the chapter on quality improvement strategies.

Figure 17.1: Heart attack mortality comparison(Source: www.hospitalcompare.hhs.gov)

Health Resources and Service Administration: This agency is the primary Federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. With respect to patient safety, HRSA manages a “Patient Safety and Clinical Pharmacy Services Collaborative (PSPC).” Currently there are over 450 community organizations of community-based health care providers participating in the PSPC. The initiative seeks to improve the quality of health care by integrating evidence based clinical pharmacy services into the care and management of high-risk, high-cost, complex patients. By embracing contemporary quality improvement methodology and sharing lessons through collaborative learning, the PSPC has realized a 54% gain in getting complex patients “under control” with respect to optimal medical management and a reduction of 49% in adverse drug events for this high risk patient population.²⁴

Office of the National Coordinator for HIT: In mid-2013, ONC released the Health IT Patient Safety Action and Surveillance plan that augmented work by the Institute of Medicine’s 2011 report Health IT and Patient Safety: Building Safer Systems for Better Care. The plan’s two goals are “use health IT to make care safer” and “continuously improve the safety of health IT”. Strategies broadly stated are as follows:

- Learn: “Increase the quantity and quality of data and knowledge about health IT safety.” This will likely include safety criteria for EHR certification and enhanced patient safety reporting.
- Improve: “Target resources and corrective actions to improve health IT safety and patient safety”. Safety goals will be aligned with meaningful use objectives. The Joint Commission will investigate the role of health IT in causing medical errors.
- Lead: “Promote a culture of safety related to health IT.” HHS will coordinate its patient safety efforts with developers, users, patient safety organizations (PSOs) and all other stakeholders.²⁵

The Food and Drug Administration: This agency plays a pivotal role in regulating, among other key areas, drugs, medical devices and radiation-emitting products. The agency manages a host of programs and initiatives to achieve its goal. Examples include:

MedWatch: The MedWatch program posts important drug alerts and provides online reporting by physicians or consumers on drugs, medical devices, biologics, dietary supplements, human food and beverages and cosmetics, animal feed and veterinary products.²⁶

The Center for Devices and Radiological Health (CDRH) is part of the FDA is responsible for the pre-market approval of all medical devices and radiation-emitting products. In 2011, the CDRH announced for public comment its intent to regulate mobile medical applications designed for use on smartphones and other mobile medical computing devices.²⁷ In September 2013 they released guidance on the unique device identification system (UDI). It is anticipated that having the UDI system in place will make reporting and recalls easier. A large database will serve as a reference for device searches. The timeline for implementation is available on the FDA web site.²⁸

Recalls, Market Withdrawals, and Safety Alerts are managed by the FDA and apply to drugs, medical devices, radiation-emitting products, food, and other key areas. Health systems, hospitals, pharmacies, and other care delivery organizations rely on their data systems and warehouses to identify patients at risk and respond appropriately to recall actions. The data systems and ability to mine and analyze the data rely on medical informatics skills and tools.

State Patient Safety Programs

States are in a position to positively influence patient safety as they are involved with purchasers and payers of healthcare and they benefit from improved patient safety, in terms of money saved. By 2010, 27 states and the District of Columbia passed legislation or regulation related to hospital reporting of adverse events to a state agency.²⁹ The regulations will involve event report analysis and valuable lessons learned.

The National Academy for Health Policy (NASHP) was established in 2000 to assist states in delivering safe patient care. They offer a patient safety toolbox to the states that have been most involved that includes information (policies, practices, forms, reports, methods, and contracts) intended to improve states' reporting systems.²⁹⁻³⁰

Non-Governmental Patient Safety Organizations and Programs

While governmental agencies and programs have a substantial voice in patient safety and quality, there are several key non-governmental organizations that are prominent actors in the patient safety and quality community.

National Patient Safety Foundation

(NPSF): The foundation is an independent not-for-profit 501(C)(3) organization founded in 1997 with the aim of improving the safety of care provided to patients. To deliver on their mission, the NPSF structures their energy around five fundamental action steps that include: (1) identifying and creating a core body of knowledge, (2) identifying pathways to apply the knowledge, (3) developing and enhancing the culture of receptivity to patient safety, (4) raising public awareness and fostering communication around patient safety, and (5) improving the status of the Foundation and its ability to meet its goals. The NPSF is a funder of patient safety-related research and hosts a large annual patient safety congress where patient safety advances, quality improvement strategies, and research are presented. Technology-related projects, similar to those identified below, are representative of those promoted at the NPSF congress.³¹

The National Quality Forum (NQF): This public-private collaborative group was organized in 1999 for the purpose of quality measure development and public reporting. They establish national standards to improve the quality of medical care and by so doing improve patient safety. Currently they have posted 741 standards (over 100 dealing with patient safety) on their web site with a new search engine and analytic tools. They have a health information technology advisory committee (HITAC) comprised of national experts. One important aspect of the work they are doing relates to the Quality Data Model (QDM). This model describes clinical concepts in a standardized format for electronic quality measures that can be generated and communicated by electronic health records.³²

The Joint Commission: In 2002, the Joint Commission began publishing National Patient Safety Goals (NPSGs) that are updated annually. The purpose of the national goals is to highlight attention to key patient safety areas ripe for improvement. These national goals are developed and updated by a widely recognized group of patient safety experts. Three of the six 2013 hospital NPSGs have potential association with HIT: identify patients correctly, improve staff communication and use medicines safely.³³ In 2008 the Joint Commission recommended that there be one national infrastructure to measure and track quality improvement data.³⁴ In addition they warned healthcare organizations, through their Sentinel Event Alert #42, that implementing health information and converging technologies can create or perpetuate patient safety risk and preventable adverse events. The alert identifies potential contributing factors of health information and converging technologies on patient safety and outlines action steps to prevent harm in this area. Some examples include assessing pre-implementation need and clinical workflow, actively engaging clinicians, ongoing monitoring, establishing training and refresher training for clinicians and staff, establishing related organizational processes, developing and testing order sets before automating, building in checks and balances to mitigate potential harm, and others.³⁵

Institute for Healthcare Improvement (IHI): The IHI instituted a plan in December 2004 to save 100,000 lives from medical errors by getting hospitals to incorporate at least one of six safety measures. A report on June 14th 2006 estimated that 122,300 deaths have been prevented through the adoption of new safety measures by more than 3,000 participating hospitals over an 18th month period. Currently the IHI, and its members, are engaged in numerous improvement projects at the nexus of patient safety, clinical quality and medical informatics. They offer free courses on healthcare improvement through “Open School” that has become required training at many institutions. A 2013 progress report is available as a PDF on their web site.³⁶

LeapFrog Group: LeapFrog is a consortium of healthcare purchasers that demand better quality. One of the four areas they promote is the adoption of inpatient computerized physician order entry (CPOE). They maintain survey safety data from over 2,500 hospitals who volunteered to submit data, as well as a calculator to determine return on investment (ROI) for hospital pay-for-performance programs. A consumer can search hospital overall patient safety and safety related to specific procedures via a search engine on their site. The Hospital Safety Score consists of 26 national safety measures used to arrive at a letter score (A-F). Hospitals are compared with the best, worst and average for these measures. In the Fall of 2013, thirty-two percent of hospitals graded received an A, twenty-six percent a B, thirty-five percent a C, six percent a D, while only one percent received an F. This represents little improvement compared to 2012. Maine had the highest percentage of hospitals receiving an A grade and Kaiser and Sentara healthcare systems scored an A for all hospitals in the system. Most data comes from Hospital Compare, discussed in the chapter on quality improvement strategies and the Leapfrog Hospital Survey. Individual hospital scores can be analyzed in detail.³⁷⁻³⁸

HealthGrades: HealthGrades is an organization that rates different aspects of medical care. On their web site is a search engine for physicians, dentists and hospitals. Hospital reports compare a variety of surgical procedures or diagnoses by state. Physician reports compare disciplinary action, board certification and patient opinions. Quality awards are posted and patient safety indicators are described as average, worse than average or better than average.³⁹

Institute for Safe Medication Practice (IMSP): Not for profit organization dedicated to medication safety that began 35 years ago. They are a patient safety organization (PSO) and as part of their focus they publish medication safety alerts for physicians and patients.⁴⁰

American Medical Informatics Association (AMIA): While not a patient

safety organization, AMIA and its members are playing a pivotal role in enhancing patient safety and quality through medical and health informatics research. This is not surprising given the association's commitment to promoting research on electronic health records, CPOE systems, medication management systems, clinical decision support, mobile technologies, electronic clinical documentation capture, and like projects that explicitly address patient safety and quality outcomes.⁴¹

Health Information Technology and Patient Safety

Medication error reduction is a prominent patient safety focus area impacted by healthcare IT. The Institute for Safe Medication Practices promotes the “five rights” of medication safety: right drug, right patient, right dosage, right route and right time.⁴⁰ It has been shown that adverse drug events (ADEs) account for up to 3.3 % of hospital admissions.⁴² To compound the issue, serious ADEs reported to the FDA increased about 2.6 fold from 1998 to 2005, as did fatalities due to medications.⁴³⁻⁴⁴ While the IOM cited a study claiming that 7,000 deaths occurred in 1993 due to medication errors, one author maintains that 31% of deaths cited were actually due to drug overdoses.⁴⁵ Fortunately, 99% of medication errors do not result in injury. About 30% of ADEs are felt to be preventable and of those about 50% are preventable at the ordering stage.⁴⁶ It is worth noting that CPOE does not prevent errors of administration (e.g. wrong patient) or timing (e.g. wrong time).⁴⁷

In spite of the fact that more drugs are prescribed for outpatients, inpatient drug use is very dangerous. Intravenous (IV) medications are associated with 54% of ADEs and 61% of serious or life threatening errors.⁴² This is due to both the route of administration and the type of drugs administered in a hospital. A 2007 monograph by the Institute of Medicine, *Preventing Medication Errors*, made several salient points:

- On average, a hospital patient is subject to one medication error per day.
- About 1.5 million preventable ADEs occur yearly with about 400,000 preventable ADEs occurring in inpatients.
- Estimated cost of \$5,857 per inpatient error resulted in about \$3.5 billion in 2006 dollars due to longer length of stay and additional services (figure excludes litigation).
- Estimates are probably low, based on how statistics were collected.⁴⁸

Technology has great potential in reducing medication errors but there are many unanswered questions. Several studies of health information technology and medication errors concluded that well-controlled studies are lacking, tend to be reported only at a select number of universities, and patient outcomes are lacking.⁴⁹⁻⁵⁰ An article in *Health Affairs* in 2006 reported on adoption of medication safety related HIT by 4,561 non-federal hospitals in 2006. The IT applications studied were: electronic medical records, clinical decision support, CPOE, bar coding medication dispensing (BarD), medication dispensing robot, automated dispensing machine, electronic medication administration records (eMAR) and bar coding at medication administration (BarA). They concluded the following:

- Larger and urban hospitals had much higher adoption rates
- On average, only 2.24 of eight applications were adopted per hospital
- One-fourth of hospitals had not adopted any of the eight technologies
- Teaching hospitals had higher rates of adoption
- The most widely adopted application was the automated dispensing machine and least adopted was bar coding for medication administration (BarA)⁵¹

A 2011 survey by the American Society of Health System Pharmacists evaluated the adoption of

pharmacy IT in the United States. They reported the following conclusions:

- 67% of respondents had at least one component of an EHR
- 50% had barcode medication administration systems
- 68% used smart pumps
- 89% used automated dispensing cabinets for drugs
- 11% used pharmacy robots
- 67% had electronic medication administration records (eMar)⁵²

A 2013 RAND report, supported by the AHRQ listed multiple patient safety strategies (PSSs) but with the exception of CPOE and medication reconciliation most did not involve health information technology.⁵³

Technologies with Potential to Decrease Medication Errors

CPOE systems and Medication Errors

As discussed in the chapter on electronic health records, CPOE has multiple potential advantages over paper based systems. That is the reason CPOE is touted as being pivotal for patient safety. The following are some of the recognized advantages:

- Improved handwriting identification
- Reduced time to arrive in the pharmacy
- Fewer errors related to similar drug names
- Easier to integrate with other IT systems
- Easier to link to drug-drug interactions
- More likely to identify the prescriber
- Ability to link to an ADE reporting system
- Helps to eliminate trailing zero-type errors
- Available for immediate analysis

- Can link to decision support to recommend drugs of choice⁵⁴

The next section is divided into inpatient and outpatient CPOE. Additional information can be found in the chapter on electronic health records.

- **Inpatient CPOE.** This functionality was recommended by the IOM in 1991. A 1998 study by Bates and colleagues demonstrated that CPOE can decrease serious inpatient medication errors by 55% (relative risk reduction).⁴⁵ In recent years there has been a substantial growth in researcher attention to measuring the impact of inpatient CPOE on reduction of prescribing errors and ADEs. This has led to several reviews and systematic reviews of the literature comparing the outcome from published studies. While CPOE was found to be effective in reducing medication errors and in some studies ADEs, researchers concluded that the cumulative research is rather modest and many studies are flawed by design. Issues related to organizational, technical, and design factors were also cited.⁵⁶⁻⁶¹

- **Outpatient CPOE.** There is a greater chance for a medication error written for outpatients because of the huge number of outpatient prescriptions written. Inpatient prescriptions, however, are more dangerous, particularly intravenous blood thinners, opiates and chemotherapy. Kuo et al. reported medication errors from primary care settings. Seventy percent (70%) of medication errors were related to prescribing, 10% were administration errors, 10% were documentation errors, 7% dispensing errors, and 3% were monitoring errors. ADEs resulted from 16% of medication errors with 3% hospitalizations and no deaths. In their judgment, 57% of errors might have been prevented by electronic prescribing.⁶²

- **Clinical Decision Support.** It is important to note that clinical decision support may be embedded within CPOE

(inpatient or outpatient), within the EHR, within mobile and converging technologies, or standalone support. It is clinical decision support that serves as the backbone for translating research into practice aiding clinicians in better diagnosis and treatment of patients. Computerized drug alerts have obvious potential in decreasing medication errors but they continue to be refined. Kuperman divided drug alerts into basic and advanced as demonstrated in Table 17.1.⁶³

Table 17.1: Basic and Advanced Drug alerts

Basic	Advanced
Drug allergy	Dose adjustment for renal disease
Dosage guidance	Geriatric dosing
Formulary decision support	Medication-related laboratory testing
Duplicate drug orders	Drug-disease contraindications
Drug-drug interactions	Drug-pregnancy checking

While drug alerts have great potential to reduce medication errors, the down side is unless the alerts are extremely well thought out they will result in “alert fatigue”. This is particularly true with drug-drug interactions (DDIs) resulting in override rates of about 90%. Very serious alerts are treated the same as mundane alerts. Work is underway to determine the most significant DDI alerts. One study determined that there were 15 very important interactions worth reporting and recommended that these be part of every CDSS. The panel recommended that a central repository of high severity interactions be created.⁶⁴ The same group of investigators later reported that only a minority of DDIs are severe or significant, therefore the alerts should not be interruptive for busy clinicians.⁶⁵

Clinical decision support has many other safety implications in addition to medication safety. Casolino et al. reported on how often patients fail to hear about results such as mammograms,

Pap smears and stool specimens for blood. They concluded that about one in 14 abnormal tests are not adequately reported to patients and/or not documented in the chart. This study reinforces the concept that safety processes and work flow must be worked out ahead of time and apparent to all clinicians or problems will occur, regardless as to whether one uses a paper-based or electronic system.⁶⁶ The relationship between EHRs and National Patient Safety Goals was addressed in an article by Sittig and Singh in 2012.⁶⁷

Health Information Exchange (HIE)

As pointed out by John Halamka, HIE has the potential to improve patient safety by better communication between disparate healthcare participants. Meaningful Use that is accomplished with HIE should provide valuable information: during the transitions of care, by populating immunization registries and personal health records and by reporting syndromic surveillance-related data to public health.⁶⁸ Very few hospitals have the IT support and system sophistication to accomplish widespread sharing of information similar to Brigham & Women’s Hospital in Boston, but contemporary advances are being realized as a result of HITECH-funded programs. Substantial gains in the use of HIEs in enhancing patient safety should spread nationally within the next three to five years.

Automated Dispensing Cabinets (ADCs)

Devices are like ATM machines, are kept on nursing units and communicate with pharmacy computers and dispense medications stocked by the pharmacy. Password protected devices keep medication records but unfortunately, there is limited evidence that these systems reduce errors or affect outcomes.^{49,69} There is some evidence to suggest, perhaps due to clinical workflow and contextual issues, that these devices could introduce patient safety challenges.⁷⁰⁻⁷²

Home Electronic Medication Management Systems

At least one company is in the process of developing an ATM-like machine to administer medications to the elderly at home. Medications are loaded into the machine as a 6x9 inch blister pack with storage for up to 10 medications for one month. The device is connected to the pharmacy via the internet so they can monitor compliance and adjust doses. The device (EMMA) gives a visual and audible alert when it is time to take a medication.⁷³

Pharmacy Dispensing Robots

Studies suggest that robotic systems save space, decrease manpower, increase the speed to fill a prescription and decrease errors. Robots are very helpful when there is a shortage of pharmacists or staff. Technology allows pharmacists to have more of a supervisory role. Ideally, systems would receive electronic prescriptions from outpatient and inpatient areas, then be checked by both the EHR and the pharmacist, then labels are printed and the prescription filled. Robots are available in different models that handle a variety of drugs (50 to 200), giving pharmacies financial flexibility.⁷⁴⁻⁷⁵

Electronic Medication Administration Record (eMAR)

This technology eliminates legibility issues as there is no need to rewrite the MAR when medications are changed or discontinued. Provides ready access to the patient's chart to see what medications the patient is on and provides allergy and timing alerts. Application is available to nurses and physicians who usually make separate rounds. Program can be web-based and can be wireless. Many eMARs integrate with EHRs, bar coding and medication reconciliation to provide a closed loop medication administration system.⁷⁶

"Smart" Intravenous (IV) Infusion Pumps

Intravenous sedatives, insulin, anticoagulants

and narcotics pose the highest risk of harm from medication errors.⁷⁶ Early IV pumps allowed for constant infusion rates without programmable alerts. Newer smart pumps can be programmed to deliver the correct amount of IV drugs and are associated with drug libraries and alerts that the dose differs from hospital guidelines. This feature is known as a "dose error reduction system" (DERS) and is particularly important if there were a decimal point error or the units of administration such as mg/hour were incorrect. The end result is that the infusion will not begin until the discrepancy is corrected. As an added benefit some pumps also wirelessly transmit data so that specific events can be captured and studied.

Smart pumps can link to eMars, CPOE and pharmacy IT systems. Evidence thus far indicates that smart infusion pumps avert serious IV medication errors. It is important to realize that even a small reduction in errors that involve dangerous IV drugs is an important advance.⁷⁷ A 2005 study found that serious medication errors were unchanged compared to a control group. This was thought to be due to the fact that the default data entry interface bypassed the error reduction system, leading many nurses to not consult the drug library. Also, alert overrides were common and there were many undocumented verbal orders. It would be important for hospitals to set the drug library as the default for the program. An unanticipated bonus of this program was the fact that the memory system of the infusion pump was a treasure trove of information, pointing out future areas of training and changes in nursing protocols.⁷⁸ Smart pumps with built in bar coding are available.⁷⁹ There is a definite trend to integrate smart pumps and other hospital devices with electronic health records and other hospital information systems.⁸⁰ In spite of smart pump sophistication, pumps can generate excessive alerts; a problem discussed later in a section on unintended consequences.

Calculators

Johns Hopkins University created a web-based pediatric total parenteral (IV) nutrition (TPN) calculator and as a result reduced medication

errors in half with an annual projected saving of \$60,000 to \$80,000. The infusion calculator was associated with 83% fewer errors.⁸¹ Other web-based and handheld medical calculators are available but little is known regarding their impact on patient safety. Calculators that are embedded into electronic health records and constitute clinical decision support will likely have the greatest impact on patient safety.

Bar Coded Medication Administration (BCMA)

BCMA involves a variety of elements: bar code printers, scanners, a network (wired or wireless) to connect to a server, server with bar coding software and integration with the pharmacy information system and any CPOE system. A typical linear bar code is most common but newer two dimensional bar codes exist that encode more information in a smaller space and can be read from different angles and include images such as patient's picture and color coded alert sections (Figure 17.2 and 17.3).

Figure 17.2: Bar codes linear and 2-D (Courtesy Endur ID)



Figure 17.3: Bar code bracelets



How does a BCMA system work? A standard scenario would be for a nurse to scan his/her ID bar code, the patient's bar code and the medication's bar code. This information could be sent wirelessly to the program server with software that determines that the correct medication is going to the correct patient at the correct time. In general, the system will

generate a warning or an approval. Studies have shown that about 35% of medication errors occur at the administration stage. Further breakdown of errors that might be prevented by BCMA include: dose omission (21%), wrong patient (4%), wrong time (4%), wrong route (1%).⁸²

Most healthcare organizations use three linear barcodes: codes 128, 39 and Reduced Space Symbology (RSS). Two dimensional barcodes are available that can store 3,000 characters of patient information. Bar codes can be placed on patient ID bands, medications, vials of blood and transfusion bags. FDA mandated that drug companies apply bar codes on unit dose medications and blood components. Barcodes must contain the national drug code (NDC) that can be used to identify medications. The price tag is likely to be \$300,000 to \$1 million for hospitals to adopt barcode technology.

Expect more innovations with 2-D (QR) codes in the future. One EHR vendor has partnered to have QR codes on vaccine bottles such that when scanned, the vaccine supply can be monitored, information can be sent to the EHR and the state immunization registry and clinical decision support can confirm that the correct patient received the correct immunization.⁸³

There are very few studies looking at patient outcomes with this technology. Poon et al. studied dispensing errors before and after implementation of BCMA at the Brigham and Women's Hospital Pharmacy. They demonstrated that the target dispensing error rate dropped by 0.25% to 0.018% (93 % relative risk reduction).⁸⁴ A 2010 follow-up study by the same author from the same hospital concluded that bar coding coupled with an eMAR reduced medication errors at the transcription and administration stages. In addition there was a reduction in potential adverse drug events; with true adverse drug events (documented harm to patients) not reported.⁸⁵ BCMA in an adult medical intensive care unit was reported in 2009. The system had the potential to improve several areas of medication management but showed an improvement in only administration time errors after implementation of a BCMA

system.⁸⁶ Veteran's Affairs hospitals have had bar coding since 1999 in their 161 hospitals. Once scanned, the software confirms that the correct medication in the correct dose and frequency has been given to the correct patient. It also updates the electronic medication record. As a result of this technology one VA hospital was able to decrease medication errors by 66% over five years.⁸⁷

Bar coding can be used for more than medication administration. It has been used for surgical sponge counts⁸⁸ and laboratory specimen labeling. As an example, an inpatient's ID bracelet is scanned and it confirms that this patient requires a certain blood test. A mobile printer prints labels that are attached to the tube of blood at the bedside.⁸⁹ A study from a pediatric oncology hospital demonstrated a decrease from 0.03% to 0.005% in mislabeling errors after one year of implementation. The incidence of unlabeled specimens continued to be the same, after implementation. There were a few misreads due to the curvature of the wrist band, that will likely be prevented with a two-dimensional (2-D) bar code band. They estimated that the cost of the system added \$1.75 to each specimen processed.⁹⁰ AHRQ funded pilot programs in multiple states, but in spite of some successes they concluded that implementation is not easy.⁹¹

Problems with BCMA include: high cost, nurse work flow issues, some meds need to be re-packaged in order to be read and scanners are not interoperable so institutions may have to buy different scanners.⁹² It is known that nurses often have to create "workarounds" to solve BCMA shortcomings.⁹³ A 2010 study concluded this technology inconsistently decreased ADEs and created several new types of medication errors that were not part of the "5 rights" approach.⁹⁴

Radio Frequency Identification (RFID)

Radio frequency identification is a relatively new technology that has some similarities to barcoding but important differences. Unlike bar

coding, RFID can be read-only or read-write capable and RFID tags can be read if wet or thru clothing; they are therefore better for blood and IV bags. Tags can be active (needs battery, larger, more memory, longer range and more expensive) or passive (smaller, cheaper, short range and no battery) (Figure 17.4) RFID tags can be low, medium or high frequency. A scanner must interface with an established database to identify the object with the RFID tag. The tags are cheap but transceivers (scanners) are expensive.

Figure 17.4: Passive RFID tag on back of a drug label (Courtesy CPTTM)



RFID is used in healthcare primarily to locate and track patients, staff and inventory, but with a few new wrinkles. RFID systems can track patients within a hospital with an active tag that works like a transmitter and gives location and time, with the ability to operate on the hospital's WiFi network. RFID tracking will also allow for better business and time analysis. In the info box on the next page is an example of RF-scanning of the surgical patient before the wound is closed to be sure no surgical sponges are left in.⁹⁵

In 2007 the Mayo clinic began using passive RFID tags attached to specimen bottles used to hold biopsies. The RFID system was provided by 3M and over 30,000 specimens have been processed. The RFID holds a unique patient number stored in a database that must match.

Surgical Sponge RFID Detection System

A retained surgical sponge after an operation is a significant patient safety issue because it usually means infection and repeat surgery. Sponges embedded with RFID technology means the abdomen can be scanned prior to closing to be sure no sponges were left in. One study of 1,600 patients showed no false positive or negative results.⁹⁵



The error rate prior to RFID was 9.2%/100 bottles and .55%/100 bottles after transition.⁹⁶ A 2008 article raised serious concerns about RFID. When an active or passive RFID tag is read by the scanner it emits electromagnetic interference (EMI). They reported frequent potentially hazardous incidents in a non-clinical scenario when devices like pacemakers and ventilators were exposed to EMI, even at distances greater than 12 inches. Although they tested only RFID tags produced by two vendors, there should be a note of caution with all RFID devices around critical equipment.⁹⁷

Medication Reconciliation

It is well known that when patients transition from hospital-to-hospital, from physician-to-physician or from floor-to-floor, medication errors are more likely to occur. Home medications are occasionally forgotten or incompletely recorded. The Joint Commission mandated hospitals must reconcile a list of patient medications on admission, transfer and discharge. Medication reconciliation is now part stage I Meaningful Use criteria. A report of “errors of transition” concluded the following: 66% occurred at transition to another level of care e.g. ICU, 22% occurred on admission and 12% occurred on discharge.⁹⁸ If all medical offices, pharmacies and hospitals had the same EHR or were connected to a shared health information organization, then the answer would be simpler and electronic. Instead, completely disparate systems that are not interoperable are found. Patients can compound

the issue by using multiple pharmacies, taking alternative drugs and not keeping records. Multiple IT solutions are available but none are comprehensive because of the disparate process. The following are vendors or initiatives related to medication reconciliation.⁹⁹⁻¹⁰²

The significance of having prior prescribing information available at the time a prescription is written should not be underestimated. Researchers reported a study in which clinicians were given six months of prescription claims data compared to a control group with no such information. Those with the additional information were more likely to change dosages (21% vs. 7%); add drugs (42% vs. 14%) and discontinue drugs (15% vs. 4%). Also, physicians with prior drug histories detected non-compliance in about one-third of patients versus none in the control group.¹⁰³ Another important issue concerning medication error reduction is the ability to reconcile all outpatient medications when a patient is admitted to a hospital. In many instances the information given by the patient is not correct. Lau reported that 61% of patients had at least one drug missing and 33% had two or more drugs missing on initial admission interview.¹⁰⁴ EHRs, HIOs and pharmacy claims data all offer the opportunity to provide additional patient drug history.

While pharmacy claims data derived from pharmacy benefits managers makes sense, it will not help the uninsured who do not have records. Also, many patients take herbal medications they fail to report and are not retrievable electronically.

Electronic Health Records and E-Prescribing

The benefits and challenges related to electronic health records, CPOE and e-prescribing are covered in the chapter on electronic health records.

Recommended Reading

The following are interesting current articles to supplement knowledge about patient safety and HIT:

- *The Economics Of Health Information Technology In Medication Management: A Systematic Review Of Economic Evaluations.* Thirty one studies were reviewed and were determined to be so heterogeneous as to prevent synthesis. The major problem was that studies included cost data but often failed to include a full economic evaluation and actual outcome data. They were therefore unable to deliver an opinion.¹⁰⁵
- *Reduction In Medication Errors In Hospitals Due To Adoption Of Computerized Provider Order Entry Systems.* Researchers predicted the potential benefit of CPOE based on a systematic review of the literature as well as combining data from the American Society of Health-System Pharmacists Annual Survey. Based on 2008 data they estimated that CPOE adoption would result in a 12.5% reduction in medication errors.¹⁰⁶
- *Adherence To Drug-Drug Interaction Alerts In High-Risk Patients: A Trial Of Context-Enhanced Alerting.* Researchers wanted to know if posting pertinent lab and other risk factors would improve compliance alerts. They looked specifically at drug-drug-interactions (DDIs) that produce an elevated potassium (hyperkalemia) level. They found poor compliance with high risk alerts with and without additional information.¹⁰⁷
- *Root Cause Analysis Reports Help Identify Common Factors In Delayed Diagnosis and*

Treatment of Outpatients. This study reviewed 111 root cause analyses in the VA system looking at delayed outpatient diagnosis and treatment over a 7 year period. Failure to follow-up and track patients were most prominent, in spite of a robust electronic health record with standard reminders. They concluded that other decision support refinements are necessary.¹⁰⁸

Barriers to Improving Patient Safety through Technology

Organizational

Medicine, as structured within the United States, is primarily a decentralized system with no unifying philosophy. Many small physician groups have limited loyalty to hospitals or other healthcare organizations. They may not interact frequently with other physician offices or healthcare organizations and may not share data. In summary, the U.S. healthcare system was not optimally designed for quality and hence information technology may not solve existing problems. With respect to patient safety, organizational barriers are often substantial and broad in scope. A critical organizational challenge to patient safety realized in hospitals and health systems is the absence of a “culture of safety.” Other organizational barriers cited in the literature include clinical workflow issues, communication challenges and a lack of teamwork among the health care team, to name just a few.^{57,59,109-113}

Financial

Who will pay for what? It is estimated that it will cost \$500 to \$700 billion dollars over the next 10 years to have a full-fledged interoperable electronic health record system nationwide. This is 3% to 4% of the total health care budget which is a lower percentage than what other industries spend on technology. In 1996 the healthcare industry spent about \$543 per worker

as compared to \$12,666 per worker spent by security brokers and other industries for information technology.¹¹³ Patient safety is organizationally represented as a cost for healthcare organizations as there is no income stream associated with keeping patients safe. Accordingly, financial constraints have been cited as a barrier to adoption of patient safety-oriented health IT. There is, however, the expectation that patient safety activities may at least in part pay for themselves through reduced litigation, and nurse time utilization.¹¹⁴

Error reporting

Reporting continues to be voluntary and inadequate at best. A 2010 Inspector General report maintained that about 85% of hospital-based errors are not reported; Medicare inpatients experience adverse events 13.5% of the time and 44% are thought to be preventable.¹¹⁵ Further-more, in a recent study of over 90,000 voluntary electronic error reports from 26 hospitals, most were from nurses and only 2% were reported by physicians.¹¹⁶ A survey of over 1,000 physicians revealed that 45% did not know if their institution had an error reporting system. Seventy percent (70%) thought the current reporting systems were inadequate. Physicians believed reporting would improve if information was kept confidential, nondiscoverable, it was quick to input and it was nonpunitive.¹¹⁷ Clearly, there are legal and licensure issues associated with error reporting. Currently, there is no universal method to standardize error reporting in the US. The FDA does have a web based portal for consumers and clinicians to voluntarily submit adverse drug events that occur post-marketing; discussed earlier in the chapter.²⁶ Previously, alerts to physicians about defective devices and drug alerts were mailed. To improve the situation the Health Care Notification Network was created that will e-mail alerts as well as public health emergencies and bioterrorism events.¹¹⁸⁻¹¹⁹

Classen et al. reported the results of using three medical error reporting tools in an evaluation of admissions to three large tertiary hospitals with robust patient safety programs. The tools were

the “global trigger tool” developed by the Institute for Healthcare Improvement, the Quality Patient Safety Indicator developed by AHRQ and the Utah/Missouri Adverse Event Classification. It should be noted that they evaluated adverse events, regardless whether harm was preventable or not. The global trigger tool utilized a non-physician primary team of chart reviewers as well as a team of physicians or secondary review. They examined discharge notes and codes, medications, operation records, all progress notes and any other note to indicate a trigger, such as antidote administered. The major findings were that the global trigger tool detected far more adverse events than the other tools and had a sensitivity of 95% and a specificity of 100%. As a result, adverse events occurred in 33% of hospital admissions. They believed that only real time reporting would be more accurate.¹²⁰

Error reporting is important but is “after the fact” so it fails to prevent morbidity and mortality. This may change as more organizations have robust IT systems coupled with artificial intelligence and rules engines. For example, the Cleveland Clinic is analyzing its patient charts with a cycle of analytics to look for potential complications while the patient is still in the hospital.¹²¹

Liability

Enterprise use of CPOE and CDSS can be associated with liability if alerts are ignored, missed or are poorly designed. This raises the issue whether there should be an approved list of drug-drug interactions all EHRs should incorporate.¹²²

Unintended Consequences

Technology is a two-edged sword. It may reduce medical errors but it also has the potential to create new ones. The following are a several examples:

Medical Alarms. Hospitals have a variety of medical alarms for medical devices: vital signs monitors, ventilators, pumps, bed alarms, etc. About 95% of alarms are for minor issues (nuisance or non-actionable alarms) and these

lead to “alarm fatigue.” The most common culprit is the constant vital signs type monitor. Due to the high number of nuisance alarms, they are ignored or the volume is turned down, resulting in great risk to a small number of patients. There is good evidence that if thresholds are reduced and there is a longer delay, alarms can be reduced by more than 80%.¹²³ This is a serious issue, such that the Joint Commission released a Sentinel Event Alert in April 2013 reporting on 98 alarm related events (2009-2012). Of the 98 reported, 80 were associated with death of the patient; 13 resulted in permanent damage and 5 required prolonged care.¹²⁴ Severe sequelae from alarm related deaths were also reported by the US Food and Drug Administration. In December 2013 the Joint Commission made medical alarms a safety goal (NPSG.06.01.01). Phase 1 begins in January 2014 and requires that hospitals study the risks unique to their organization. Phase 2 begins in 2016 with the requirement to have in depth plans to mitigate the risk and educate the entire staff regarding their plan.¹²⁵

Infusion Pumps. Infusion pumps can be a time saver for the nursing staff and can improve patient safety. However, like many technologies they can also cause new errors. For example, the pumps cannot tell if the correct drug is being administered to patient A, unless it is validated through another system such as CPOE. Because these pumps deliver drugs intravenously they can cause life-threatening situations. In the opinion of the ESRI Institute about 75% of pump errors would be prevented if the pumps were integrated into CPOE, and any system involved with medication management.¹²⁶

Distractions related to mobile devices. There is evidence that healthcare workers continue to use their mobile devices for text messaging and access to social media, etc. while on the job leading to distractions, not unlike what occurs while driving.¹²⁶

Electronic health records are penetrating the healthcare system. Compared to paper charts they are more readable and provide better access to the record, resulting in improved

quality and safety. On the other hand, data can be missing and/or incorrect, there can be typographical entry errors, and older information is sometimes copied and pasted into the current record. Systems need to be in place that regularly assess the quality, accuracy, and completeness of patient information contained within electronic health records.¹²⁷

Future Trends

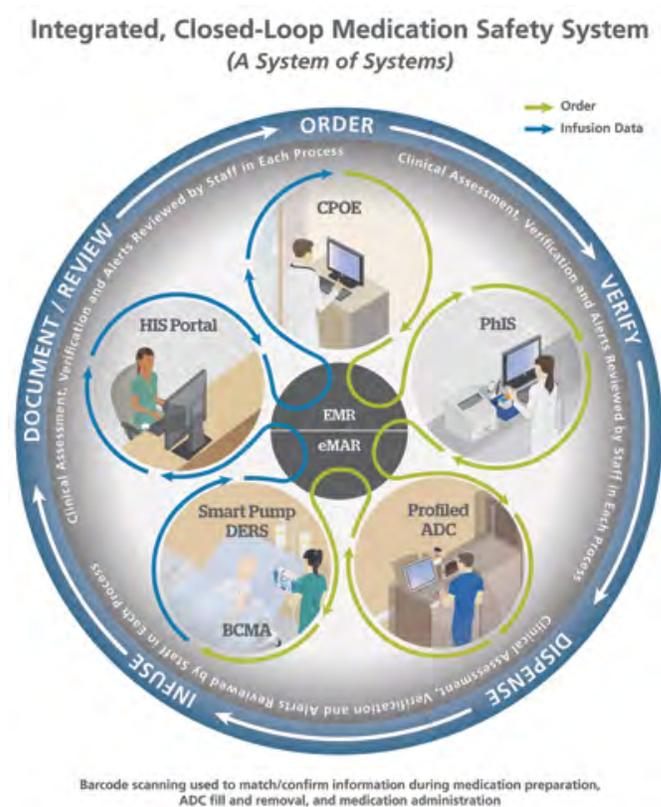
It is anticipated that there will eventually be standardized patient safety parameters and triggers as well as a universal reporting system. Once that is in place there will be a movement from retrospective to real time data analysis to detect and/or prevent adverse patient events. This will require a very robust information technology system with a data warehouse that is assisted by evidence based rules engines and artificial intelligence to pick up issues real time. A few noteworthy healthcare organizations are already using business intelligence to analyze medical errors, in order to make changes across the enterprise.¹²⁸ Healthcare can also anticipate more penalties from payers who are becoming less tolerant to healthcare systems associated with greater than average adverse events.

Jha and Classen are of the opinion that patient safety reporting should be part of Meaningful Use such that EHR vendors must include patient safety features to record, track and trend adverse events.¹²⁹ This would likely require mandated inpatient and outpatient adverse event capture in the EHR but how often would this require human inputting?

Closed-loop medication safety systems are starting to make a significant impact in a few healthcare systems. The idea is to integrate all of the medication processes together such that the CPOE/CDSS, ADCs, BCMA, smartpumps and eMARs are, in effect, one system.¹³⁰ Stage 2 meaningful use objectives are consistent with this approach when they mandate automated tracking using assistive technologies (BMCA, RFID) to follow a medication from order to administration and using an eMAR. Children’s Hospital of Minnesota is the first pediatric

hospital to create such as system.¹³¹ Figure 17.5 shows how this might work.

Figure 17.5: Closed-loop medication safety systems (Courtesy PSQH)



Key Points

- Patient safety is a major issue facing U.S. medicine today. Far too many people die from medical errors each year.
- Both governmental and non-governmental organizations and programs are tackling patient safety challenges in healthcare organizations; health IT projects are broadly supported by these organizations as a strategy to improve current conditions.
- There is great hope that information technology, particularly clinical decision support as part of the electronic health record, will improve patient care and safety.
- There is some evidence that clinical decision support and alerts may reduce medication errors.
- Bar code medication administration also appears to reduce some medication related errors but is expensive and complicated.
- A dedicated and focused patient safety strategy and culture should accompany any deployment of health information technology.

Conclusion

Better studies are needed to clearly demonstrate health information technology consistently improves patient safety. Until then, healthcare organizations will have to rely on anecdotal and limited studies. Somewhat surprising, there is not a national database or method to store and analyze medical errors.¹¹⁷ Moreover, CEOs and CIOs will be looking for a reasonable return on investment. However, if improved patient safety means a larger market share, fewer law suits or a better hospital ranking by the state or federal government, then adoption will likely occur. According to HealthGrades, there is evidence that the highest ranked hospitals for quality have lower mortality rates.¹³² Additionally, it appears that the most wired hospitals also have lower mortality rates but it is too early to establish clear-cut cause and effect.¹³³

One could also draw on the experience of the Veterans Affairs hospitals to show how their electronic health record has markedly improved the quality of care and efficiency.¹³⁴ But, is their dramatic systemic improvement solely due to their EHR or is it due to the visionary Dr. Kiser who saw the need for modernization and the establishment of a culture of quality and safety? A study by Menachemi et al. evaluated 98 Florida hospitals' IT adoption and patient outcome measures and concluded there was a definite correlation. They felt that IT systems for clinicians provided up-to-date guidelines at the point of care.¹³⁵ The relationship between HIT and patient outcomes is likely to be more complicated and involves more than just technology, such as the effects of better leadership, training, etc.

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Chapter 18

Telemedicine

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Learning Objectives

After reading this chapter the reader should be able to:

- State the difference between telehealth and telemedicine
- List the various types of telemedicine consultations, such as teleradiology and teleneurology
- List the potential benefits of telemedicine to patients and clinicians
- Identify the different means of transferring information with telemedicine, such as store and forward
- Enumerate the most significant ongoing telemedicine projects

Introduction

According to the Office for the Advancement of Telehealth (OAT), Telehealth is defined as:

“the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration”¹

Similar to the term e-health, telehealth is an extremely broad term. A review by Oh et al. found 51 definitions for e-health, suggesting that the term is too general to be useful and the same is probably true regarding telehealth.² One could argue that Health Information Organizations (HIOs), Picture Archiving and Communication Systems (PACS) and e-prescribing are also examples of telehealth if they exchange

healthcare information between distant sites.

Clearly, telehealth is the broader term that incorporates clinical and administrative transfer of information, whereas telemedicine relates to remote transmission or exchange of only clinical information. In this chapter the term telemedicine is used, instead of telehealth and defined as follows:

“the use of medical information exchanged from one site to another via electronic communications to improve patients' health status”³

Telemedicine was postulated in the 1920s when an author from Radio News magazine demonstrated how a doctor might examine a patient remotely using radio and television. Ironically this was proposed before television was even available (Figure 18.1).⁴ The first instance of remote monitoring has been attributed to monitoring the health of astronauts

in space in the 1960's.⁵ Very rudimentary telemedicine has been conducted using telephone communication for the past fifty years or more. With the advent of the internet and video conferencing many new modes of communication are now available.

Figure 18.1: Early Telemedicine (Courtesy Radio News)



The goal of telemedicine ultimately is to provide timely and high quality medical care remotely. Telemedicine is becoming increasingly popular for the following reasons: (1) With the rising cost of healthcare worldwide, newer delivery models are appearing that will include telemedicine. In the case of the United States where Medicare will not reimburse for readmission for certain diseases new strategies are needed to prevent readmissions, to include telemedicine. (2) There is a shortage of primary care and intensivist physicians. Moreover, they are maldistributed to urban and not rural areas. Remote delivery of medical care with telemedicine is a partial fix. (3) Additional means are needed to deliver medical care, given the rise in chronic diseases and our graying population. (4) Telemedicine results in improved collaboration among physicians and disparate healthcare organizations. (5) Telemedicine raises patient satisfaction when it results in better access to specialty care, less

time lost from work and/or fewer long distant trips to tertiary medical centers.

Like many of the other topics in health informatics covered in this textbook there are multiple interrelationships. Telemedicine can be employed for disease management and as a strategy for improved patient care and communication, thus being part of consumer health informatics. Telemedicine is slowly being integrated with a variety of technologies and platforms such as electronic health records, health information organizations, mobile and picture archiving and communication systems. Due to the pervasive nature of mobile technology, it is also a player in telemedicine.

Telemedicine is part of healthcare reform internationally, in that it aims to improve access to high quality care and education remotely. It can be used for populations at risk, such as rural, indigent and elderly patients. As medical care becomes more patient-centric telemedicine will become part of the patient centered medical home and accountable care organization models.

Very recently telemedicine has been adopted by many major US healthcare delivery systems, such as Saint Joseph's Healthcare, Geisenger and Sentara, to improve access to medical care and hopefully reduce spiraling costs.⁶⁻⁸

Telemedicine Communication Modes

In this chapter multiple ways are presented for patients to receive remote care, starting from simple e-mail to complex audio-video teleconferencing. In the past several years new telemedicine technologies and business models have appeared with more on the way. Table 18.1 shows several of the communication modes used in telemedicine, along with pros and cons.

Telemedicine Transmission Modes

There are three telemedicine transmission modes:

- Store-and-forward. Images or videos are saved and sent later. As an example, a primary care physician takes a picture of a rash with a digital camera and forwards it to

Table 18.1: Telemedicine Communication Modes

Communication Mode	Pros	Cons
Patient-Portal secure-messaging	Asynchronous. Able to attach photos. Response can be formatted with template. Could use VoIP. Audit trail is available	Not as personal as live visit. Usually not connected to EHR or other enterprise information but may be in the future
Telephone	Widely available, simple and inexpensive. Real-time	Not asynchronous. Unstructured. No audit trail. Only real-time
Audio-Video	Maximal input to clinician. Can include review of x-rays, etc. Perhaps more personal than just messaging	Currently, most expensive in terms of networks and hardware, but that is changing

a dermatologist to view when time permits. This method is commonly used for specialties such as dermatology and radiology. This could also be referred to as asynchronous communication.

- Real time. A specialist at a medical center views video images transmitted from a remote site and discusses the case with a physician. This requires more sophisticated equipment to send images real time and often involves two way interactive telemonitors. The specialist is able to see the patient and ask questions. Telemedicine also enables the sharing of images from peripheral devices such as electronic stethoscopes, otoscopes, etc. This would be an example of synchronous communication.
- Remote monitoring. A technique to monitor patients at home, in a nursing home or in a hospital for personal health information or disease management.

Telemedicine Categories

In this chapter Telemedicine is divided into the categories noted below based on current knowledge and initiatives. It should be pointed out that virtual patient visits (televisits or e-visits) could be part of telemedicine or consumer

health informatics. Virtual visits will be discussed in the chapter on consumer health informatics.

- Televisits: see chapter on consumer health informatics
- Teleconsultations: teleradiology, teledermatology, etc.
- Telemonitoring:
 - Telerounding: hospital inpatients
 - Telehomecare: monitoring physiological parameters, activity, diet, etc. at home

Teleconsultations

Teleconsultation is a worldwide phenomenon because specialists tend to practice in large metropolitan areas, and not in rural areas. Most programs consist of a central medical hub and several rural spokes. Programs attempt to improve access to services in rural and underserved areas, to include prisons. This reduces travel time and lowers the cost for specialists and patients alike. Programs have the potential to raise the quality of care delivered and help educate remote rural patients and physicians. The most commonly delivered services are mental health, dermatology,

cardiology and orthopedics. According to the American Telemedicine Association (ATA), as of 2013 there about 200 telemedicine networks in the United States serving roughly 3000 practice sites.⁹

Teleradiology

The military has taken the lead in this area partly due to the high attrition rate of radiologists and the desire to enhance radiology support for military deployments. By 2007 most Army x-rays became digital, which helped the storage, transmission and interpretation of images. With this newer technology a computerized tomography (CT) scan performed in Afghanistan can be read at the Army medical center in Landstuhl, Germany. Another example of military teleradiology can be found on the Navy hospital ships Mercy and Comfort where digital images can be transmitted to shore based medical centers for interpretation or consultation.

In the civilian sector, vRad (formerly NightHawk Radiology Services) helps smaller hospitals by supplying radiology services remotely. All are board certified; most trained in the United States and carry multiple state licenses. They list a staff of 400+ radiologists and interpret seven million studies per year. They offer conventional radiology as well as CT, MRI, Ultrasound and Nuclear Medicine interpretation.¹⁰

In mid-2013 The American College of Radiologists published Teleradiology Practice Guidelines. The Task Force outlined benefits as well as challenges to the practice.¹¹

Another more common but important example of teleradiology is the practice of radiologists reading films after-hours at home. They must have high resolution monitors and high speed connections to the internet but with this set up and voice recognition software; they can be highly productive at home. This is becoming the standard practice for radiologists. Instead of driving in or staying at the hospital at night to interpret images, they can deliver interpretations while at home.

Teleneurology

Treatment of stroke with intravenous clot busting drugs has become the standard of care and can result in a small reduction in mortality and increase in the odds of going home and walking better.¹² Many regions lack neurologists to see patients with stroke-like symptoms to determine if they need clot-busting drugs (thrombolytics) or need to be transferred to a higher level of care. This is, in part, due to the increased malpractice risk and decreased reimbursement situation of treating emergency patients. With the advent of telemedicine, the case can be discussed real time and the patient and their x-rays can be viewed remotely by a stroke specialist. One company, REACH Call Inc. developed a web-based solution that includes a complete audio-visual package so neurologists can view the patient and their head CT (CAT scan). REACH Call Inc. was developed by neurologists at the Medical College of Georgia. Because the program is web-based, the physician can access the images from home or from the office. Likewise, the referring hospital only has to have an off-the-shelf web camera, a computer and broadband internet connection.¹³ Specialists-on-Call is a Massachusetts based organization that has 40 part time or full time neurologists on board to handle emergency consults via telemedicine for about 60 private community hospitals. In 2011 they added telepsychiatry and in 2013 teleintensivists. Their capabilities include the ability to transfer head CT images and bidirectional audio and video conferencing with remote physicians and families. To accomplish this they have an infrastructure that consists of a PACS, a call center, an electronic health record and videoconferencing equipment. The cost for this service is not inexpensive; for a 200 bed hospital it would cost \$400 per day and \$40,000 for initial installation fees. It is unknown if third party payers will eventually reimburse for this service.¹⁴⁻¹⁵ A teleneurology study is reported later in this chapter.

Teleconcussion is a new indication for teleneurology consultation whereby a patient with head trauma is evaluated remotely. An

article from the Mayo clinic on this approach is posted in the recommended reading section of this chapter.

Telepharmacy

Like teleradiology, this field arose because of the shortage of pharmacists to review prescriptions. Vendors now sell systems with video cameras to allow pharmacists to approve prescriptions from a remote location. This is very important at small medical facilities or after-hours when there is not a pharmacist on location.¹⁶⁻¹⁷ A 2011 survey documented that 60% of hospitals have 24 hour review of medication orders by pharmacists and 11% use a telepharmacy company.¹⁸ The North Dakota Telepharmacy Project operates 56 remote sites where pharmacy technicians receive approval for a drug by distant pharmacists via teleconferencing. About 73% of counties are covered with this project, in addition to two counties in Minnesota. This initiative is supported by North Dakota State University. In this manner a full drug inventory is possible even in small rural communities and the pharmacists still perform utilization reviews and other services remotely.¹⁹

Telemental Health

The shortage of mental health professionals have helped to drive telemental health (also called telepsychiatry) services. Several studies have indicated that telepsychiatry is equivalent to face-to-face psychiatry for most patients.²⁰ The American Psychiatric Association promotes telepsychiatry, primarily for remote or underserved areas, using live video teleconferencing. During a telesession, there can be individual or group therapy, second opinions and medication reconciliation. In general, virtual visits help team medicine and patient satisfaction has been good. On the American Psychiatric Association web site, there are valuable telemental health resources.²¹ Another telepsychiatry trend that is appearing is the use of free commercial-off-the-shelf (COTS) audiovisual programs, such as Skype. Voyager

Telepsychiatry uses this popular program to hold virtual telepsychiatry sessions.²² One of the most important areas for telepsychiatry is for US military members who return from war with Posttraumatic Stress Disorder (PTSD) and Traumatic Brain Injury (TBI). About 40% of veterans live in rural areas, where transportation may be an issue. The VA has opened three Veterans Rural Health Resource Centers in Iowa, Utah and Vermont to help develop and evaluate telemedicine programs.²³

A comprehensive resource “The Online Couch” was published in mid-2012 that categorized technology-enabled treatment of depression into: computer-based cognitive behavioral therapy (CCBT), online counseling, online social networks, mobile platforms, games and virtual reality. The report makes the point that depression is extremely common in the adult population and because there is a shortage of mental health providers, a cost barrier and stigma associated with mental health visits, alternative approaches are needed. CCBT has been endorsed in the United Kingdom for use in the National Health Service, specifically for the treatment of depression (Beating the Blues) and panic/phobic disorders (FearFighter). The University of Pittsburg Medical Center has now also adopted Beating the Blues approach and will use it in the patient centered medical home model. Other technology-related approaches are mentioned, such as interactive voice response, email, chat and video, but are beyond the scope of this chapter. Market challenges, provider perspectives and payments are addressed.²⁴

The web site Telemental Health Technologies Compared offers the ability to search for applications focused on private practice, provider networks, the enterprise and the consumer. For example, 90 different technologies are listed under private practice. One platform offers online CBT for insomnia, depression, anxiety, panic, phobias, obsessive compulsive disorder and addiction, with literature references. This comparison web site makes the point that 38 state counseling boards have policies addressing online counseling and 18 states mandate that telemental services be

reimbursed at the same level as face-to-face therapy.²⁵

Telemental health networks and organizations have arisen in the past few years. For example, JSA Health Telepsychiatry offers 24/7 coverage by board certified clinicians for emergency departments, rural health clinics, homeless shelters, schools, correctional facilities and cruise ships.²⁶

A 2013 full text review article on telemental health provides insight into the impact on quality of care, access, cost, technology, constraints, legal/ethical and privacy/security issues.²⁷

Teledermatology

With the advent of good quality digital cameras and cell phones with medium quality cameras, the concept of teledermatology was born. The Teledermatology Project, created in 2002, has the goal of providing free worldwide dermatology expertise, particularly for third world countries and the underserved. Physicians can easily obtain a teleconsultation and diagnostic and therapeutic advice using the store and forward mode. A 2003 survey indicated that there were 62 teledermatology programs in the United States, in 37 states.²⁸⁻²⁹ iDoc24 is a Teledermatology project that began in Sweden for the European Union. It was designed for those patients who were traveling or did not have access to their physician and had a new skin condition. Patients can take a picture of their skin lesion with a digital camera or cell phone (app available) and forward it (can be anonymous) as an attachment to a text message and it would be followed by a response by a dermatologist within 24 hours. The image can also be integrated with the regional personal health portal that is part of the Swedish National Health Service. The goal is to provide better service, answer anonymous requests and decrease overall face-to-face visits to dermatologists.³⁰

Direct Dermatology is a 2013 web service for patients to upload pictures of their skin problem and receive recommendations from a team of US

board-certified dermatologists within 2 business days. They also offer the ability for physicians to submit patient dermatology issues and photographs. The service costs \$85 and is not submitted to third party payers. This platform is supported by the California Healthcare Foundation and Kresge Foundation.³¹

A review article points out that teledermatology can reduce the need for face-to-face visits with a Dermatologist and can help with education and training of clinicians. Importantly, the correlation between face-to-face evaluations and store and forward images from cameras or cell phone cameras is high. Other dermatologic procedures that can benefit from remote care include teledermoscopy and teledermatopathology.³²

There are also smartphone apps that will help screen for risk of skin cancer such as Mole Detect and University of Michigan SkinCheck that help screen for melanoma and are available through the Apple App Store. Images taken with the phone camera can be stored and shared with physicians.³³

For more details on teledermatology, readers are referred to a review article by the California HealthCare Foundation.³⁴

E-Mail Teleconsultation

Audio and video teleconferencing is not the only way to communicate remotely. The Army has established a teleconsultation service for deployed military clinicians, based on e-mail communication. The secure service is available 24/7 for all branches of the military with most responses completed in less than six hours. Almost every specialty is available to the military physician while on ships, the battlefield or part of humanitarian or disaster relief operations. Since 2004 over 11,300 consultations have been completed and 163 evacuations avoided. The most common specialty consult requested is dermatology (60%), followed by infectious diseases (10%). The program is administered as part of the Office of the Surgeon General's Teleconsultation Program.³⁵

Telemonitoring

Telerounding

This is a new concept developed to help address the shortage of physicians and nurses. Telerounding is being rolled out in facilities with reasonably good reviews, in spite of obvious criticisms that it further compromises the already strained doctor-patient relationship.

Robot Rounding. A study in 2005 in the *Journal of the American Medical Association* showed that surgeons could make a second set of rounds using a video camera at the patient's bedside (InTouch Robots). A physician assistant makes the actual rounds, backed up by the attending physician remotely via the robot. Robot units are five and a half feet tall, weigh 220 lbs. and have a computer monitor as a head. The cost is more than \$100,000 each or they can be leased for \$5,000 monthly plus \$5,000 per viewing station. At this time they are being used in 20 plus hospital systems in the United States. They can move around and can project x-ray results to the patient. Ellison et al. reported on urological patients who either received face-to-face rounds post-operatively or robotic telerounding. They concluded that robotic rounding was safe and well received by patients. Two-thirds of patients stated they would rather see their own physician remotely than a stranger making rounds in person.³⁶⁻³⁷ One of the leading companies to offer robots has expanded the use of the robots for telestroke care, hospital and operating room consultations and E-ICU rounding, discussed in the next section.³⁸

E-ICU Rounding. In the United States it is stated that approximately 35,000 intensivists (physicians who specialize in ICU care) are needed, but only 6,000 exist. Moreover, in spite of the fact that hospital beds are not increasing, ICU beds are. Therefore, remote monitoring makes sense particularly during nighttime hours when physicians might not be present. The Leapfrog Group has advocated care delivered by intensivists for all ICUs as one of its four patient safety recommendations; but this goal remains elusive.³⁹ Hospitals that use e-ICUs believe there

are patient safety and financial benefits but both need to be proven. An e-ICU service may be less expensive than recruiting full time intensivists. Also, because ICU care can cost \$2,500 daily, any cost saving modality that positively affects length of stay or mortality will gain market attention. Avoiding law suits in the ICU also means cost savings. It is estimated that over 100 hospitals now have e-ICU programs, even though there is no reimbursement by insurers.⁴⁰

A few large healthcare systems have created their own eICU systems but most have used the VISICU platform. It was founded by two intensivists from Johns Hopkins in 1998 and later purchased by Phillips Electronics Healthcare division. As of 2013, 350 hospitals in 40 hospital systems use this technology. Their approach is to provide two-way video and audio communication, standardization of care, clinical decision support and robust graphical displays of physiological data. They have a research arm with more than 1.5 million patient stays archived. This platform extended support of care outside the ICU in 2007. A mobile (eCareMobile™) unit (Figure 18.2) is used to monitor sick patients on medical surgical floors, emergency departments, step-down units and post anesthesia units.⁴¹

Figure 18.2: eCareMobile™ unit (Courtesy VISICU)



The cost for e-ICUs is significant in light of the uncertain benefits. The University of Massachusetts Memorial Health Care network spent \$8 million to create a virtual ICU network to connect eight intensive care units. Specialists can now remotely view electronic health records, nursing notes, test results and video images of patients as well as access the latest clinical

practice guidelines.⁴² Sutter Health paid more than \$25 million to establish its VISICU e-ICU system. Based on their analysis they have saved about \$2.6 million in treatment costs by preventing deaths due to sepsis, a major cause of deterioration and death in acutely ill patients. In addition, they estimate that if sepsis is treated early, the ICU stay is shortened by four days.⁴³ It is unfortunate that many understaffed rural hospitals will not be able to afford intensivists or these services unless they are part of a larger network or there is reimbursement by insurers.

The return on investment from eICUs is unclear. Kumar reported costs of eICU programs in 2013 based on the Veterans Health Administration system and estimated that it would cost between \$70,000 and \$87,000 per ICU-bed for implementation and the first year of support. Based on their review of the literature eICUs could be associated with a several thousand dollar loss or gain per patient admitted to the ICU.⁴⁴ In spite of the many potential virtues of the e-ICU, an early article by Berenson et al. expressed the opinion that the actual value of e-ICUs was far from proven and there was a major interoperability issue between the e-ICU software and critical ICU systems like IV fluids and mechanical ventilation.⁴⁵ Another early article in by Thomas et al. evaluated the medical care in six ICUs before and after the implementation of an e-ICU system. They concluded that there was not an overall improvement in mortality or length of stay.⁴⁶ A more recent meta-analysis by Young et al. showed a decreased mortality and length of stay (LOS) in the ICU but not the overall hospital mortality or length of stay.⁴⁷ An article from a single academic medical center reported a lower hospital mortality and length of stay, improved guideline adherence and reduced preventable complications.⁴⁸ However, as pointed out in an editorial, it is not known if eICUs can improve care in rural/remote settings and whether hired intensivists on site would be more valuable.

In December 2013 a large non-randomized study was reported based on results from 56 ICUs in 19 US healthcare systems. More than 118,000 patients were studied (including a control

group). They found that mortality was lower in the eICU group and hospital and ICU LOS was lower. The factors leading to reduced mortality and LOS were intensivists reviewed case within one hour of admission; use of performance data; adherence to ICU EBM/CPGs and quicker alert response times.⁴⁹

The bottom line is that further research is needed to provide the kind of detail necessary to determine the benefit of this type of telemedicine. For example, is the benefit greater for a small hospital with limited ICU expertise compared to a large integrated ICU system with an abundance of intensivists?

Most articles reviewed included the Phillips eICU system but other healthcare organizations have developed their own solutions. For example, in the Department of Veteran Affairs VISN (Veterans Integrated Service Network) 19, the Denver VAMC serves as the hub for four rural smaller VA hospitals. The telehealth system is ready on call to mobilize a rapid response team when called by a critical care nurse. The goal is to rapidly stabilize a patient so they can stay local or be transferred safely. This hybrid system does have the advantage of using the same EHR in every hospital and mobile medical carts. Another unique aspect of their system is the ability for outlying surgeons to operate on a patient at the telehealth hub but be able to participate in virtual rounds remotely as the patient recovers.⁵⁰

Telehomecare

Telehomecare is remote monitoring of the patient at home. One healthcare expert has stated that “home is the new hub of health” which implies the home needs to be interoperable with the rest of the healthcare system.⁵¹ It usually involves monitoring vital signs, weights, blood sugars, etc. that can be sent via a wired or wireless mode from homes to physicians’ offices, health information exchanges, etc. While home telemonitoring can also include fitness programs and “aging in place” technologies, the chapter will focus on chronic disease management and post-acute

care monitoring. The goal is to better educate and monitor patients at home in an effort to provide better patient-centric healthcare, while reducing readmissions and unnecessary emergency room visits, thus saving money. There are multiple reasons telemonitoring is burgeoning:

- Chronic diseases are on the rise that will likely increase hospitalizations, readmissions and unnecessary emergency room visits. Measures like home monitoring might decrease this trend. The goal is to intervene immediately, rather than wait till the next appointment.
- Medicare changed reimbursement to home health agencies from the number of visits to a diagnoses based system, leading to decreased reimbursement for visiting nurses.
- Telemonitoring programs potentially support audio and visual communication with patients at home and therefore can reduce home visits by a nurse or physician. Nurses can make visits only if there is a problem, such as a change in symptoms or vital signs.
- One consulting organization predicts a nursing shortage of 800,000 and a physician shortage of 85,000 to 200,000 by the year 2020.⁵²
- Baby boomers are tech savvy and more likely to demand services like telemonitoring.
- Monitoring may be possible using the ubiquitous cell phone and new microsensors.
- Linking home monitoring devices to EHRs with decision support and health information exchanges will increase the functionality of this new technology. The potential to save costs is attractive but elusive and will require high quality confirmatory studies.
- CMS has administered Medicare Medical Home Demonstration projects to test the “medical home” and “hospital at home”

concepts. Medical groups will be paid for coordination of care, health information technology, secure e-mail and telephone consultation and remote monitoring. Details are preliminary and available on the CMS site.⁵³ Accountable Care Organizations (ACOs) may also incorporate telemedicine. For additional information on the patient-centered medical home model and ACOs see the chapter on quality improvement strategies.

- The Affordable Care Act will reduce payments to hospitals deemed to have excessive readmission rates for heart failure, acute myocardial infarction (heart attack) and pneumonia. This may help drive more monitoring and technology at home.⁵⁴

Many health IT vendors are developing home monitors and new sensors that will transmit information to a physician’s office or other healthcare organizations. Programs will be interactive and include patient education for issues such as drug compliance. This data may interface with an electronic health record, health information organization (HIO) or web site for others to evaluate. Some predict that houses (smart homes) will be wired with multiple small sensors known as “motes” that will monitor daily activities such as taking medications and leaving the house. The information would be transmitted to a central organization that would notify the patient and/or family if there was non-compliance or a worrisome trend.

Telemonitoring is actually a process with multiple steps depicted in Figure 18.3.

Figure 18.3: Telemonitoring cyclical process



Home Telemonitoring System Examples

More than 50+ companies offer technology to monitor patients at home and the list continues to grow and include large companies such as Intel and General Electric. Devices can be standalone or be integrated with another system such as an electronic health record or personal health record. Devices connect externally using USB, Bluetooth, ZigBee, telephony (POTS), WiFi and 3G/4G telecommunication networks. The list of available sensors continues to grow. Table 18.2 lists current and future home sensors that assist telemonitoring.

Health Buddy is a FDA approved device that is certified by the National Committee for Quality Assurance and used by the Veterans home telemedicine programs. Health Buddy (Bosch Healthcare) is used by over 12,000 patients and has been shown in one study (of limited design) to increase medication compliance and reduce outpatient visits.⁵⁵⁻⁵⁶ Additional studies are reported in another section. The Centers for Medicare and Medicaid Services tested the system with about 2,000 patients with chronic diseases and the results are in the section on Telemedicine Studies. Features include:

- Data is sent via phone lines
- Device comes with desktop decision support software
- Program covers 45 disease protocols
- Device connects to a glucometer, BP machine, weight scales and peak flow meter for asthmatics
- Program is interactive with patients; it asks questions daily

HoneyWell HomMed has over 15,000 monitors currently in use and more than 300,000 patients have been monitored. Features include:

- *Genesis Touch* device is based on a Samsung tablet with connectivity to their management platform via 4G or Wifi. Vital signs can be recorded and audio-video conferencing can take place. Peripheral

devices can be connected via Bluetooth for blood pressure, weigh and oximetry monitoring.

- *Genesis DM* device is designed for disease management of heart failure, diabetes and chronic obstructive lung disease (COPD)
- *LifeStream Connect* is a new option that interfaces with EHRs
- *LifeStream Analytics* analyzes data from the management suite.⁵⁷

Table 18.2 Home telemonitoring sensors

Sensor	Purpose
Weight	Disease management
Blood Pressure	Disease management
Glucose	Disease management
Oximeter	Disease management
Spirometry	Disease management
Temperature	Acute monitoring
Medication tracker	Drug compliance
PT/INR	Anticoagulant monitoring
Home security and other functions	Infrastructure monitoring
Motion detectors/chair and bed sensors	Quality of life monitoring and safety
Fitness	Quality of life monitoring

More Telemonitoring Systems

- **MyCareTeam:** a fee for service diabetic portal developed in cooperation with Georgetown University. Hypertension and weight are also monitored. The application now integrates with Allscripts EHR.⁵⁸
- **WellDoc:** a chronic disease management platform intended for sharing data from mobile devices with clinicians and nurse managers. It offers patient coaching for diabetes, cardiovascular disease, respiratory disease, oncology, mental health and wellness. In 2013, they launched BlueStar which is a special type 2 diabetic program reimburseable by insurance companies.⁵⁹
- **Voluntis:** French patient relationship management platform based on the web-based medpassport and mobile infrastructure. They specialize in asthma, heart failure and diabetes management (see info box).⁶⁰⁻⁶¹
- **Intel Health Guide:** Intel along with General Electric has entered the telehomecare market with a comprehensive program called Care Innovations. One product line, *ConnectRCM* offers wellness surveys, brain games, medication reminders, biometric data collection and messaging. Another product line, *Connect Caregiver is a beta program for caregivers* and *Connect Guide* is a chronic disease management module.⁶²
- **ViTelCare T400 (Bosch Healthcare):** this system includes a touch screen monitor that can measure and store blood pressure, blood glucose, weights and oximetry data. Includes disease specific alerts, interactive programs and patient education for heart failure, hypertension, diabetes, COPD, depression, PTSD and substance abuse. Data is transmitted over phone lines, WAN/LAN or broadband connections.⁶³

group that didn't receive the home monitoring system. The results of this project are reported in the next section.⁶⁴

Georgia Partnership for Telehealth (GPT): Georgia has 159 counties, many at the



Diabeo

Telemedicine system is part of Voluntis disease management programs and consists of smartphone software and a web portal diabetic management teams can access. Software has insulin calculators based on blood glucose, diet and activity.

Six month study (TeleDiabi 1 Study) of poorly controlled insulin dependent diabetics showed improvement in HbA1C levels using Diabeo, compared to control patients. Those patients who used the system and received feedback from the diabetic team experienced the most benefit.⁶⁰⁻⁶¹

Telemedicine Initiatives

The following section provides a sampling of some interesting telemedicine initiatives:

Informatics for Diabetes Education and Telemedicine (IDEATel): The largest government sponsored telemedicine program in the US. The project evaluated approximately 1,650 computer illiterate patients living in urban and rural New York State. Patients received a home telemedicine unit that consisted of a computer with video conferencing capability, access to a web portal for secure messaging and education and the ability to upload glucose and blood pressure data. These same subjects were assigned a case manager who was under the supervision of a diabetic specialist. They used the Veterans Affairs clinical practice guidelines on diabetes. They were compared to a control

poverty level. This network is the first statewide effort to link 36 rural hospitals and clinics with specialists at eleven large urban hospitals. Project created partnerships among Wellpoint (Blue Cross/Blue Shield) and the state

government. Importantly, telemedicine consults were reimbursed as office visits due to a new Georgia law and 20 specialties were felt to be appropriate for telemedicine. In 2012, GTP had 75,000 visits at 350 locations. The top categories for encounters were wound care and telepsychiatry.⁶⁵⁻⁶⁶

University of Texas Medical Branch at Galveston: Program is the largest telemedicine system in the world with 300 locations and 60,000 annual telemedicine sessions. Sixty per cent of visits deal with a prison population. They also offer specialty services in neurology, addiction medicine and psychiatry.⁶⁷

Teleburn at the Ottawa Telemedicine Network (OTN): A central burn center uses telemedicine to treat burn patients in this Canadian Province. Specialists can view videos or digital photos of burn patients for initial determination or follow up. They also offer a variety of other telemedicine services.⁶⁸

CampusMD: 2013 telehealth service for students on a 24/7/365 basis. Students or parents can purchase unlimited access to an MD for about \$18 monthly.⁶⁹

TelePediatrics: The University of Rochester created the Health-e-Access program in 2001. The program was initially set up to connect pediatricians to inner city child care centers and elementary schools using telemedicine and two-way video conferencing via the internet. The program has allowed the children and their parents to not leave the centers or their jobs. The program was started by grants but insurers have been willing to cover this initiative, presumably because it cuts down on emergency room visits. The director of the project has stated that he believes about 28% of pediatric visits to the emergency room in upstate New York could have been treated with telemedicine.⁷⁰

The Virtual Dental Home Demonstration Project is a California university-based dental initiative in which remote dental hygienists and dental assistants use imaging to connect patients at risk with dentists. Approximately, half are

able to be treated locally and half are referred for in-person dental visits.⁷¹

California Central Valley Teleretinal Program: Using a non-proprietary, open source web-based program (EyePACS) images can be forwarded to an ophthalmologist for interpretation. Images are stored on a SQL Server and images are viewed with a web browser. A simple software program on the PC allows for uploading images to the server. There is e-mail notification to the consultant and back to the individual who sent the images. As of 2011, they had screened 53,000 patients at a cost of \$15 per patient.⁷²⁻⁷³

Northwest Telehealth: A consortium of 4 healthcare systems created the Inland Northwest Health Services, located in Spokane, Washington. This initiative has 100 sites using advanced audio-visual technology. They offer the following services: clinical care (15 specialties), teleER, telepharmacy, distance education, administrative and operational planning/coordination.⁷⁴

Federal Communications Commission (FCC): In 2006 they announced a \$400 million budget for pilot projects to promote broadband networks in rural areas. The goal is to create networks for public healthcare organizations and non-profit clinicians that will eventually connect to a national backbone. The network could be used for telemedicine or other medical functions in rural areas. In 2007 the FCC created a \$417 million fund that would support pilot projects to connect more than 6,000 hospitals, research centers, universities and clinics. The FCC paid up to 85% of the cost to design, engineer and construct the networks. Internet2 or the LambdaRail Network will be used. Many of the projects will involve multi-state areas and most will enhance telemedicine. Much of the funding will come from the Universal Service Fund that derives from a fee added to consumers and telecommunication companies. The New England Telehealth Consortium announced in January 2008 that it will use the \$24.7 million in FCC grant money to link 555 clinics, physician offices, hospitals, public health offices and universities in Maine, Vermont and New

Hampshire. The network will act like a second internet to allow the transmission of records and x-rays and the creation of videoconferences. In early 2009, Congress directed the FCC to develop a National Broadband Plan with goal of providing broadband access to every American and funded it as part of the American Recover and Reinvestment Act (ARRA). In 2010 the FCC posted the Plan on a new web site.

In 2013, The Federal Communications Commission launched Healthcare Connect Fund that dedicates \$400 million yearly to support the broadband access nationwide, particularly in rural areas. This will support telemedicine initiatives that require substantial bandwidth. At the time of publication the following applicants are eligible: community health (and mental health) centers, migrant health centers, local health departments, post-secondary educational institutions (including academic centers and medical schools), public or not for profit hospitals and rural health clinics.⁷⁵

International Telemedicine

In many chapters international initiatives are included to demonstrate that health information technology is being embraced by both developed and developing nations. This is particularly true regarding mobile technology initiatives. Other countries are facing the same challenges with rising chronic diseases, disparities in healthcare delivery and rising healthcare costs. Cost is a clear barrier but fortunately, the cost for telemedicine interventions is falling.

As more international authors are added telehealth/telemedicine initiatives that are innovative and informative will be highlighted. More information can be gained by visiting the International Society for Telemedicine and eHealth which is linked to the World Health Organization and has 13 working groups.⁷⁶

International Case Study

United Kingdom Department of Health Whole System Demonstrator Program

This is the largest (3000 patients, 177 practices actually analyzed) cluster randomized telemedicine trial underway to study the impact of technology (secure messaging, home telemonitoring, etc.) on diabetes, coronary heart disease and chronic lung disease. The study looked at outcomes, use of services, user and professional experiences, etc. Results published in June 2011 BMJ indicate: a reduction in emergency admissions, emergency department visits, elective admissions, reduction in bed days and a reduction in mortality.

Subsequently, another study looked at the cost effectiveness of this telehealth project by analyzing the QALY (quality adjusted life years). They concluded that telehealth added expense to the overall care of patients but did not added to years lived and therefore had a low probability of being cost effective.⁷⁷⁻⁷⁹

Recommended Reading

The following are a sample of some of the more interesting and recent telemedicine articles to appear in the medical literature:

- *Assessing Telemedicine: A Systematic Review Of The Literature.* A 2001 systematic review of telemedicine by Roine et al. looked at reported patient outcomes, administrative changes or economic assessments. Of 1,124 potential articles, 50 were felt to fit criteria for review. Most of the studies reviewed pilot projects and were of low quality. They felt that teleradiology, teleneurosurgery (looking at head CT scans before transfer), telepsychiatry, the transmission of echocardiograms, the use of electronic referrals to enable e-mail consultations and video teleconferencing between primary and secondary clinicians had merit. They also felt that it was impossible to state the economic value of telemedicine based on current evidence.⁸⁰
- *Care Coordination/Home Telehealth: the Systematic Implementation of Health Informatics, Home Telehealth and Disease Management to Support the Care of Veteran Patients with Chronic Conditions.* The US Department of Veterans Affairs operates perhaps the largest telehomecare networks in the world. This is partly due to the fact that the VA has transitioned from inpatient to outpatient and home care. Also, with so many active duty members returning injured from the war zone they will eventually need telehomecare. Their Care Coordination / Home Telehealth program is also a disease management program. The VA currently runs three programs: telehomecare, teleretinal and a video teleconferencing services that link 110 hospitals and 380 clinics. Data from home devices inputs into the VA's EHR. A study of 17,000 VA home telehealth patients was reported in late 2008. Although the cost per patient averaged \$1,600, it was considerably less expensive than in-home care. They utilized individual care coordinators who each managed a panel of 100-150 general medical patients or 90 patients with mental health related issues. They promoted self-management, aided by secure messaging systems and a major goal was early detection of a problem to prevent an unnecessary visit to the clinic or emergency room. 48% were monitored for diabetes, 40% for hyper-tension, 25% for heart failure, 12% for emphysema and 1% for PTSD. Patient satisfaction was very high. This study showed a 19% reduction in hospitalizations and a 25% reduction in the average number of days hospitalized.⁸¹⁻⁸²
- *Effectiveness of Home Blood Pressure Monitoring, Web Communication, and Pharmacist Care on Hypertension Control: A Randomized Controlled Trial.* The Electronic Communications and Home Blood Pressure Monitoring study compared home blood pressure (BP) monitoring along with a BP web portal, with and without the assistance of a pharmacist. The web portal was integrated with an enterprise EHR. In the group that received assistance from the online pharmacist, they showed significantly more patients achieving control than those who were monitored and had web portal access but no interaction with a pharmacist. Results might not pertain to other diseases and requires patients to have internet access and pharmacists to be able to have EHR access.⁸³
- *Web-Based Collaborative Care for Type 2 Diabetes.* Web-based care for diabetes was evaluated by the same group (Group Health) who evaluated hypertension control in the above paragraph. They compared a group of Type 2 diabetes who received "usual care" with another group who had access to a web portal linked to an EHR. The web-based program included secure e-mail messaging with clinicians, feedback on blood sugar results, educational web resources and an interactive online diary to record diet, etc. After one year the control of diabetes, based on a glycated hemoglobin was marginally better (decrease of .7%) but there was no

difference in blood pressure or cholesterol control between the two groups. There was no correlation between improvement and the number of times the web portal was accessed. They only used one care manager so it is unknown if their results would have been different with multiple care managers.⁸⁴

- **Diabetes Quality of Care and Outpatient Utilization Associated with Electronic Patient-Provider Messaging: A Cross-Sectional Analysis.** Group Health conducted another study of 1,500+ diabetics aged >18 years old to determine if those who used secure messaging with their clinician had better blood sugar, blood pressure and cholesterol control. Only 19% of patients chose to message their physician. Those that did had better blood sugar control, but not better control of blood pressure or cholesterol but had a higher rate of outpatient visits. Patients were not randomized for this study and the study was not prospective, so results are more difficult to interpret.⁸⁵
- **IDEA TEL Studies.** The one year results of the IDEA TEL were published in late 2007 and showed mild improvement in blood sugars, cholesterol and blood pressure compared to the control project. Patient and physician satisfaction were positive but detailed cost data was lacking. Ironically, Medicare claims were higher in the study patients than in the control group, for unclear reasons.⁸⁶ The five year results were published in 2009 and although they showed some statistically significant improvement in blood sugar, cholesterol and blood pressure control, they were of doubtful clinical significance. Importantly, users of this technology had a dropout rate greater than 50%.⁸⁷ In 2010 a final report from this group concluded that “telemedicine case management was not associated with a reduction in Medicare claims.”⁸⁸
- **Telestroke Care.** Teleneurology or telestroke care was evaluated by a study by

Meyer in 2008. They compared the outcomes of patients with a possible impending stroke and consultation by telephone, versus full video teleconferencing. Correct treatment decisions were made more frequently (98% versus 82%) for the teleconferencing sessions, but patient outcomes were the same. There was no difference in death rates or hemorrhaging after the clot busting drugs (thrombolytics) were administered.⁸⁹ An excellent review article on stroke telemedicine was published by Demaerschalle et al. in the Mayo Clinic Proceedings.⁹⁰ The jury is out whether stroke telemedicine is cost effective or a reasonable choice, compared to telephonic consultation.⁹¹

- **Telephone-Delivered Collaborative Care for Treating Post-CABG Depression.** A study reported in JAMA in 2009 looked at whether telephone delivered care for post cardiac bypass depression by nurses would be equivalent to usual care. In this randomized controlled trial telephonic collaborative care was superior in terms of mental health-related quality of life, physical functioning and mood symptoms at eight-month follow up.⁹²
- **Heart Failure Telemedicine.** An international meta-analysis of 10 randomized controlled trials looked at remote patient monitoring (RPM) of heart failure patients. They concluded RPM reduced the risk for all-cause mortality and hospitalization for heart failure. The number needed to treat (discussed in evidence based medicine chapter) was 50 for all-cause mortality and 14 for heart failure hospitalization.⁹³ Another Cochrane meta-analysis also showed benefit of telemedicine⁹⁴ while a 2010 telephone monitoring study reported no benefit, thus again, no consensus.⁹⁵
- **HealthBuddy Studies.** The telemonitoring *HealthBuddy* was evaluated by CMS and another research group using claims data to evaluate the economic impact of this tool in patients with COPD, heart failure or diabetes. Importantly, only 37% of eligible

patients opted to join the program. CMS was unable to show cost savings compared to a control group whereas the research group showed small savings but did not factor in the cost of the monitoring devices.⁹⁶⁻⁹⁷

- *Effect of Telephone-Administered vs Face-to-Face Cognitive Behavioral Therapy on Adherence to Therapy and Depression Outcomes Among Primary Care Patients: a Randomized Trial.* Subjects were randomized to usual CBT or 18 sessions of telephone CBT. Fewer subjects discontinued telephone therapy (21% vs 33%). Overall treatment success was similar but face-to-face CBT was superior at six months.⁹⁸
- *Teleconcussion: An Innovative Approach to Screening, Diagnosis and Management of Mild Traumatic Brain Injury.* The Mayo Clinic presented a case study of a 15 year old boy in Arizona with a post-concussion syndrome with persistent headaches evaluated by a remote consultant.⁹⁹
- *A Randomized Controlled Trial of Telemonitoring in Older Adults with Multiple Health Issues to Prevent Hospitalizations and Emergency Department Visits.* Telemonitoring (daily biometrics, symptom reporting and videoconferencing), using Intel Health Guide was compared with usual care in elderly adults in the Mayo Clinic system over a one year period. There was no difference between the two study groups at one year. The mortality was higher in the telemonitoring group (14.7%) compared to usual care (3.9%) for unclear reasons.¹⁰⁰
- *Impact of Critical Care Telemedicine Consultations on Children in Rural Emergency Departments.* Study looked at physician-rated quality of care for children seen in emergency department of rural hospitals in California. They found that quality was higher for patients who received telemedicine consults, compared to telephone consultation or no consultation. Telemedicine was associated with more

changes in diagnostic and therapeutic approaches and patient satisfaction was high.¹⁰¹

- *Effectiveness of Telemonitoring Integrated Into Existing Clinical Services On Hospital Admissions for Exacerbation of Chronic Obstructive Pulmonary Disease: Researcher Blind, Multicentre, Randomized Controlled Trial.* This well designed study was reported in 2013, and failed to show a reduction in readmission for COPD one year after randomization or improvement in quality of life. The intervention consisted of a touch screen used for symptom and treatment queries and oxygen saturation measurements.¹⁰²

Barriers to Telemedicine

The barriers to telemedicine are similar to the barriers to all health information technology covered in other chapters. The most significant barriers are as follows:

- *Limited reimbursement.* Most telemedicine networks are created with federal grants. Medicare will reimburse if there is a formal consultation linked by live two-way video conferencing and the patient resides in a professional shortage area. Medicare will reimburse physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, clinical psychologists and clinical social workers. The originating sites can be offices, hospitals, skilled nursing homes, rural health clinics and community mental health centers. Medicare reimburse for telemedicine services for initial inpatient care, outpatient care, pharmacologic management, end stage renal disease-related visit and psychiatric diagnostic interviews. Clinicians at the remote site submit claims using the correct CPT or HCPCS codes as well as the telemedicine modifier GT Patients pay 20% of the approved Medicare-approved amount. Interactive audio-video systems must be used and store and forward technology is

permitted only in demonstration projects in Alaska and Hawaii.¹⁰³ In 2013 Medicare allowed 21 outpatient and inpatient CPT/HCPCS codes for Telemedicine.¹⁰⁴ States have the ability to cover Medicaid telemedicine care but must comply with state and federal guidelines.¹⁰⁵ There is some flexibility in the federal law, such that participating states may reimburse both the referring physician and consultant as well as some aspects of the technology platform. A 2011 survey found that 45 states have some form of Medicaid reimbursement for telehealth.¹⁰⁶ Many private insurers don't cover telemedicine, but a few provide the same coverage as face-to-face visits. As of mid-2013, nineteen states mandate that private insurers reimburse for telemedicine services as they do for in-person services.³

- **Limited research showing reasonable benefit and return on investment.** A systematic review of telehealth economics concluded that standard economic evaluation methods were not used therefore the results were not generalizable.¹⁰⁷ A review of 80 systematic reviews of telehealth effectiveness reported 21 were positive, 18 found the evidence promising but limited and 41 reported the evidence is limited and inconsistent.¹⁰⁸ In summary, the studies on telemedicine are mixed and are of low quality. Most studies are based on a small patient population as large randomized controlled trials are expensive. Therefore results can't be generalized to every population. Similarly, many studies are not conducted over a long period of time so attrition rates might not be accurately reported. Moreover, there are many flavors of technology (telephone, smartphone, internet, interactive device, etc.) used in telemedicine making comparisons more difficult. It does seem like the addition of a skilled healthcare worker, such as a nurse or pharmacist, is necessary to experience benefits from a telemedicine program. Healthcare organizations that have excellent

health IT support as well as disease management teams are the most likely to benefit from telemedicine. In this early stage of telemedicine, the technology by itself does not seem to produce significant benefit.

- **High cost** or the limited availability of high speed telecommunications.
- **Bandwidth issues**, particularly in rural areas where telemedicine is most needed. VPN connections slow the process further.
- **High resolution images** or video require significant bandwidth, particularly if x-rays or images or pills have to be read by remote clinician. Telepsychiatry may require lower resolution. The following are average file sizes (megabytes): Xray 10 MB, MRI 45 MB, Mammogram 160 MB and 64 slice CT 3,000 MB.¹⁰⁹
- **State licensure laws** when telemedicine crosses state borders. Some states require participating physicians to have the same state license. In 2011 CMS loosened the requirements for telehealth. The new rule will allow hospitals receiving telehealth services to be privileged and credentialed from the hospital providing telehealth services.¹¹⁰
- **Lack of standards**
- **Lack of evaluation by a certifying organization.**
- **Fear of malpractice** as a result of telemedicine. Who is going to evaluate telemonitoring data 24/7?
- **Ethical and legal challenges.** Kluge reviews the challenges faced international with telemedicine.¹¹¹
- **Sustainability** is a concern due to an inadequate long term business
- **Lack of sophistication** on the part of the patient, particularly in the elderly and under-educated.

UVA Center for Telehealth



The University of Virginia created this network in 1994 to provide care for rural underserved patients. This network already has more than 40 subspecialists in 85 locations in Virginia. They will now host the new Mid-Atlantic Telehealth Resource Center that will support Delaware, Kentucky, Maryland, North Carolina, the District of Columbia and West Virginia. They are one of 12 Telehealth Resource Centers in the US.¹¹²

Telemedicine Organizations and Resources

Organizations

- Office for the Advancement of Telehealth (OAT): falls under Health Resources and Services Administration (HRSA) that is an agency of the Department of Health and Human Services. Its goal is to promote telemedicine in rural/underserved populations, provide grants, technical assistance and “best practices.”¹
- Regional Telehealth Resource Centers: The United States now has 14 telehealth resource centers created to set up a national telehealth network.¹¹³
- American Telemedicine Association (ATA): a non-profit international organization with paid membership that began in 1993. Individual state telemedicine policies are included on their web site. ATA has created a set of telemedicine standards and guidelines covering telemental health, diabetic retinopathy, teleradiology, tele-dermatology, telerehabilitation, telemedicine operations and telepathology. Goals of the ATA are as follows:
 - “Educating government about telemedicine as an essential component in the delivery of modern medical care
 - Serving as a clearinghouse for telemedicine information and services
 - Fostering networking and collaboration among interests in medicine and technology
 - Promoting research and education including the sponsorship of scientific educational meetings and the Telemedicine and e-Health Journal
 - Spearheading the development of appropriate clinical and industry policies and standards”³
- USDA Rural Development Telecommunications Program: The USDA has a program to finance the rural telecommunications infrastructure. In 2007 there were grants and loans totaling \$128 million to achieve the goals of broadband access for distant learning and remote medical care. The USDA Rural Development agency has funded several e-ICU programs in the US, including the study by Avera Health noted in an above section.¹¹⁴
- The Agency for Healthcare Research and Quality (AHRQ): AHRQ has funded a number of telemedicine projects looking at virtual ICUs, telewound projects, cancer management, medication management, heart failure management and others.¹¹⁵

Resources

- Sarashon-Kahn J. *The Connected Patient*. The California Health Care Foundation. February 2011 www.chcf.org
- Lykke F, Holzworth M, Rosager M et al. Telemedicine: An Essential Technology for Reformed Healthcare. www.csc.com

- For an international perspective: International Society for Telemedicine & eHealth <http://www.isfteh.org/>

Future Trends

Telemedicine is a relatively new field created because of the misdistribution of physicians, the need for remote delivery of medical care and the emergence of nascent technologies. Televisits will likely increase if found to be helpful to patients and clinicians for minor illnesses, even if reimbursement lags. Teleconsultation is on the rise worldwide to address access problems for populations at risk: rural, poor, incarcerated,

elderly and those with multiple chronic diseases. Telemonitoring is complex because it traditionally required sophisticated and expensive technology as well as skilled human intervention to deliver virtual ICU care or home telemedicine. With cell phone cameras, web cams and simple programs such as Skype™ the technology is maturing and more affordable. It is unknown whether newer healthcare delivery models such as accountable care organizations to increase access to expert care, while saving money.

Key Points

- Telehealth is a neologism that relates to long distance clinical care, education and administration
- Telemedicine refers to the remote delivery of medical care using technology
- Almost all specialties now have telemedicine initiatives
- In spite of the lack of reimbursement, virtual ICUs have gained in popularity because they have perceived benefits
- Telehomecare is a new telehealth initiative that has appeared due to the graying of the US population and the increase in chronic diseases
- Lack of uniform reimbursement, lack of standards and lack of high quality outcome studies have impacted the adoption of telemedicine

Conclusion

Telemedicine is still in its infancy in the United States and in most areas of the world. New organizations such as the Middle East Society of Telemedicine (MESOTEL) have emerged to cover the Middle East and North Africa.¹¹⁶ The barriers are largely financial due to the high cost to set up the system and the lack of reimbursement in many cases. With the price of telemedicine systems dropping, telemedicine for rural patients is likely more cost-effective than referral to distant urban specialists. If the FCC and ARRA initiatives are successful and/or HIOs flourish, healthcare may have the infrastructure required for telemedicine throughout the United States. Transmission and storage of large images and the ability to compare old and new imaging studies will be greatly aided by Internet2, LambdaRail and

modern web PACS. If future studies prove there is substantial return on investment then it is a matter of time before more payers support telemedicine. At this time, successful telemedicine programs require an engaged patient and physician, a supportive infrastructure, disease managers and payer reimbursement.

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Chapter 19

Medical Imaging Informatics

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JOHN D. GRIZZARD

Learning Objectives

After reading this chapter the reader should be able to:

- Describe the history behind digital radiology and the creation of picture archiving and communication systems (PACS)
- Enumerate the benefits of digital radiology to clinicians, patients and hospitals
- List the challenges facing the adoption of picture archiving and communication systems
- Describe the difference between computed and digital radiology
- Outline the field of medical imaging informatics
- Understand new imaging technologies such as web PACS and mobile imaging viewer

Introduction

The field of medical imaging informatics has been slowly evolving over the past three decades and is a subspecialty under biomedical informatics. However, others consider imaging informatics as a subspecialty under Radiology. As an information science, it studies every facet of imaging; acquisition, storage, interpretation and sharing to improve patient care. The field tends to include radiologists and scientists involved with medical physics. Imaging informaticians must understand how imaging data moves throughout the medical enterprise and how it interacts with electronic health records, voice recognition dictation systems, computer-aided diagnosis software, health information organizations, etc. Specialists in this field must also have a good understanding

of workflow, networks, security, data quality, hardware and software similar to the skill set needed for electronic health records. The supporting group for the field is the Society for Imaging Informatics in Medicine or SIIM.¹ More information about the history of medical imaging informatics is presented in detail by Branstetter.² While Teleradiology could be discussed in this chapter it has been included in the chapter on Telemedicine.

This chapter will discuss the field of medical imaging informatics and the various technologies such as Picture Archiving and Communication Systems (PACS) that have revolutionized the field of Radiology.

Definitions

Medical Imaging Informatics: According to the Society for Imaging Informatics in Medicine (SIIM) “is the study and application of processes of information and communications technology for the acquisition, manipulation, analysis and distribution of medical image data.”¹

Picture Archiving and Communication Systems (PACS): is a medical imaging technology which provides economical storage of, and convenient access to, images from multiple modalities.²⁻³

History

Digital imaging appeared in the early 1970’s by pioneers such as Dr. Sol Nudelman and Dr. Paul Capp. The first reference to PACS occurred in 1979 when Dr. Lemke in Berlin published an article describing the functional concept. In 1983, a team led by Dr. Steven Horii at the University of Pennsylvania began working on the data standard Digital Imaging and Communications in Medicine (DICOM) (see chapter on data standards) that would facilitate image sharing. The US Army Medical Research and Materiel Command installed the first large scale PACS in the US in 1992.⁴ The University of Maryland hospital system was the first to go “filmless” in 1999.⁵

Transitioning to PACS

Medical imaging has progressed along a pathway very similar to conventional photography in that there has been a gradual shift from analog images printed on film to digital images captured on electronic media. This transformation has occurred slowly over time, and has been made possible by variety of technical innovations. The initial impetus for this change came about as the result of the development of digital imaging technologies; specifically computed tomography, ultrasound, and magnetic resonance imaging in the 1970’s and 80’s. These modalities resulted in digital images that were displayed on monitors at dedicated workstations attached to the source devices. Images could be printed onto film, but

the underlying technology was that of digital image acquisitions.

It quickly became apparent that reviewing images at a computer monitor in this “softcopy” format had significant advantages over the prevailing film-based technology in use at the time. Specifically, images could be viewed without delay as soon as they were prepared by the scanner, without the need for film processing. In addition, if the scanner manufacturer supplied an additional workstation, images could be viewed at a remote location in the radiology department as soon as they were available. Developing costs, and the time required for image development would vanish, and storage of films would become greatly simplified. In addition, image retrieval would also be greatly facilitated. (It used to be said that if a radiologist had been a bad person during life and was sent to hell, he would spend eternity looking through film jackets for old studies).

The transition to a completely filmless radiology department was impeded by the extensive initial costs that were involved. Although, in general, films would no longer be printed, printing would remain part of the process as referring physicians would often request a copy of the studies. Therefore, it was difficult to go completely filmless, and so a small fraction of residual printing costs would remain.

Conventional radiographs were initially obtained in the usual fashion and then placed through film scanners in order to make digital viewing of the images possible. Eventually computed radiography and digital radiographs became available, but meant that many conventional radiology rooms would have to be significantly upgraded. Computer-based image archiving would also be necessary, requiring significant expense. Lastly, in order to link the various imaging technologies with the image archive, a comprehensive and fast network would need to be built. Although going filmless had the advantages of decreasing printing costs and increasing speed, these initial capital outlays were formidable. However, over time, the advantages of digital filming became sufficiently

attractive, and the extensive upfront capital costs of doing away with film and moving to completely digital imaging diminished as computer hardware and network technology rapidly evolved, and PACS systems gradually started to become economically viable.

An additional obstacle to the widespread adoption of PACS technology was that initially the scanner vendors had proprietary imaging formats. That is, a CT scan performed on one manufacturer's equipment could not be viewed using another manufacturer's imaging workstation. Over time, it became apparent that a uniform imaging and communications strategy was required. The DICOM (DICOM = Digital Imaging and Communications in Medicine) standard was developed in order to facilitate image sharing and transmission, and this development greatly facilitated the adoption of PACS.

DICOM was developed by the National Electrical Manufacturers Association, along with the American College of Radiology, and provided a mechanism for the accurate handling, storing, printing, and transmitting of digital image information for medical images. The standard enables the integration of imaging equipment, image archiving storage systems, imaging workstations, printers, and network hardware from a variety of different manufacturers to be combined into a picture archiving and communication system. In other words, instead of each manufacturer and piece of equipment speaking a different and unique language, all the manufacturers and equipment makers were now speaking the same language. Initial iterations of the DICOM standard were developed beginning in the mid-and late 1980's, but in 1993 the DICOM 3.0 standard was released, and was found to be very robust, and widespread adoption soon followed.⁶ Further information about DICOM can be found in the chapter on data standards.

Most hospitals and radiology groups have made the transition from analog to digital radiography. To their credit, radiologists have pushed for this change for years but have had to wait for better technology and financial support

from their healthcare organizations. Early pioneers understood that a digital system would mean no more bulky film jackets, frequently lost films and slow retrieval. The technology is now mature and widely accepted but cost is still an issue at smaller healthcare organizations. Initially, hospitals purchased film digitizers so routine x-rays could be converted to the digital format and this was followed by scanning the digital image directly into the PACS.

Importantly, with the increasing use of electronic health records (EHRs), there is a need to integrate PACS with EHRs, hospital information systems (HISs) and radiology information systems (RISs). The Veterans Health Administration launched a nationwide teleradiology network in 2007 to provide radiology coverage to all of its region and the PACS interfaces with its EHR (Vista).⁷

One of the future challenges of teleradiology will be to share PACS images among disparate healthcare organizations.⁸ SuperPACS is a new concept that would allow a radiology group that serves multiple sites with different PACS, radiology information systems (RISs) and hospital information systems (HISs) to view the sites as a single entity.⁹ PACS was initially associated with expensive work stations (\$50,000) using thick-client technology. Now the trend is for thin or smart clients that permit clinicians to access PACS via a web browser from the office or home.¹⁰ Health Information Organizations (see chapter on health information exchange) are beginning to link to web-based PACSs (also known as Medical Imaging Cloud) so images from different organizations can be viewed and shared.

PACS is made possible by faster processors, higher capacity disk drives, higher resolution monitors, more robust hospital information systems, better servers and faster network speeds. PACS is also frequently integrated with voice recognition systems to expedite report turnaround. PACS usually has a central server that serves as the image repository and multiple client computers linked with a local or wide area network. Images are stored using the DICOM data standard. Input into PACS can also occur

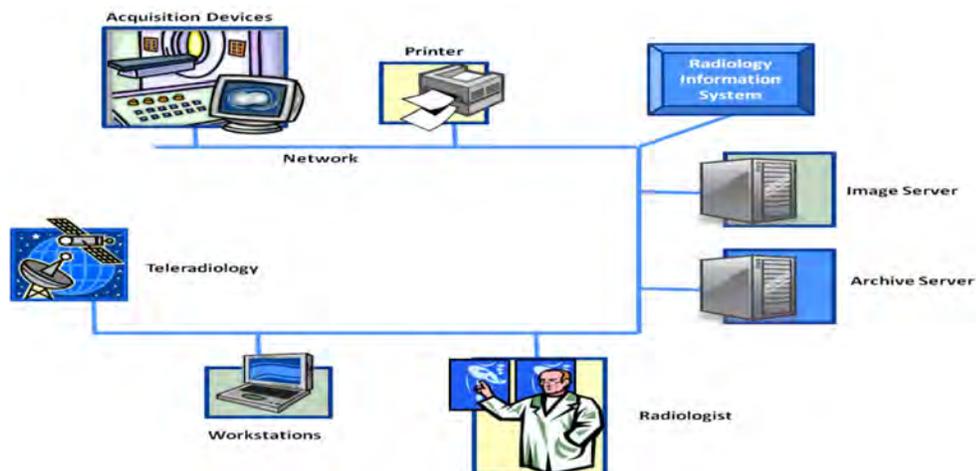
from a DICOM compliant CD or DVD brought from another facility or teleradiology site via satellite. Most diagnostic monitors are still grayscale as the majority of the imaging modalities render their images in grayscale, and grayscale monitors are relatively less expensive compared to color. Newer “medical monitors” have 2,048 x 2,560 pixel resolution and can display 1,000+ shades of grey instead of the 256 shades of grey seen on a standard desktop monitor. A historical perspective of the development of PACS in the United States is chronicled in this reference.¹¹

It is important to point out that many facilities with digital systems or PACS still print hard copies or have some non-digital services. This could be due to physician resistance, lack of resources or the fact that it has taken longer for certain imaging services such as mammography to go digital. *Full PACS* means that images are processed from ultrasonography (US), magnetic resonance imaging (MRI), positron emission tomography (PET), computed tomography (CT), routine radiography and endoscopy. *Mini-PACS*, on the other hand, is more limited and processes images from only one or two modalities.¹² As an example, cardiologists will often adopt a mini-PACS, and will use it to display only echocardiography and cardiac catheterization images.

PACS Key Components

- **Digital acquisition devices:** the devices that are the sources of the images. Digital angiography, fluoroscopy and mammography are the newcomers to PACS. CT, MRI and ultrasound scanners have always been inherently digital
- **The Network:** ties the PACS components together—that is, it is the pathway for image transmission from the scanners to the image archive, and from there to the radiologist at a reading station.
- **Database server:** high speed and robust central computer to process information. This answers the request of the reading radiologist to provide the images to him at his workstation.
- **Archival server:** responsible for storing images. A server enables short term (fast retrieval) and long term (slower retrieval) storage. HIPAA requires separate back up, usually off-site to prevent data loss in a disaster situation
- **Radiology Information system (RIS):** system that maintains patient demographics, scheduling, billing information and interpretations
- **Workstation or soft copy display:** contains the software and hardware to access the PACS. Replaces the standard light box or view box. This is where the radiologist reviews the imaging study and dictates his diagnostic report.
- **Teleradiology:** the ability to remotely view images at a location distant from the site of origin removed¹³

Figure 19.1: PACS Key Components



Types of Digital Detectors

- Computed radiography (CR): after x-ray exposure to a special cassette, a laser reader scans the image and converts it to a digital image. The image is erased on the cassette so it can be used repeatedly. (Figure 19.2)
- Digital radiography (DR): does not require an intermediate step of laser scanning.¹³

identified in the HIS and an order created that is sent to the RIS via an HL7 protocol (HL7 and its members provide a framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information). Orders will go to the imaging device via the DICOM protocol and the image is created in DICOM format and sent to the PACS server. Images are stored on the image archive, and the reading physician (radiologist) is notified of a pending study. The study is then read by the radiologist at a computer workstation using high-resolution monitors and viewing software available from a variety of different vendors. (see Figure 19.3 of typical PACS screen)

Typical PACS Workflow

As already noted, a PACS should interface with both the HIS and RIS. Typically, the patient is

Figure 19.2: Computed Radiography

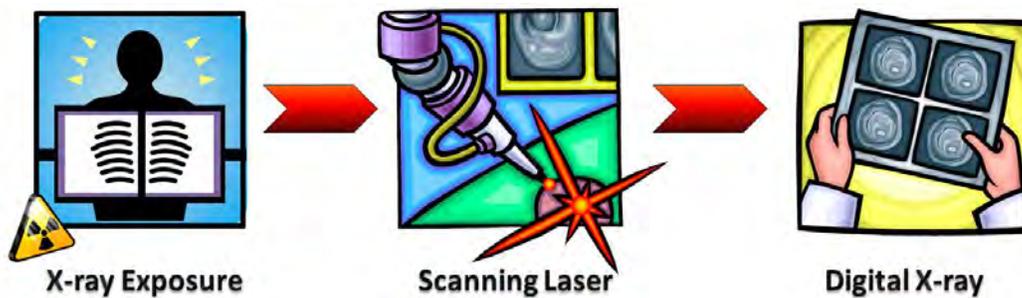
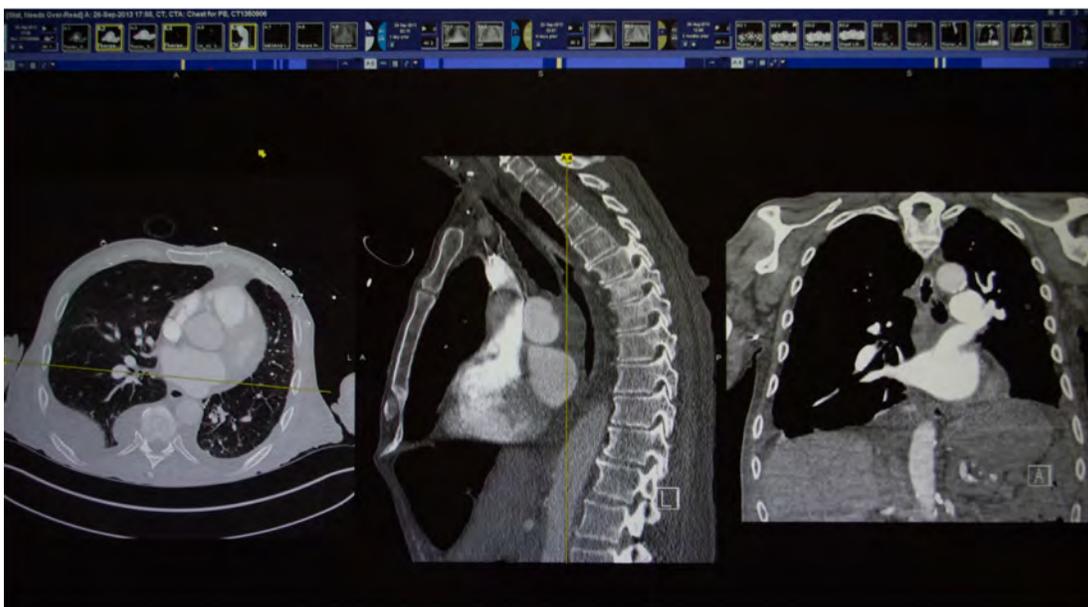


Figure 19.3: PACS Screen (Courtesy Dr. J. Grizzard)



Viewing software typically allows comparison of the present examination with any prior imaging studies so that interval changes can be detected. In this instance, it is remarkably easy for the radiologist to directly compare the present examination with multiple prior examinations, as these are easily sorted using the computer software provided by the workstation vendor. Therefore, comparison can be made to multiple prior studies without having to endlessly search through a film jacket to find the studies. These studies can be viewed side-by-side, or above and below one another, depending on the radiologist's preference. In addition, the PACS workstations allow linking of the studies such that image locations that are similar on two different studies performed at two different times can be reviewed in unison. These workstations allow manipulation of the brightness and contrast of the images, and also facilitate measurement of the densities of objects seen in the images in order to detect such things as fluid or calcification. The images can be magnified, and zoomed up for better evaluation of small and fine structures. Many workstations allow visualization of the image data set with multi-planar reformations. These allow one to view the images simultaneously from the front, from the side, and in the axial or standard imaging plane, and to cross register at the views with one another.

At the completion of the physician's detailed review of the images, a diagnostic report is generated by the radiologist, often using voice recognition software. The dictation is then reviewed, and any corrections made if necessary. The report is then stored on the PACS server linked to the images, and is also sent back to the HIS via an HL7 message so it can be viewed as part of the medical record.

Web Based Image Distribution

Diagnostic imaging plays a significant role in the medical care a patient receives. Reliance on paper-based patient records across geographic and institutional borders can decrease the ability

for care providers to have immediate access to the patient's entire medical record and imaging history without the implementation of a health information exchange system. Similarly, having patient images present only within a single health care system limits what would otherwise be a potentially widely available resource. Additionally, both patients and referring physicians increasingly request the widespread distribution of images, which can reduce the need for duplicate studies, and allow more rapid diagnosis and treatment. The most readily available means for rapidly and widely disseminating medical imaging is via the internet, using the World Wide Web. Erin Chesson states that "the power and reach of the web is empowering the health imaging world – completing the loop from radiology to specialist and back to the referring physician and even the patient." Furthermore, the benefits of web-based technology provide on-demand, online access to electronic images regardless of the location of patient records, reports and images.¹⁴

Unfortunately, the DICOM imaging format that has enabled the development of PACS and the interoperability of imaging resources from different vendors has served as something of an impediment to the use of the World Wide Web for image distribution. Specifically, DICOM images are not browser compatible -- that is to say, DICOM images cannot be viewed using a standard internet browser, as can JPEG, GIF, PNG and other file formats. One solution to this problem is for the browser to serve as a link to a server which can open and display the images, and then stream them to the viewer. In this instance, client software must be present on the viewing computer to allow this functionality. In many respects, most of the PACS vendors have developed these products to "Web-enable" their PACS, and provide remote viewing. Usually this entails downloading a small application (thin client) from the PACS vendor that enables the remote viewing station to act like a modified PACS workstation. Changes in browser technology will frequently necessitate updating of this client software mini application.

An alternative type of system enables direct viewing in the browser without client software, enabling its use on any computer with internet functionality. This type of solution is known as a "zero-footprint" Web viewer. As stated previously, DICOM is not intrinsically viewable within an Internet browser. Therefore, for a browser to render the images, they must first be converted to an imaging format that is compatible and can be opened by a conventional browser. Heart Information Technologies WebPAX viewer is one such imaging system, and is a true zero-footprint web-based PACS. In this system, DICOM images are pre-converted to GIF files (which are browser compatible), which are then embedded in a webpage. To provide readers with more details regarding Web based PACS more information is available on the heartit.com web site.¹⁵

Although both systems confer a tremendous advantage in terms of more widely distributing medical images, the zero-footprint viewer has the additional advantage of not requiring additional software, and without requiring

periodic updates as browser technologies change. In addition, no maintenance is required on the computer involved, as no client software has been downloaded or requires maintenance.

Regardless of the solution used, web-enabled or Web-compatible PACS operates through the web environment, much like the ASP model electronic health record, discussed in the second chapter. Table 19.1 compares the legacy PACS with web-based PACS. According to PACS marketing manager, Al Dryer of Agfa Healthcare, web-based PACS "is an application that uses different web technologies in a very open manner, regardless if the user is on a PC or Mac, using Linux or Windows for the operating system."¹⁶ Web based PACS is facilitated by remote server rendering or processing of the images in 2D, 3D and 4D. This requires robust bandwidth but perhaps the end user to use a thin client or "dumb terminal" or "virtual desktops" which reduces costs, is more secure, more reliable and is available from any location with Internet connectivity.¹⁷

Table 19.1: Legacy PACS compared to web PACS¹⁷

Legacy PACS	Web PACS
Only available on computers with proper software installed	Available anywhere with internet access
Upgrades must be manually installed	Upgrades are done centrally or are not necessary
Multiple user interfaces	One user interface
Difficult to integrate with health information exchanges	Easy to integrate with health information exchanges
Difficult to link to multiple EHRs	Easier to link to EHRs
Labor intensive for PACS administrator for maintenance and training	Much less labor intensive for maintenance and training
Could involve multiple operating systems	One operating system
Less likely to be standards-based	Utilizes JPEG compression, DICOM, HL7 and IHE profiles

Its goal is to offer seamless availability to radiologists, referring physicians, clinicians and nursing staff wherever they need images, i.e. at their office facilities, in the electronic health record, at their homes or wherever there is access to a remote, secure computer. To the patient it means that their physician has access to all of the medical information required to make informed decisions regarding their medical care: recent and previous images and reports, lab results, medication history, and other pertinent information.¹⁷

For example, a patient with a fractured lumbar spine can enter the emergency department at a medical facility located 90 miles away from Spokane, WA. The Emergency department (ED) physician there may be undecided about transporting the patient via helicopter to Spokane for neurosurgery, says Jon Copeland, CIO of Inland Imaging. The availability of web PACS affords medical personnel the technology to contact Spokane and request the physicians

there to view the patient's images. At the same time, the ED physician can contact a neurosurgeon at his home, who can log in from a home system using the web viewer to analyze the patient's back images for his recommendations. "Without shared, single image environment, this would not be possible," says Copeland.¹⁴ For a real-world story about web-based PACS, see case study in the Infobox.

Other medical facilities such as Frederick Memorial Hospital and Peninsula Regional Hospital in Maryland are moving forward in planning for a health information exchange network. Marylanders will finally have the ability to retrieve their medical data regarding health care not just locally but regionally as well. Frederick Memorial also offers about 165 physicians a cost-effective means to log into its system for information exchange. There is also a physician portal available to physicians to view lab and PACS.¹⁸

Case Study: Cardiac PACS

"I was at a meeting in San Francisco, California and was contacted by the MRI technologists at my hospital regarding a complicated cardiac MR case," John Grizzard, Associate Professor of Radiology at Virginia Commonwealth University (VCU), recalls. "The physician covering the service wanted to consult with me regarding a case where there appeared to be a mass in the heart." Dr. Grizzard, who is also section chief of non-invasive cardiovascular imaging at the VCU Medical Center, was able to open a browser on his notebook computer, and log on to his department's WebPAX server. In seconds the entire cardiac MRI study opened up on his screen in the browser — over 800 cinematic motion images of the heart, moving at the patient's actual heart rate. "I was able to confirm the suspected diagnosis of a cardiac tumor, and did so from three time zones away, using a pretty vanilla laptop computer and a standard web browser. I didn't need any special client software; I used just a regular off the shelf browser, and it worked. The beauty and the difficulty inherent in cardiac imaging is that you need to see the heart move. And you must see it moving in real time — or in a rhythm that approximates the patient's heart rate. Using Webpax, I was able to do this." Subsequent surgery confirmed the diagnosis of a cardiac mass, so the story does not have an entirely happy ending, but the ability to remotely view minutes-old motion studies of a patient's heart thousands of miles away demonstrates the power of WebPAX, a true zero-footprint web-based PACS that can display DICOM images using any standard internet browser.¹⁹

The Consolidated Imaging Initiative (CI-PACS) in southern Maine, developed by MaineHealth and the Maine Medical Center, implemented a regional health information exchange system for radiology for rural hospitals. The system offers a shared, standards-based, interoperable PACS in two hospitals, Franklin Memorial Hospital and Miles Memorial Hospital. The last phase, web access rollout, provided for digital images to be web-based accessible, soft copy review, to the additional clinical areas. The system also provided access to remote sites and physicians' offices using the link into the hospital's CI-PACS connection.²⁰

The Ochsner Health System in New Orleans integrates seven hospitals and 35 clinics. The hospital system had already implemented a widespread electronic clinical documentation process, "and had evolved its EMR platform forward" explains Dr. Lynn Witherspoon, CIO of the Ochsner Health System. The next goal was to use PACS in order to allow referring and ordering physicians access to patient images. According to Dr. Witherspoon, integrating all patient information for electronic accessibility to physicians is where PACS came in. He said, "PACS allowed us to put a web portal in the EMR. So now they'll open a folder on a patient record in the EMR, and they can open the PACS – PACS-EMR integration."²¹

PACS and Mobile Technology

Until recently, the U.S. Food and Drug Administration (FDA) had prohibited physicians from using radiology images displayed on mobile devices to make an official diagnoses. In February 2011, the FDA approved the first primary diagnostic radiology application for mobile devices. Performance evaluation reviewed by the FDA consisted of tests for measured luminance, image quality (resolution), and noise referenced by international standards and guidelines. This new mobile radiology application will provide physicians access to

view medical images on the Apple iPhone, iPad, and iPod. Keith Dreyer, D.O., Ph.D., vice-chair of radiology for informatics at Massachusetts General Hospital and serves as an associate professor of radiology at Harvard Medical School, stated in the May, 2011, RSNA publication news, "I see these devices being a mainstay for radiologists on call away from a clinical workstation." He further states, "The devices may currently be too limited in functionality and screen size to provide adequate throughput for a heavy case load, but for answering an immediate question, they will be quite adequate for many examination types."

This new mobile application is named the Mobile MIM and includes a VueMe version for patients. While the viewers are free, there is a charge for storing and viewing images on the company's servers. The FDA emphasized that this application should only be utilized when there isn't access to a PACS workstation to view images and to make medical diagnosis of CT, MRI imaging and PET examinations.²²⁻²³

Evidence is building in favor of mobile device usage in medicine. These systems have a high potential to improve efficiency and communication in medical imaging. Polomar Pomerado Health (PPH) in San Diego began a mobility initiative in July 2011 with Cisco Cius tablets. These tablets are internally built platforms named "MIAA (Medical Information Anytime Anywhere)." According to Orlando Portale, chief innovation officer at PPH, this mobile medical device makes available electronic health information to incorporate radiology reports and images.

Another example of mobile use is at John Hopkins' department of radiology and radiological sciences. The radiology department is providing iPads for all residents. Carl Miller, MD, chief resident, states "We think [the iPad] has tremendous potential to transform clinical education in radiology." Furthermore, according to Paul Nagy, PhD, visiting associate professor at John Hopkins University radiology department in Baltimore, "we've seen PACS vendors respond, migrating their platforms onto the iPad."²⁴

Image Resolution

The adoption of mobile imaging technology has thus far been somewhat limited because of concerns regarding inadequate imaging resolution. Randall Stenoien, President, Innovative Radiology, PA, and CEO of Houston Medical Imaging, LLC, says “As radiologists, we adhere to FDA or American College of Radiology (ACR) criteria in terms of the resolution of the studies and the quality of the monitors. We have to test our monitors where we are going to read cases.” Dr. Stenoien is optimistic regarding the direction towards making diagnosis on mobile devices. He continues “The mobile app is a web-based interface using PACS, which is going to be browser agnostic - whether you’re using Firefox, Safari, or Internet Explorer. That, for me, is going to make a huge difference in my practice for referring docs. Using an iPad, the referring doctor can log-in to see their patients’ images without having to push the images at all.”²⁵

According to Elliot K. Fishman, MD, FACR, John Hopkins University Department of Radiology, Baltimore, MD, mobile devices do have drawbacks. The screens are smaller compared to workstation monitors, and presently users are not able to dictate reports or view comparison films side by side. On the up side, there are features on the iPad and iPhone that place these devices on the same level, or above, the vigorous PACS. Lawrence White, Senior Marketing Manager for GE Healthcare Imaging Solutions-PACS Mobility, confirms that the technology is available. The biggest adjustment is in the user experience. According to White, the experience from the standpoint of navigating an iPad or Android or Tablet is going to be similar, thus the reason GE has developed an application on a “native graphic user interface rather than trying to port it on an existing application.” The most recent “iteration of the iPad screen supports a 9.7-inch (diagonal) LED-backlit glossy widescreen at 1024 x 768-pixel resolution at 132 pixels per inch (ppi). Although the iPhone 4’s screen spans just 3.5-in diagonally, at 960 x 640-pixel resolution at 326 ppi, it is equipped with the latest Apple Retina display for sharper images, videos, and text.”

Google’s Android operating system allows the radiologist to select screen size and resolution that is compatible with his/her interpretation needs and/or user preference.²⁵

Dr. Stenoien concludes, “The trend in radiology and in medicine in general is to have the radiologist available all the time. If we have an FDA-cleared way of providing some of these services, it is really going to make us a lot more mobile.”²⁵

ResolutionMD Mobile

In September 2011, Calgary Scientific received FDA approval to market ResolutionMD Mobile as a medical imaging diagnostic application. The new mobile device supports several mobile devices and operating systems. Calgary Scientific’s conducted multiple hands-on trials, performed using patient data that evaluated reading performance among mobile devices and standard PACS workstations, results showed equivalent diagnostic performance. On the primary diagnosis, the radiologists unanimously concluded that in office lighting conditions, there was no change in switching from the mobile device in dim lighting to the PACS workstation.

ResolutionMD mobile’s server-based software application allows physicians immediate access to the display, reports, and analysis of patient images such as CT and MR, stored within any healthcare facility, and to submit a clinical diagnosis via their medical devices. Images are not permanently stored on the mobile devices. ResolutionMD mobile performs on 3/4G wireless, and “ensures that no highly sensitive or confidential patient information is retained on the mobile device.”²⁶⁻²⁸

OsiriX Mobile DICOM Viewer

OsiriX is a free DICOM PACS open source viewer for the MAC operating system. OsiriX 64 Bit is newer faster fee-based option. OsiriXMD is fee based and FDA cleared as a Class II device. OsiriX HD is an Apple App for the iPhone and iPad available for \$29.99.²⁹

PACS for a Hospital Desktop Computer

The AGFA IMPAX 6.3 PACS is an example of a client-server based system used by the US Navy.³⁰ The PACS receives HL7 messages from the hospital information system (HIS) and provides diagnostic reports and other clinical notes along with the patient's images. Although resolution is slightly better with special monitors, the quality of the images on the standard desktop monitor is very acceptable for non-diagnostic viewing (see Figure 19.4). Any physician on the network can rapidly retrieve and view standard radiographs, CT scans and ultrasounds. The desktop program is intuitive with the following features:

- Zoom-in feature for close-up detail
- Ability to rotate images in any direction
- Text button to see the report
- Mark-up tool that does the following to the image:
 - Adds text
 - Has a caliper to measure the size of an object
 - Has a caliper to measure the ratio of objects: such as the heart width compared to the thorax width
 - Measures the angle: angle of a fracture

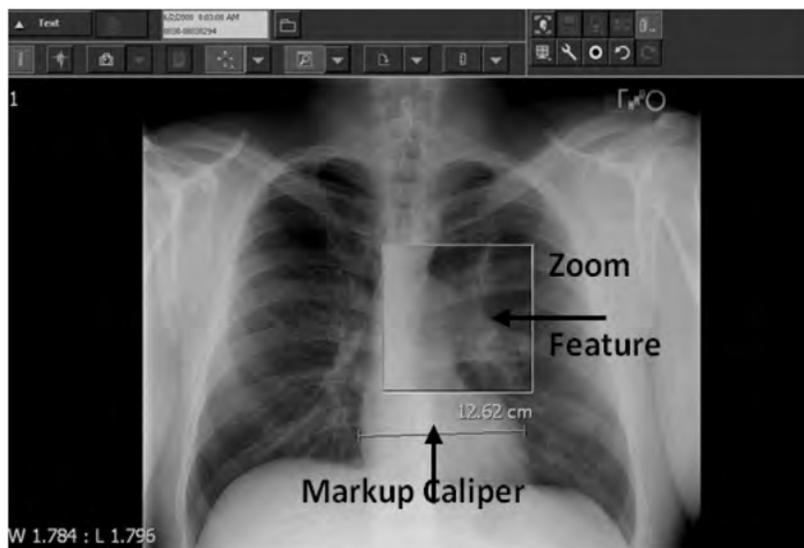
- Measures the square area of a mass or region
- Adds an arrow
- Right click on the image and short cut tools appear
- Export an image to any of the following destinations:
 - Teaching file
 - CD-ROM
 - Hard drive, USB drive or save on clipboard
 - Create an AVI movie

The following are two scenarios that point out how practical PACS can be for the average primary care physician:

Scenario #1: An elderly man is seen in the emergency room at the medical center over the weekend for congestive heart failure and is now in your office on a Monday morning requesting follow up. The practice is part of the Wonderful Medicine Health Organization, so the physician pulls up his chest x-ray on the office PC.

Scenario #2: A physician is seeing a patient visiting the area with a cough and on his chest x-ray a mass in his left lung is noted. The image is downloaded on a CD (or USB drive) for the patient to take to his distant PCM where he will receive a further work up.

Figure 19.4: Chest X-ray viewed in PACS



PACS Advantages and Disadvantages

PACS Advantages

- Replaces a standard x-ray film archive which means a much smaller x-ray storage space; space can be converted into revenue generating services and it reduces the need for file clerks
- Allows for remote viewing and reporting; to also include teleradiology
- Expedites the incorporation of medical images into an electronic health record
- Images can be archived and transported on portable media, e.g. USB drive and Apple's iPhone
- Other specialties that generate images may join PACS such as cardiologists, ophthalmologists, gastroenterologists and dermatologists
- PACS can be web-based and use "service oriented architecture" such that each image has its own URL. This would allow access to images from multiple hospitals in a network.
- Unlike conventional x-rays, digital films have a zoom feature and can be manipulated in innumerable ways
- Improves productivity by allowing multiple clinicians to view the same image from different locations
- Rapid retrieval of digital images for interpretation and comparison with previous studies
- Fewer "lost films"
- Reports are more likely to accompany the digital image
- Radiologists can view an image back and forth like a movie, known as "stack mode"
- Quicker reporting back to the requesting clinician
- Digital imaging allows for computer aided detection (CAD)³¹
- Increased productivity. Several studies have shown increased efficiency after converting to an enterprise PACS. In a study by Reiner,

inpatient radiology utilization increased by 82% and outpatient utilization by 21% after transition to a film-less operation, due to greater efficiency.³² In another study conducted at the University of California Davis Health System, transition to digital radiology resulted in: a decrease in the average image search time from 16 to two minutes (equivalent to more than \$1 million savings annually in physician's time); a decrease in film printing by 73% and file clerk full time equivalents (FTEs) dropped by 50% (equivalent to more than \$2 million savings annually).³³ The Health Alliance Plan implemented PACS at Henry Ford Health Systems in 2003. Results indicate: turnaround time for film retrieval dropped from 96 hours to 36 minutes; net savings of \$15 per film and key players noted significant time savings.³⁴

PACS Disadvantages

- Cost is the greatest barrier, although innovations such as open source and "rental PACS" are alternatives
- New legislation cutting reimbursement rates for certain radiology procedures, thus decreasing capital that could be used to purchase a PACS³⁵
- Expense and complexity to integrate with hospital and radiology information systems and EHRs
- Lack of interoperability with other PACSs
- Bandwidth limits may require network upgrades
- Different vendors may use different DICOMs tags to label films
- Viewing digital images a little slower than routine x-ray films
- Workstations may require upgrades if high resolution monitors are necessary

Recommended Reading

The following is a recent article that discusses issues related to PACS and medical imaging

- *The Impact of PACS on Clinician Work Practices in The Intensive Care Unit: A Systematic Review of the Literature.* Authors performed a systematic review to determine the impact of PACS on workflow and other issues related to ICU care. Data would suggest that PACS improves efficiency and clinical decision making but may reduce communication between the clinician and the radiologist. They do point out, however, that many articles come from the same institution and no randomized controlled trials have been published so generalizability is limited.³⁶
- *Imaging Informatics: Essential Tools For The Delivery Of Imaging Services.* This 2013 review discusses the fact that the new field of imaging informatics involves much more than just interpreting digital images, it involves secure storage, delivery, sharing and quality analytics that support research and education. The need for better data standards, standardized reporting and terminologies is also discussed, as well as new standards that will capture and expose image metadata. Radiology clinical decision support is mentioned as a means to reduce inappropriate exam ordering.³⁷
- *Biomedical Imaging Informatics In The Era Of Precision Medicine: Progress, Challenges, And Opportunities.* This 2013 review article describes the current status of

the field and challenges such as managing large data sets, developing data standards for interoperability and the need for combined efforts among organizations that deal with medical imaging.³⁸

Future Trends

In spite of its expense PACS has become the de facto standard of care for medical imaging. Making digital images available to all medical staff in a user friendly manner has been a quantum leap forward. Towards this goal, Stage 2 Meaningful Use requires both eligible professionals and hospitals to incorporate (or make accessible) through their electronic health records more than 10% of images ordered. Additionally, there is also a trend towards web based PACS because it is more capable and is a better fit for large healthcare organizations, health information organizations and newer delivery models such as accountable care organizations. This is being supported and facilitated by faster networks, better monitor resolution and more digital imaging. Similarly, there will be better mobile platforms (smartphones and tablets) for viewing images by primary care and specialty physicians, patients and radiologists. Newer image standards are likely such as DICOM GSPS, DICOM SR and AIM (annotation and image markup) to make image reporting and mining standardized.³⁷

Key Points

- PACS is the logical result of digitizing x-rays, developing better monitors and medical networks
- PACS is well accepted by radiologists and non-radiology physicians because of the ease of retrieval, quality of the images and flexibility of the platform
- PACS is a type of teleradiology, in that, images can be viewed remotely by multiple clinicians on the same network
- Cost and integration are the most significant barriers to the widespread adoption of PACS
- Web-enabled PACS will promote better interoperability and sharing
- Mobile devices such as smartphones and tablet PCs offer a new viewing platform

Conclusion

PACS and digital imaging result from a predictable technological evolution beyond traditional film. For that reason, PACS has become a mainstream technology for moderate to large healthcare organizations. Like electronic health records (EHRs) PACS is an expensive technology to implement, but unlike

EHRs, there is greater acceptance by clinicians. EHRs and Health Information Organizations will benefit by being interoperable with web PACS. Healthcare organizations will be looking for ways to interpret and distribute a wide range of images to the entire organization. The technology is moving closer to thin client or zero client web-based PACS for maximum flexibility and interoperability for the enterprise.

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Chapter 20

Bioinformatics

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Learning Objectives

After reading this chapter the reader should be able to:

- Define bioinformatics, translational bioinformatics and other bioinformatics-related terms
- State the importance of bioinformatics in future medical treatments and prevention
- Describe the Human Genome Project and its important implications for health care
- List major private and governmental bioinformatics databases and projects
- Enumerate several bioinformatics projects that involve electronic health records
- Describe the application of bioinformatics in genetic profiling of individuals and large populations

Introduction

This chapter will discuss bioinformatics, the biomedical informatics sub-discipline that has gained increasing prominence in recent years thanks to initiatives such as the Human Genome Project, discussed in a later section. Bioinformatics can trace its formal beginning to 1970, when the term was first introduced in scientific literature.¹ In many ways bioinformatics has evolved independent of health informatics and thus has its own sets of definitions and background information.

Definitions

The chapter begins with some common definitions and in the next section provides a short genomics primer.

Bioinformatics, many aspects of which are often referred to as Computational Biology, is a general description of “the field of science in which biology, computer science and information technology merge to form a single discipline.”² Bioinformatics makes use of fundamental aspects of computer science (such as databases and artificial intelligence) to develop algorithms for facilitating the development and testing of biological hypotheses, such as: finding the genes of various organisms, predicting the structure or function of newly developed proteins, developing protein models and examining evolutionary relationships.³⁻⁴

- Translational bioinformatics focuses on the “development of storage, analytic and interpretive methods to optimize the transformation of increasingly voluminous biomedical data into proactive, predictive, preventive and participatory health.”⁵ Simply put, translational bioinformatics is the specialization of bioinformatics for human health.
- Genomics is the field that analyzes genetic material from a species.
- Proteomics is the study at the level of proteins (e.g., through gene expression).
- Pharmacogenomics is the study of genetic material in relationship with drug targets.
- Metabolomics is the study of genes, proteins or metabolites.
- Metagenomics is the analysis of genetic material derived from complete microbial communities harvested from natural environments.⁶
- A phenotype is the observable characteristic, structure, function and behavior of a living organism. Size and hair color could be examples. Phenotype is strongly guided by the genotype. Phenome refers to the total phenotypic traits.
- Genotype is based on the raw genetic information that is associated with a phenotype or regulation of biological function.⁷ The genome is the total of the genotypic traits.

Genomic Primer

The human body has about 100 trillion cells and each one contains a complete set of genetic information (chromosomes) in the nucleus; exceptions are eggs, sperm and red blood cells. Humans have a pair of 23 chromosomes in each cell that includes an X and Y chromosome for males and two Xs for females. Offspring inherit one pair from each parent. Chromosomes are listed approximately by size with chromosome 1 being the largest and chromosome 22 the

smallest. Organisms have differing numbers of chromosomes (e.g., our closest extant primate relatives, chimpanzees, have 24 pairs). Chromosomes consist of double twisted helices of deoxyribonucleic acid (DNA). DNA is composed of four sugar-based building blocks (“nucleotides”: adenine [A], thymine [T], cytosine [C], and guanine [G]) that are generally found in pairs (“Watson-Crick” pairing: A-T, C-G). DNA is often referred to as the “blueprint for life.” As such, a given organism’s DNA encodes its full complement of proteins essential for cellular function. Some of the encoding of DNA also enables it to control the expression of proteins or affect how other portions of DNA may be decoded based on a particular biological context (e.g., to accommodate for faulty DNA decoding or DNA damage that may be encountered due to environmental phenomena). Genes are regions on chromosomes that encode instructions, which may result in proteins that then in turn enable biological functions. The process of decoding genes involves transcribing the DNA into ribonucleic acid (RNA) and then translation into amino acids that form the building blocks for proteins (Figure 20.1). Collectively, the complete set of genes is referred to as a “genome” (based on the combination of the terms “gene” and “chromosome”).

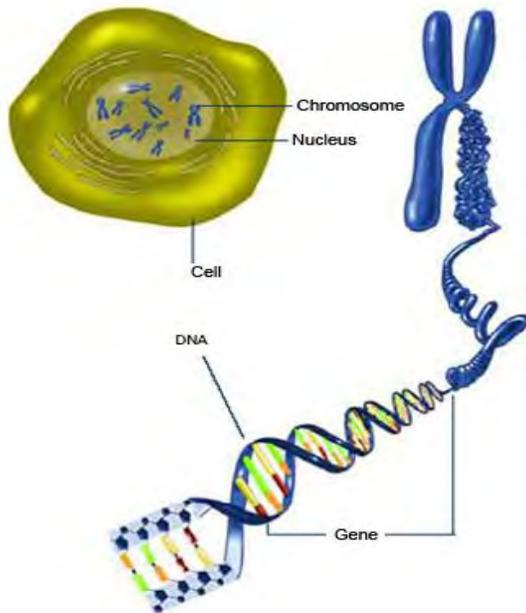
It is estimated that humans have between 20,000 and 30,000 genes and that genomes are about 99.9% the same between individuals. Variations in genomes between individuals are known as single nucleotide polymorphisms (SNPs) (pronounced “snips”). There are three general types of alterations: single base-pair changes, insertions or deletions of nucleotides, and reshuffled DNA sequences. As an example, one individual might have a chromosome with the sequence TGGC, while another might have the sequence TAGC. Each of these is referred to as an allele. Although SNPs are common, their significance is complex and difficult to decipher.⁸⁻¹⁰

A great deal of progress has been made with genetic testing and our understanding of the human genome and genetic variations. Genome-wide associations studies (GWASs) are

being conducted where two groups of participants are studied; those with a disease of interest, compared with those without the disease. The variations or SNPs discovered are said to be associated with the disease, but true cause and effect is often unclear.¹¹ Similarly, phenome-wide association studies (PheWAS) are being carried out comparing genes to disease associations, most recently using the electronic health record for phenotypical information.

Genetic material can be obtained from blood, saliva, skin and hair samples. Full genome sequencing has historically been an expensive and complicated process, although it is expected that the cost of full genome sequencing will drop to approximately US\$1000 in the next decade. DNA profiling is a simpler technique that only determines if the material came from an individual or group (e.g., to complete an entire DNA profile it currently costs about US\$100). This cost differential is largely because SNP genotyping analyzes about 0.1% of the genome in contrast to every single nucleotide.

Figure 20.1: Genes (Courtesy of Nat. Inst. of General Medical Sciences)

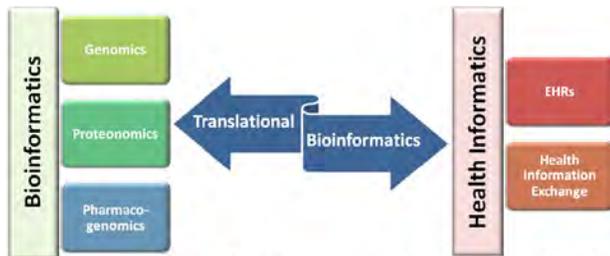


Importance of Bioinformatics

Besides diagnosing the 3,000 to 4,000 hereditary diseases that are currently known, bioinformatics may be helpful to discover future drugs targets, develop personalized drugs based on genetic profiles and develop gene therapies to treat diseases with a strong genomic component, such as cancer. One approach that has been explored to enable gene therapies involves the use of genetically altered viruses that carry human DNA. This approach, however, has not been definitely shown to work and has not been for general use by the FDA. Manipulation of genomes in other organisms, such as microbes, has shown promise for energy production (“bio-fuels”), environmental cleanup, industrial processing and waste reduction. Genetically engineered plants could also be made to be drought or disease resistant.

This chapter will deal primarily with transformational bioinformatics (TBI), a relatively newly identified area of focus in bioinformatics that is focused primarily on the study of data contained within exponentially growing genetic and clinical databases. A significant goal of TBI is to enable bi-directional crossing of the translational barrier between the research bench and the bed in the medical clinic. With growing genome-wide and population-based research data sets, more genotype-phenotype associations are being uncovered that potentially can detect and treat diseases with a genetic component earlier. Such associations may also help create tailor made drugs for higher efficacy. Figure 20.2 demonstrates the bidirectional nature of data and information flow between bioinformatics and health informatics. The emergence of translational bioinformatics is primarily due to the rapid advances in both sub-disciplines. In other words, a variety of advances in bioinformatics, such as faster and cheaper DNA sequencing, and more widespread adoption of electronic health records have made this possible.

Figure 20.2: Translational bioinformatics (Adapted from Sarkar et al)¹²



Pharmacogenomics is an excellent example of how translational bioinformatics can be used within the context of pharmaceutical development to make use of genomic information for better drug discovery and utilization. Drug companies are faced with the huge expense of drug development, the long road to producing a new drug and expiring patents. Drug failures are common and can be due to complex combination of a lack of clinical efficacy, side effects and commercial issues. Unfortunately, animal models are often inadequate for the development and evaluation of drugs for treating human conditions. It is thus the goal to use genetic information for:

- New indications for an old drug (drug repurposing)
- New targets for existing drugs (e.g., treatment of tongue cancer using RET inhibitors)
- Drugs to work better in certain patient groups (gender, age, race, ethnicity, etc.) with possible genetic variants
- Knowing ahead of time what drugs to avoid due to higher incidence of side effects that are genetically modulated
- Develop clinical decision support in electronic health records based on pharmacogenomics¹³⁻¹⁴

Multiple projects are underway to integrate genetic and clinical data that will be discussed later in the chapter. Electronic health records (EHRs) and health information exchanges

(HIEs), which are rapidly becoming ubiquitous, thanks in large part to federal mandates, are poised to contribute massive amounts of patient information (including demographic, laboratory, and clinical data). It is important to also note that in addition to genomic and clinical data, environmental data may offer valuable insights into the understanding and eventual treatment of disease.

Bioinformatics Projects and Centers

The Human Genome Project

One of the greatest accomplishments in biomedicine was the completion of the Human Genome Project (HGP). This international collaborative project, sponsored by the US Department of Energy and the National Institutes of Health, was started in 1990 and finished in 2003. In the process of acquiring the human genome (as a complete set of DNA sequences, encompassing all 23 chromosomes), genome sequences for a number of other key organisms (“model” organisms) were also acquired. These included the *Escherichia coli* bacterium, fruit fly (*Drosophila melanogaster*), and house mouse (*Mus musculus*). By mid-2007 about three million differences (SNPs) had been identified in human genomes. Appreciating the potential significant societal impact, the HGP also addressed the ethical, legal and social issues associated with the project. Since the completion of the HGP, attention is now more focused on the development of approaches to analyze and learn from volumes of data representing increasing numbers of individuals.^{11,15-16} These analyses include the annotation of information associated with disease onto chromosomes. Figure 20.3 displays the DNA sequencing of just chromosome number 12. Huge relational databases are necessary to store and retrieve this information. New technologies continue to emerge that reduce the necessity to sequence an entire human genome, such as DNA arrays (gene chips) that help speed the analysis and comparison of DNA fragments.¹⁷ The cost of the

HGP was close to \$3 trillion; by 2010, a single gene chip could detect over a million variations in the base-pairs in a genome costing only several hundred dollars and taking only a few hours.⁷

National Human Genome Research Institute (NHGRI)

NHGRI is an NIH institute that provides many educational resources on their web site. Like other NIH institutes, they conduct and fund research within their intramural division, as well as support extramural research with external partners. Their health section has multiple resources for patients and healthcare professionals with particular emphasis on the Human Genome Project. The “Issues in Genetics” section covers important controversies in policy, legal and ethical issues in genetic research. They include a large glossary (200+) of genetics-related definitions, also available as a software app for the iPhone and iPad.¹⁷

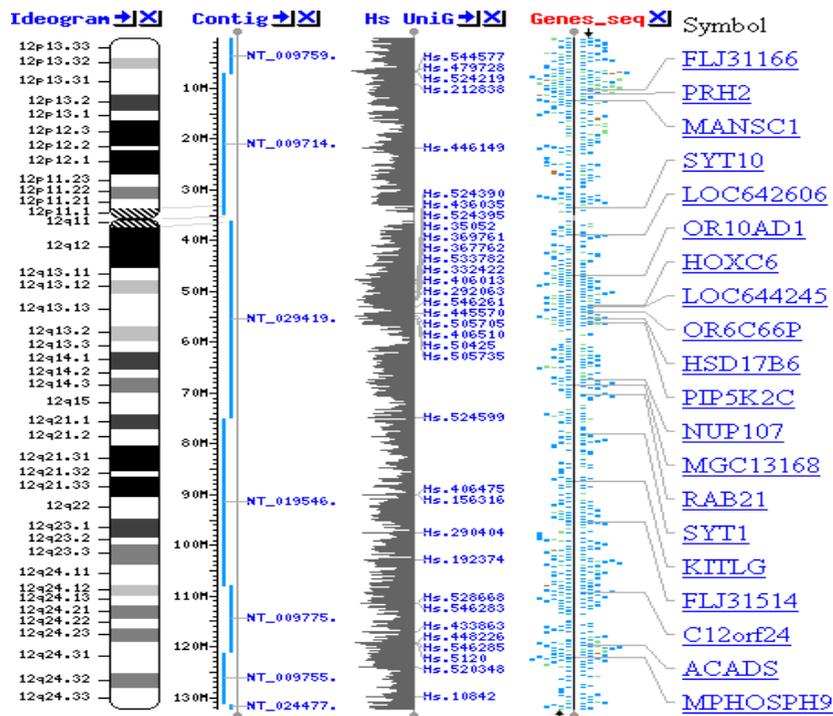
In 2003, NHGRI launched the Encyclopedia of DNA Elements (ENCODE) Project. ENCODE is

comprised of a consortium of laboratories with the goal to study and characterize the functional elements of the human genome. All ENCODE data are free for research purposes. In 2012, 1640 data sets were published, which continue to produce controversy. For example, ENCODE researchers posited that 80% of the human genome is active and performing a role (and thus not “junk” DNA as has been previously thought).

Human Microbiome Project (HMP)

It is estimated that less than 0.01% of microbes on Earth have been cultured, characterized, and sequenced. As an exception, the complete genome for the common human parasite *Trichomonas vaginalis* was reported in 2007 in the journal *Science*.¹⁸ The HMP is an NIH-sponsored initiative that catalogued the myriad of organisms that co-exist with humans and heretofore have been rarely studied (e.g., flora from oral, nasal, skin, and the gastrointestinal tract).

Figure 20.3: Chromosome 12 (Courtesy of the National Library of Medicine)



The HMP used metagenomics, as explained in the definitions section. As detailed on the HMP web site their goals were as follows:

- Determine whether individuals share a core human microbiome
- Understand whether changes in the human microbiome can be correlated with changes in human health
- Develop new technological and bioinformatic tools needed to support these goals
- Address the ethical, legal and social implications raised by human microbiome research ⁶

Human Variome Project

This Australian initiative began in 2006 with the goal to create systems and standards for storage, transmission and use of genetic variations to improve health. Rather than catalogue “normal” genomes they focus on the abnormalities that cause disease. Another aspect of their vision is to provide free public access to their databases.¹⁹

The PhenX Project

The goal of this project is to identify 15 high-quality, well established measures and standards for each of 21 research domains. Standardization is important so that phenotypical, risk factors and environmental exposures can be compared. For example, if everyone used a common set of standards data could be more readily compared or combined to gain more statistical power.²⁰⁻²¹

1000 Genomes Project

This is an international initiative with the goal to catalogue and study the genomes of 2500 individuals from 26 populations, looking for genetic variations that occur at a frequency of about 1%. The data will be free for researchers and hosted on Amazon’s Web Services. Currently, the project has produced 200 terabytes of data.²²

Pediatric Cancer Genome Project

St. Jude’s Children’s Hospital-Washington University created this initiative in an effort to combat childhood cancer. Data generated from 600 subjects will be offered free to researchers. As an example of a positive result from this project, in 2013, two gene variations associated with 50% of low grade gliomas (brain tumors) were identified.²³

IBM Clinical Genomics

IBM in Israel, in collaboration with the Fondazione IRCCS Istituto Nazionale dei Tumori in Italy, created a biomedical platform to offer personalized cancer care. It will be using “Watson”-like computing to analyze patient records, family history, genetic profiles, and pathology records to deliver specific recommendations.²⁴

Global Alliance

In June 2013 a Global Alliance was formed to share genetic and clinical information. The Alliance was formed by 70 medical and research organizations from 40 countries. They will develop standards for sharing genetic information, information technology platforms with open standards and patient consent policies.²⁵

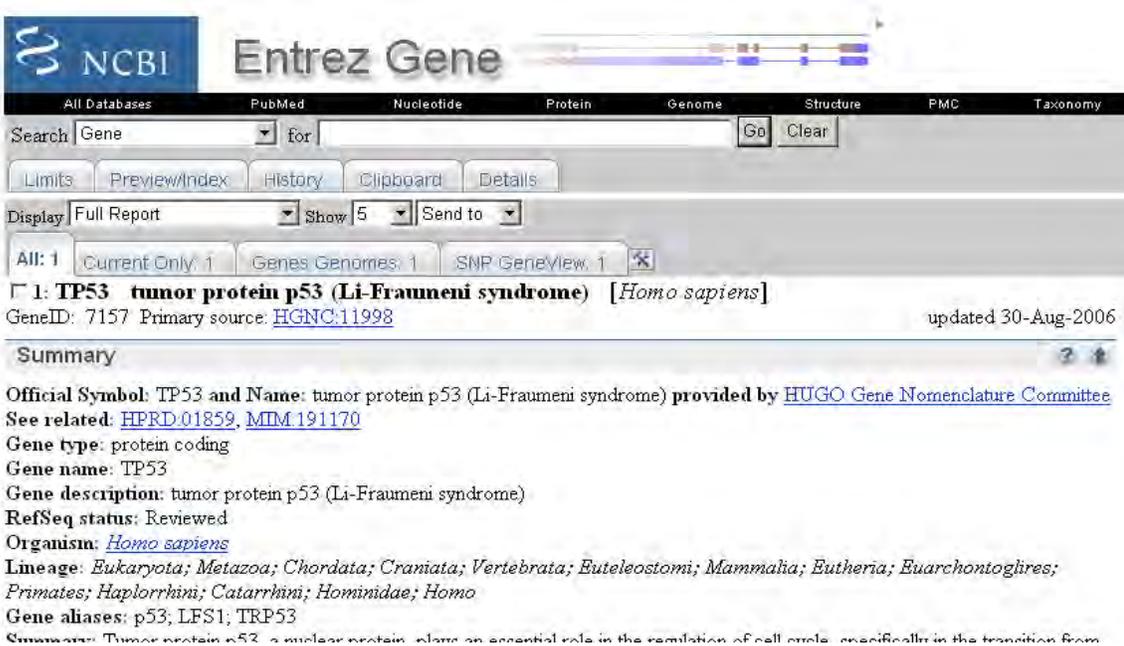
National Center for Biotechnology Information (NCBI)

The NCBI was created in 1988 as part of the National Library of Medicine at the National Institutes of Health. It hosts thousands of databases associated with biomedicine (including the popular MEDLINE and GenBank databases) and thereby is considered one of the world’s largest biomedical research centers. The NCBI provides access to sequences from over 285,000 organisms (via GenBank), including the complete genomes of thousands of organisms (via NCBI Genome). Genomes represent both completely sequenced organisms and those for which sequencing is still in progress. Popular NCBI databases, which are linked by a common interface (Entrez), are listed in Figure 20.4.

Figure 20.4: NCBI Databases (Courtesy National Library of Medicine)

 Nucleotide: sequence database (includes GenBank)	 UniGene: gene-oriented clusters of transcript sequences
 Protein: sequence database	 CDD: conserved protein domain database
 Genome: whole genome sequences	 3D Domains: domains from Entrez Structure
 Structure: three-dimensional macromolecular structures	 UniSTS: markers and mapping data
 Taxonomy: organisms in GenBank	 PopSet: population study data sets
 SNP: single nucleotide polymorphism	 GEO Profiles: expression and molecular abundance profiles
 Gene: gene-centered information	 GEO DataSets: experimental sets of GEO data
 HomoloGene: eukaryotic homology groups	 Cancer Chromosomes: cytogenetic databases
 PubChem Compound: unique small molecule chemical structures	 PubChem BioAssay: bioactivity screens of chemical substances
 PubChem Substance: deposited chemical substance records	 GENSAT: gene expression atlas of mouse central nervous system
 Genome Project: genome project information	 Probe: sequence-specific reagents

Figure 20.5: Entrez search for tumor protein (Courtesy National Library of Medicine)



NCBI Entrez Gene

All Databases PubMed Nucleotide Protein Genome Structure PMC Taxonomy

Search Gene for Go Clear

Limits Preview/Index History Clipboard Details

Display Full Report Show 5 Send to

All: 1 Current Only: 1 Genes Genomes: 1 SNP GeneView: 1

1: **TP53 tumor protein p53 (Li-Fraumeni syndrome)** [*Homo sapiens*]
 GeneID: 7157 Primary source: [HGNC:11998](#) updated 30-Aug-2006

Summary

Official Symbol: TP53 and **Name:** tumor protein p53 (Li-Fraumeni syndrome) provided by [HUGO Gene Nomenclature Committee](#)
See related: [HPRD:01859](#), [MIM:191170](#)
Gene type: protein coding
Gene name: TP53
Gene description: tumor protein p53 (Li-Fraumeni syndrome)
RefSeq status: Reviewed
Organism: *Homo sapiens*
Lineage: *Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini; Catarrhini; Hominidae; Homo*
Gene aliases: p53; LFS1; TRP53
Summary: Tumor protein p53, a nuclear protein, plays an essential role in the regulation of cell cycle, specifically in the transition from

On the Genome project web site one can search for specific genes or proteins from different species. Figure 20.5 demonstrates the result of an Entrez Gene search for a tumor protein (TP53).

The NCBI site also provides access to BLAST+ (new Basic Local Alignment Search Tool) that enables the identification of significantly related (based on a “expectation” value or “e-value”) nucleotide or protein sequences from within the protein and nucleotide databases.²⁶

GenBank

This database was established in 1982, and is the NIH sequence database that is a collection of all publicly available DNA sequences. Along with EMBL (Europe) and DDBJ (Asia), GenBank is a member of the International Nucleotide Sequence Database Consortium (INSDC), which provides free access to sequence data from nearly anywhere with an internet connection. As of this writing, there are approximately 154,192,921,011 bases in 167,295,840 sequence records in the traditional GenBank divisions (for the latest statistics, see: <http://www.ncbi.nlm.nih.gov/genbank/statistics>). Interestingly, many biological and medical journals now require submission of sequences to a database prior to publication, which can be done with NCBI tools such as BankIt.²⁷

The Online Mendelian Inheritance in Man (OMIM)

This is another NCBI database of genetic data and human genetic disorders. It was originally developed and sponsored by Johns Hopkins University and Dr. Victor McKusick, a pioneer in genetic metabolic abnormalities. It includes an extensive reference section linked to PubMed that is continuously updated.²⁸

World Community Grid

This project was launched by IBM in 2004 and simply asked people to donate idle computer time. By 2007 over 500,000 computers were involved in creating a super-computer used in

bioinformatics. Projects include Help defeat Cancer, Fight AIDS@Home, Genome Comparison and Human Proteome Folding projects. This grid promises to greatly expedite biomedical research by analyzing complex databases more rapidly as a result of this grid.²⁹

Pharmacogenomics Knowledge Base (PharmGKB)

This Stanford University based resource catalogues the relationships between genes, disease and drugs. There are sections on drugs, medical literature, variant genes, pathways, diseases and phenotypes that are searchable.³⁰

Framingham Heart Study SHARe Genome-Wide Association Study

In 2007, the Framingham Heart Study began a new phase by genotyping 17,000+ subjects as part of the FHS SHARe (SNP Health Association Resource) project. The SHARe database is located at NCBI's dbGaP and will contain 550,000 SNPs and a vast array of phenotypical (combined characteristics of the genome and environment) information available in all three generations of FHS subjects. These will include measures of the major risk factors such as systolic blood pressure, total, LDL and HDL cholesterol, fasting glucose, and cigarette use, as well as anthropomorphic measures such as body mass index, biomarkers such as fibrinogen and C-reactive protein (CRP) and electrocardiography (EKG) measures such as the QT interval. As a result of this initiative, they have been able to publish multiple articles on genetic associations and heart disease.³¹

The Mayo Clinic Bipolar Disorder Biobank

Researchers at the Mayo clinic and other institutions are analyzing the genetic and clinical information on 2000 patients in their biobank to determine genetic aspects of bipolar disorder. It is hoped that data generated from this project will lead to earlier and better treatment of this mental health disorder.³²

Informatics for Integrating Biology and the Bedside (i2b2)

i2b2 is a National Institutes of Health National Center for Biomedical Computing initiative located at Harvard Medical School. The Center has developed open source software that will enable investigators to mine existing clinical data for research. At this time there are 72 member institutions, including 12 that are international. The project was designed to allow users to query a system-wide de-identified repository for a set of patients meeting certain inclusion or exclusion criteria. On the web site, users can download client-software, client-server software and the source code.³³ The i2b2 infrastructure has been shown to be generalizable to multiple sites for a range of clinical conditions.³⁴

For more information on translational bioinformatics and related databases in the context of biomedicine, readers are referred to the textbook edited by Shortliffe and Cimino.³⁵

Personal Genomics

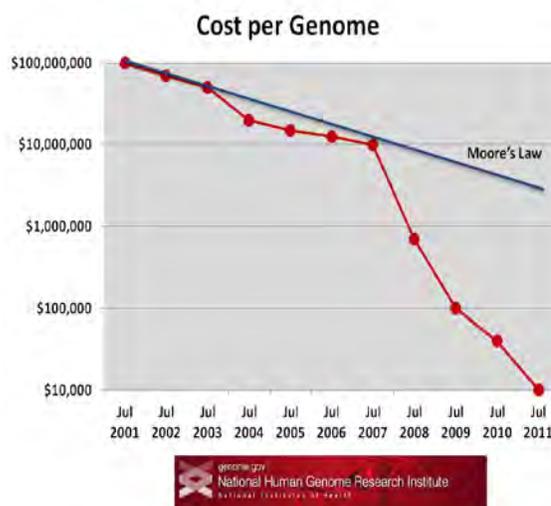
The availability of population-based genetic data, the decreasing cost for human genome determination and the availability of commercial personal genetic testing companies provide greater personal uses of genomics data.

Population Studies: There are a number of ongoing initiatives that will leverage genomic data in the context of population studies. For instance, Oracle Corporation has partnered with the government of Thailand to develop a database to store medical and genetic records. This initiative was undertaken to offer individualized “tailor made” medications and to offer bio-surveillance for future outbreaks of infectious diseases such as avian influenza.³⁶ Not all such initiatives have been successful. Perhaps the best known is DeCODE Genetics Corporation, which aimed to collect disease, genetic and genealogical data for the entire population of Iceland; however, it filed for chapter 11 bankruptcy in 2009.³⁷ Nonetheless, DeCODE continues some operations and the

development of personal genomics based solutions, largely in partnership with organizations such as Pfizer.

Decreasing Cost of Human Genome Determination: Coinciding with the completion of the HGP, the NHGRI has kept track of the cost to perform DNA sequencing of an entire human genome over the past decade. As Figure 20.6 indicates the cost has dropped from an initial cost of \$100,000,000 to a current cost of less than \$10,000 per genome in 2013. Notably, the decrease in cost of genome sequence is exceeding Moore’s Law (attributed to Intel co-founder Gordon Moore, and states that the cost of computing power will be halved every 18 months based on advances in technology).¹¹

Figure 20.6: Cost per Genome over time (Courtesy National Human Genome Research Institute)¹¹



Personal Genetics Testing. Many patients may want to know their own genetic profile, even if the consequences are uncertain. The following are examples of personal genetics companies (“direct to consumer genomics”):

- DNA Direct is a company that offers online genetic testing and counseling. They offer both patient and physician education and have staff genetic counselors.³⁸

- AncestryDNA is a separate service offered by Ancestry.com. Their analysis will determine ethnicity estimates and will identify remote cousins. Saliva samples are needed, the cost is \$99 and the turn around time is about six weeks.³⁹
- 23andMe is a direct to consumer online genetic testing company. For \$99 they will send a testing kit to homes based on analyzing saliva with a turnaround time of four to six weeks. Currently, they look for 240 diseases, multiple carrier states and drug response conditions (a substantial increase in the last two years). They also offer an analysis of ancestry based on the genetic profile.⁴⁰ In 2010 a genome wide association study (GWAS) was published that used this technology and showed that patient questionnaire results correlated well with genetic results. Additionally, they were able to describe five new genotype-phenotype associations: freckling, photic sneeze reflex, hair curl and failure to smell asparagus.⁴¹ Google's co-founder Sergey Brin has funded a project through this company to study the genetic inheritance of Parkinson's disease. They hope to recruit 10,000 subjects from various organizations and offer a discount price for complete analysis. In late 2013 the FDA instructed the company to stop performing genetic analyses for medical conditions until they receive 510(k) (pre-market) clearance.⁴²
- Myriad™ specializes in genetic testing for cancers with a hereditary component, such as breast, ovarian, colon, prostate and pancreatic cancer.⁴³ A sentinel Supreme Court decision took place in 2013 that determined that Myriad could not patent BRAC gene testing.⁴⁴

However, as pointed out by Harold Varmus (American Nobel-prize winner, who was a former director of the NIH, and the current director of the NCI), personal genetics "is not

regulated, lacks external standards for accuracy, has not demonstrated economic viability or clinical benefit and has the potential to mislead customers."⁴⁵

In order for genetics to enter the mainstream, new technologies and specialties will need to be developed and numerous ethical questions will arise. Just finding the abnormal gene is the starting point. Genetic tests will have to be highly sensitive and specific to be accepted. In general, patients may not be willing to undergo major procedures (e.g., a prophylactic mastectomy or prostatectomy to prevent cancer) unless the genetic testing is nearly perfect. It is also important that genetic counseling be available to help patients understand the implication of genetic susceptibility tests (versus genetic guarantee of disease, such as the mutations associated with Huntington's disease).

Additionally, the Genetic Information Nondiscrimination Act of 2008 was passed to protect patients against discrimination by employers and healthcare insurers based on genetic information. Specifically, the Act prohibits health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on genetic information and bars employers from using individuals' genetic information when making decisions related to hiring, firing, job placement, or promotion.⁴⁶

Many obstacles face the routine ordering of genetic tests by the average patient. Ioannidis et al. pointed out that in order for genetic testing to be reasonable several facts must be true. The disease of interest must be common. Even with breast cancer, when seven established genetic variants are evaluated, they only explain about 5% of the risk for the cancer. If the disease (e.g., Crohn's disease) is rare, then the test must be highly predictive. In order for genetic testing to be relevant one should have an effective treatment to offer, otherwise there is little benefit. The test must be cost effective, as many currently are too expensive. As an example, screening for sensitivity to the blood thinner

warfarin (Coumadin) makes little sense at this time due to cost.⁴⁷

A 2010 Lancet journal commentary also warned of additional concerns. Whole-genome sequencing will generate a tremendous amount of information that the average physician and patient will not understand without extensive training. At this point, health care lacks adequate numbers of geneticists and genetic counselors that understand the implications of data being made available thanks to continued advances in biotechnology. Patients will need to sign an informed consent to confirm that many of the findings will have unclear meaning. They will have to deal with the fact that they may be found to be carriers of certain diseases that *may* have impact on childbearing, etc. Genetic testing may cause many further tests to be ordered, thus leading to increased healthcare expenditures. As more information about whole-genome sequencing is gained, more patients will desire it but who will pay for it? And, can the costs be justified?⁴⁸

Two other recent articles drive home additional practical points. When the risk of cardiovascular disease based on the chromosome 9p21.3 abnormality was evaluated in white women, it only slightly improved the ability to predict cardiovascular disease above standard, well-accepted risk factors.⁴⁹ Meigs et al. looked at whether multiple genetic abnormalities associated with Type 2 diabetes would be predictive of the disease. They found that the score based on 18 genetic abnormalities only slightly improved the ability to predict diabetes, compared to commonly accepted risk factors.⁵⁰

For more information regarding future bioinformatics trends, readers are referred to the review paper by Altman and Miller.⁵¹

Genomic Information Integrated with Electronic Health Records

Eventually, the patient's genetic profile may be an additional data field within the electronic health record. Recently, gene variants have been

identified for diabetes, Crohn's disease, rheumatoid arthritis, bipolar disorder, coronary artery disease and multiple other diseases.⁵² There are a number of forward-looking initiatives that have started on the path to integrate genomic data with traditional clinical data, for example:

- In 2006 the Veterans Affairs health care system began collecting blood to generate genetic data that it will link to its EHR. The goal is to bank 100,000 specimens as a pilot project and link this information to new drug trials. The new voluntary program was officially launched in 2011 and is known as the Million Veteran Program (MVP). MVP will link genetic, military exposure, health and lifestyle into a single database.⁵³
- Kaiser Permanente created the Research Program on Genes, Environment and Health and in the first phase two million members will be surveyed to determine their medical history, exercise and eating habits. As of mid-2013, the goal is to collect genetic, medical and environmental information on 500,000 of its members. Kaiser plans correlative studies with its 15 years of digital health information, collected through its electronic health record system. Because the average age of participants is 65 it is anticipated that excellent information about aging will be generated. For example, they are measuring telomere length (the tips of chromosomes) that is thought to correlate with aging. This NIH funded initiative was completed in 15 months, thanks to newer technologies. It is anticipated that data will be analyzed and available to other researchers by the 2012-2013 time frame.⁵⁴⁻⁵⁵
- The Electronic Medical Records and Genomics (eMERGE) Network is a consortium of nine healthcare organizations with significant investments in both EHR and genomic analytics across the United States. The National Human Genome Research Institute organizes this network, with additional funding from the National Institute of General Medical Sciences. An important theme is electronic health records

are a vital resource for complex genomic analysis of disease susceptibility and patient outcomes in diverse patient populations. The October 2013 issue of *Genetics in Medicine* is devoted to discussing the progress of eMERGE. It is pointed out that for EHRs to support genomic information they must:

1. Store data in structured format
2. Data must be standards based
3. Phenotypic information must also be stored as structured data
4. Data must be available for use by rules engines
5. EHRs must be able to display information needed by the clinician based on phenotypic and genotypic data.

All of these requirements have challenges that must be addressed. At the top of the list is adequate training of clinicians so they can deal with genomic data and privacy protections of the data. Importantly, will the clinical decision support for interpretation be part of commercial EHRs or reside in a data warehouse? ⁵⁶⁻⁵⁷

- Vanderbilt University recently published a strong correlation between their genetic biorepository known as BioVU (genotype) with clinical information (phenotype) obtained from their electronic health record. The diseases studied were rheumatoid arthritis, multiple sclerosis, Crohn's disease and type 2 diabetes. ⁵⁸
- Mount Sinai BioMe Project has collected genetic profiles from about 26,000 patients in its biobank so they can link it with clinical data in the EHR and their clinical data warehouse. Their goal is to collate this information on 100,000 patients. ⁵⁹
- The Mayo Clinic Biobank began in 2009 with the goal of including genetic information on 50,000 of their patients. In 2013 they reported that they were a little over half way there. While their biobank is smaller than other organizations they are able to collate data from more than 15 years in their EHR. Their research focus is very broad and not targeted to one disease. The volunteer participation rate is high at 29% and their patient population is highly

educated, compared to the general population. ⁶⁰

SNOMED CT is making changes to its codes to include genetic information and the National eHealth Initiative is developing "use cases" for family history and genetics so standards can be created by organizations like the Health Information Technology Standards Panel (HITSP). Organizations such as Partners HealthCare, IBM, Cerner and data mining vendors are all gearing up to add genetic information to what is currently known about patients and integrate that with electronic health records. ⁶¹

The Agency for Healthcare Research and Quality (AHRQ) is developing computer-based clinical decision support tools to help clinicians use genetic information to treat conditions with a strong genetic component, such as breast cancer. Such tools that could be integrated into EHRs are: whether women with a family history of breast cancer need BRCA1/BRCA2 testing and which women who already have breast cancer may benefit from additional genetic testing. ⁶²

It is surprising that family history is often overlooked by clinicians and that it usually does not exist as computable data for analysis. To our knowledge, no electronic health record collects this information in a common computable format and uses it for clinical decision support; family history data are generally entered as unstructured text that can be of varying quality (based on provider-patient interviews). Input of family history is a menu objective for stage 2 meaningful use. Data standards have been developed so family history can be part of EHRs and PHRs, in order to be shared. ⁶³ There is a government sponsored free web tool available for the public to record their family history using the newest data standards. In this way, the results can be saved as a XML file and shared by EHRs and PHRs. The site, *My Family Health Portrait*, is available for English or Spanish speaking patients, is easy to use and does not store any patient information on the site. Instead, patients can store the XML file on their personal computers. ⁶⁴ The program is open source and downloadable from this site. ⁶⁵ A

consortium in North Carolina has developed a self-administered family history tool for the collection of data and creation of clinical decision support for primary care physicians. The tool, known as MeTree will collect information on 48 conditions with a genetic component but provide clinical decision support for only five common conditions. Researchers will study how this information impacts appropriate testing as well as implementation hurdles.⁶⁶

In late 2013 a family history tool for pediatricians was released as a collaborative effort by several medical organizations. Data collected is structured and can be inputted from handheld devices, such as tablets. The program includes 35 genetic-related conditions with associated clinical decision support tools (actionable information) for pediatricians to help children at risk. The pedigree created includes first, second and third degree relatives. The program utilizes HL7 standards but does not currently integrate with EHRs.⁶⁷

For further information about the role of EHRs and genomics readers are referred to these citations.⁶⁸⁻⁷⁰

Recommended Reading

The following are several recent and interesting articles related to bioinformatics:

- *Invited Commentary: Genetic Prediction for Common Diseases: Will Personal Genomics Ever Work?* The author is responding to an article about atrial fibrillation where including 3 gene variants did not improve on prediction. The point is made that thousands of gene variants have been discovered but few improve predictability of disease for several reasons discussed in the commentary.⁷¹
- *Risk models for progression to advanced age-related macular degeneration using demographic, environmental, genetic and ocular factors.* Much is known about the genetic and non-genetic risk factors for age-related macular degeneration. The authors build prediction models taking into account multiple factors which one day could be included in EHRs.⁷²
- *Genetic testing behavior and reporting patterns in electronic medical records for physicians trained in a primary care specialty or subspecialty.* This is the first article to report on the ordering of genetic tests trends by multiple physicians at a large academic medical center. Tests were ordered primarily on childbearing women, primarily by internal medicine and ob-gyn physicians. Twenty gene tests accounted for 88% of the volume, with tests for cystic fibrosis and prothrombin variants being the most common. They point out that the genetic tests had no standard reporting format and appeared as free text in EHRs.⁷³
- *The CLIPMERGE PGx Program: clinical implications of personalized medicine through electronic health records and genomic-pharmacogenomics.* The article describes the pilot program that will study the pharmacogenomics of 1500 patients at Mount Sinai that are part of the Biome Biobank program. They note that about 100 pharmacogenomic variants have been found and are associated with FDA drug information. The CLIPMERGE PGx program will create an external system that integrates with their EHR and includes a risk assessment engine that generates alerts (clinical decision support) in the EHR.⁷⁴
- *Digital Family History and Data Mining.* The authors created a digital family history on 330 male Vietnam-era prisoners of war. They were able to use the presence or absence of a family history of type 2 diabetes as a research variable, demonstrating the potential value of a digital family history in research.⁷⁵
- *Evaluation of Family History Information Within Clinical Documents and Adequacy of HL7 Clinical Statement and Clinical Genomics Family History Models for Its Representation: A Case Report.* The authors evaluated family history in clinical documents to determine adequacy of existing models. They found that HL7

Clinical Genomics Family History Model and HL7 Clinical Statement Models would represent most family histories but refinements are needed.⁷⁶

- *Systematic Comparison of phenome-wide association study of electronic medical record data and genome-wide association study data.* The study reported in 2013 was conducted using data from five institutions in the eMERGE network. They tested 3,144 SNPs for an association with 1358 diseases (phenotypic information) using data from electronic health records on almost 14,000 patients. They replicated prior associations and discovered new ones, particularly single loci SNPs associated with multiple diseases (pleiotropy).⁷⁷
- *Genetic data and electronic health records: a discussion of ethical, logistical and technological considerations.* This is an excellent early 2014 summary of the issues/challenges extant with potential incorporation of genetic data into electronic health records. They reiterate the need for standardized content, genetic clinical decision support, compression and storage of massive genetic data.⁷⁸

First, new gene associations will continue to be reported. For example, in 2013 researchers in Switzerland described the CRT1 polymorphism that is associated negatively with BMI and fat mass in psychiatric and non-psychiatric patients.⁷⁹ Second, the cost to perform complete genome sequencing will continue to drop but it must be accompanied by competent analysis to be meaningful. It is likely newer technologies will continue to improve and make both sequencing and interpretation cost effective in the next decade. Third, the time to complete sequencing will continue to shorten. As a result, infectious diseases and birth defects can be diagnosed in several days.⁸⁰⁻⁸¹ Fourth, companies such as 23andMe will continue to offer more tests each year and at a lower price such that patient demand may exceed the ability to know what to do with the data, making this a “disruptive technology”. They will also require FDA clearance. Fifth, with the advent of meaningful use there will be more decision support associated with both family history and genomic information that correlates with phenotypical information, risk factors and lab results. Lastly, with integration of robust data from multiple sources within the electronic health record there will be a better understanding of what factors turn genes on or off, a field known as epigenetics.⁸²

Future Trends

Given the rapidly evolving nature of bioinformatics, multiple trends seem likely.

Key Points

- Traditionally, bioinformatics has been a field remote from clinical medicine, but translational bioinformatics will likely bridge this gap
- Advances in biotechnology (such as genome sequencing) will likely introduce a treasure trove of genetic information that will enable deeper understandings of the manifestation of disease as well as the development of a new cadre of therapeutics over the next decade
- The inclusion of genetic profiles is being contemplated for electronic health records
- At this time, direct to consumer genetic testing is still in its early stages, and cannot be used as a replacement for traditional clinical tests (but may be used to complement)

Conclusion

The Human Genome Project and bioinformatics may seem foreign to many clinicians. The promise of translational bioinformatics is to transform biological knowledge (such as can be inferred from genomic data) into clinically actionable items. The success of translational bioinformatics will not be realized until clinicians can access and clinically interpret data that tells them who should be screened for certain conditions and which drugs are effective in which patients as part of day-to-day practice. In the meantime, biomedical scientists and companies will continue to add to the many

genetic databases, develop genetic screening tools and get ready for one of the newest revolutions in medicine. The American Health Information Community (AHIC) recommended in 2008 that the federal government should prepare for the storage and integration of genetic information into many facets of health care.⁸³ Their recommendations will initiate the necessary dialogue that must take place to prepare for bioinformatics to align with the practice of medicine. But, as pointed out by Dr. Varmus: “the full potential of a DNA-based transformation of medicine will be realized only gradually, over the course of decades.”⁴⁵

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Chapter 21

Public Health Informatics

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Learning Objectives

After reading this chapter the reader should be able to:

- Define public health informatics (PHI)
- Define public health surveillance and how data is used in public health
- Explain the significance of information technology in the field of public health
- Explain the significance of syndromic surveillance for early detection of bioterrorism, emerging diseases and other health events
- Explain the significance and scope of global public health informatics
- Understand the workforce needs and competencies of a public health informatician
- List several of the current surveillance systems used in the field of public health
- Explain the function and purpose of the Public Health Information Network

Introduction

Public health is another medical sector that has been greatly influenced by advances in information technology over the past two decades. Central to the core functions of public health is effective disease surveillance. The overarching goal has been to monitor a variety of medical diseases and conditions rapidly and accurately so as to intervene as early as possible to detect, prevent, and mitigate the spread of epidemics, the effects of natural disasters, and bioterrorism. With the advent of the internet, ubiquitous computing, electronic health records

and health information organizations, this vision is now possible.

For much of the 20th Century, public health reporting and surveillance consisted of physicians, hospitals and clinics sending paper reports to local health departments, that in turn forwarded information to state health departments who sent the final data to the Centers for Disease Control and Prevention (CDC) via mail or fax and finally to the World Health Organization (WHO) for certain diseases. Although paper reports are still used, the shift to electronic media and information technology has

facilitated—more efficient methods of public health surveillance, community based outbreak detection and disease control.

The most critical component in any disease investigation is the availability of timely data and information to pinpoint the possible source of the outbreak. The proliferation of information technology into public health and medical fields have significantly improved disease surveillance and enhanced early detection of community or population based epidemics. Global events, ranging from the September 11, 2001 terrorist attacks, the emergence of severe acute respiratory syndrome (SARS) in 2002 in China and Middle East respiratory syndrome (MERS) in 2012, to the recent global H1N1 influenza outbreak reinforces the need for robust interoperable surveillance systems. The terrorist events of September 11, 2001 in particular, the subsequent anthrax attacks across the United States elevated and reinforced public health to a national security issue increasing the need for biosurveillance and real-time data analysis to detect and respond to disease outbreaks and health events more rapidly.

In the following sections public health informatics (PHI) definitions, public health surveillance systems, syndromic surveillance, geographic information systems and global public health informatics are discussed.

Definitions

- Public health: “the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals.”¹
- Public health informatics: “the systematic application of information and computer science and technology to public health practice, research and learning....”²
- Public health surveillance: “the ongoing systematic collection, analysis, and interpretation of health-related 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 final link in the surveillance chain is the application of these data to prevention and control.”³

- Syndromic surveillance: “surveillance using health-related data that precede diagnosis and signal a sufficient probability of a case or an outbreak to warrant further public health response.”⁴

Public Health Surveillance

Public health surveillance is essential to understanding the health of a population. Until recent years, public health surveillance was primarily paper-based. However, with the increasing shift towards eHealth, public health surveillance has embraced the field of public health informatics.⁵ In order to monitor disease events in a large population one needs interoperable technologies such as standards-based networks, databases and reporting software. Current electronic surveillance systems employ complex information technology and embedded statistical methods to gather and process large amounts of data and to display the information for networks of individuals and organizations at all levels of public health. Public health surveillance serves to:

- Estimate the significance of the problem
- Determine the distribution of illness
- Outline the natural history of a disease
- Detect epidemics
- Identify epidemiological and laboratory research needs
- Evaluate programs and control measures
- Detect changes in infectious diseases
- Monitor changes in health practices and behaviors
- Assess the quality and safety of health care, drugs, devices, diagnostics and procedures
- Support planning ⁶

Types of Surveillance Systems

Public health surveillance systems can be classified based on data collection purpose and

design. Table 21.1 demonstrates the more common categories.⁷⁻¹¹

Table 21.1: Types of Surveillance Systems

Surveillance System	Definition/Description	Examples
Case surveillance systems	<p>Collect data on individual cases of a health event or disease with previously determined case definitions in respect to criteria for person, time, place, clinical & laboratory diagnosis</p> <p>Analyze case counts and rates, trends over time and geographic clustering patterns</p> <p>Historically, case surveillance has been the focus of most public health surveillance.</p>	National Notifiable Disease Surveillance System (NNDSS)
Syndromic surveillance systems	<p>Collect data on clusters of symptoms and clinical features of an undiagnosed disease or health event in near real time allowing for early detection, rapid response mobilization and reduced morbidity and mortality</p> <p>Data can be obtained through specific surveillance systems as well as existing epidemiologic data such as insurance claims, school and work absenteeism reports, over the counter (OTC) medication sales, consumer driven health inquiries on the Internet, mortality reports and animal illnesses or deaths for syndromic surveillance.</p> <p>Geographic and temporal aberration and geographic clustering analyses are performed with real-time syndromic surveillance data.</p> <p>Syndromic surveillance systems can also be used to track longitudinal data and monitor disease trends.</p>	<p>Real-time Outbreak Detection System (RODS)</p> <p>Biosurveillance Common Operating Network (BCON)</p> <p>BioSense 2.0</p>
Sentinel surveillance systems	<p>Collect and analyze data from designated agencies selected for their geographic location, medical specialty, and ability to accurately diagnose and report high quality data. They include health facilities or laboratories in selected locations that report all cases of a certain health event or disease to analyze trends in the entire population.</p> <p>Pros: Useful to monitor and identify suspected health events or diseases</p> <p>Cons: Less reliable in assessing the magnitude of health events on a national level as well as rare events since data collection is limited to specific geographic locations.</p>	<p>PulseNet</p> <p>FoodNet</p> <p>ILINet</p>

Table 21.1: Types of Surveillance Systems (cont.)

Surveillance System	Definition/Description	Examples
Behavioral surveillance systems	<p>Collect data on health-risk behaviors, preventative health behaviors, and health care access in relation to chronic disease and injury.</p> <p>Analyze the prevalence of behaviors as well as the trends in the prevalence of behaviors over time.</p> <p>Information is most commonly collected by personal interview or examination</p> <p>Inferential and descriptive analysis methods such as age-adjusted rates, linear regression, and weighted analyses are used.</p> <p>Most acute when conducted regularly, every 3 to 5 years</p>	<p>Behavioral Risk Factor Surveillance System (BRFSS)</p> <p>Youth Risk Behavior Surveillance System (YRBSS)</p> <p>National Health Interview Survey (NHIS)</p> <p>Pregnancy Risk Assessment Monitoring System (PRAMS)</p>
Integrated Disease Surveillance and Response (IDSR)	<p>Incorporates epidemiologic and laboratory data in systems designed to monitor communicable diseases at all levels of the public health jurisdiction, particularly in Africa.</p> <p>Useful for: detecting, registering and confirming individual cases of disease; reporting, analysis, use, and feedback of data; and preparing for and responding to epidemics.</p>	
Clinical Outcomes Surveillance	<p>Monitors clinical outcomes to study disease progression or regression in a population.</p> <p>Analyzes the rates of and factors associated with clinical outcomes using descriptive and inferential methods such as incidence rates from probability samples</p>	<p>Medical Monitoring Project that monitors and tracks HIV patients</p>
Laboratory Based Surveillance	<p>Collects data from public health laboratories, which routinely conduct tests for viruses, bacteria, and other pathogens.</p> <p>Used to detect and monitor infectious and food-borne diseases based on standard methods for identifying and reporting the genetic makeup of specific disease-causing agents.</p> <p>Commonly used in case surveillance and sentinel surveillance</p>	<p>PulseNet</p> <p>National Case Surveillance for Enteric Bacterial Disease (CDC)</p>

The CDC has a helpful web page dedicated to surveillance programs for state, tribal, local and territorial public health officials.¹²

Syndromic Surveillance

Syndromic surveillance is part of meaningful use; therefore a basic understanding is important. Syndromic surveillance means symptoms are monitored (like diarrhea or cough) before an actual diagnosis is made. If, for example, multiple individuals complain of stomach symptoms over a short period of time, one can assume there is an outbreak of gastroenteritis. The important thing to remember is that syndromic surveillance systems do not identify the cause of the outbreak, rather they provide data comparisons which allows public health official to initiate outbreak investigation techniques.

In addition to the obvious sources of health data, public health officials can also monitor and analyze: unexplained deaths, insurance claims, school absenteeism, work absenteeism, over the counter medication sales, Internet based health inquiries by the public and animal illnesses or deaths.⁸

Initially, public health officials were very interested in detecting trends or epidemics in infectious diseases, such as severe acute respiratory syndrome (SARS) and avian influenza. After the terrorist attacks and anthrax outbreak in 2001, they have had to improve biosurveillance to detect bioterrorism. The objective is to “identify illness clusters early, before diagnoses are confirmed and reported to public health agencies and to mobilize a rapid response, thereby reducing morbidity and mortality.”¹³ The challenge is to develop elaborate systems that can sort through the information and reduce the signal to noise ratio. The syndrome categories most commonly monitored are:

- Botulism-like illnesses
- Febrile (fever) illnesses (influenza-like illnesses)
- Gastrointestinal (stomach) symptoms
- Hemorrhagic (bleeding) illnesses

- Neurological syndromes
- Rash associated illnesses
- Respiratory syndromes
- Shock or coma

Ambulatory electronic health records (EHRs) are a potentially rich source of data that can be used to track disease trends and biosurveillance. EHRs contain both structured (e.g. ICD-9 coded) data as well as narrative free text. Hripcsak et al. assessed the value of outpatient EHR data for syndromic surveillance. Specifically, they developed systems to identify influenza-like illnesses and gastrointestinal infectious illnesses from Epic® EHR data from 13 community health centers. The first system analyzed structured EHR data and the second used natural language processing (MedLEE processor) of narrative data. The two systems were compared to influenza lab isolates and to a verified emergency room (ER) department surveillance system based on “chief complaint.” The results showed that for influenza-like illnesses the structured and narrative data correlated well with proven cases of influenza and ER data. For gastrointestinal infectious diseases, the structured data correlated very well but the narrative data correlated less well. They concluded that EHR structured data was a reasonable source of biosurveillance data.¹⁴

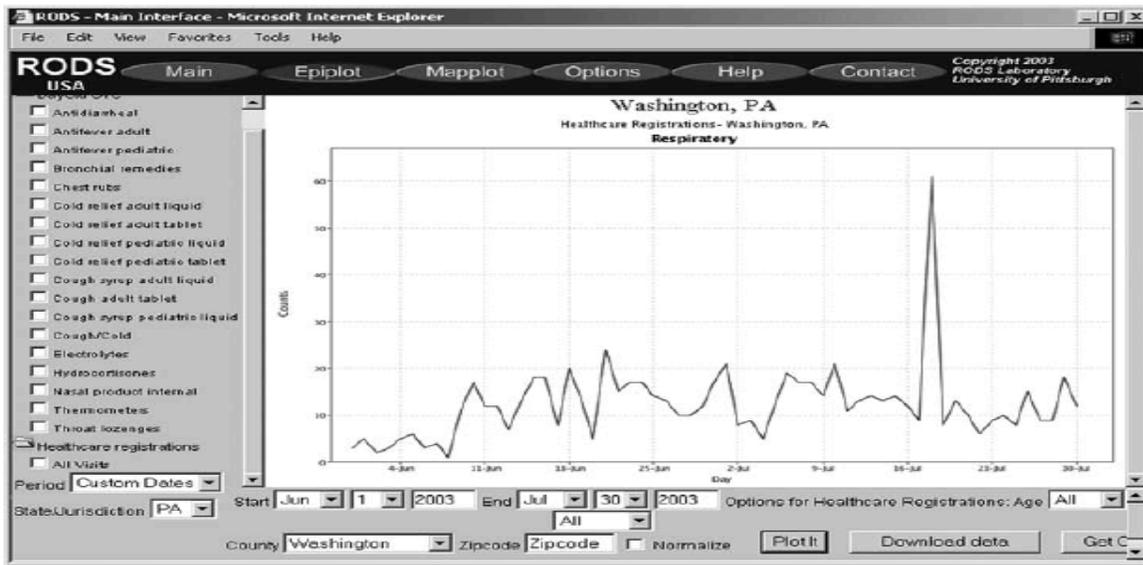
Real-Time Outbreaks Detection System (RODS)

The RODS system was initially developed by researchers at the University of Pittsburg and was the first real-time detection system for outbreaks. RODS collected patient chief complaint data from eight hospitals in a single health-care system via Health Level 7 (HL7) messages in real time, categorized these data into syndrome categories by using a classifier based on International Classification of Diseases, Ninth Revision (ICD-9) codes, aggregated the data into daily syndrome counts and analyzed the data for anomalies possibly indicative of disease outbreaks. Much like the ESSENCE system, RODS system started with a set of mutually exclusive and exhaustive categories of eight syndromic categories.

However, as the program has gone through revisions and refinement, the categories have been reduced to seven as follows: respiratory, gastrointestinal, botulinic, constitutional,

neurologic, rash and hemorrhagic. Figure 21.1 shows the daily counts of respiratory cases for Washington County, PA, in the period June-July 2003 utilizing RODS.

Figure 21.1: Daily counts of respiratory cases six month period, Washington County, PA 2003



Source: Real-Time Outbreak and Disease Surveillance project.
 * The June 2003 increase corresponds to new hospitals being added to the system.
 † The sudden increase on July 18, 2003, was caused by 60 persons reporting to one emergency department within 4 hours for carbon monoxide exposure.

In order to increase the adoption of the RODS system, the University of Pittsburg started offering software free of charge to public health departments. In 2003 the software was offered under an open source license and since then many more agencies have adopted the software for their use.¹⁵

Distribute

This project was created by the International Society for Disease Surveillance (www.syndromic.org), with the goal of supporting emergency department (ED) surveillance of influenza like illnesses (ILI). Figure 21.2 shows ILI reported over the last year in south eastern United States (region IV).¹⁶

Figure 21.2: Proportion of ED visits for ILI weekly 2011 (Courtesy Distribute)

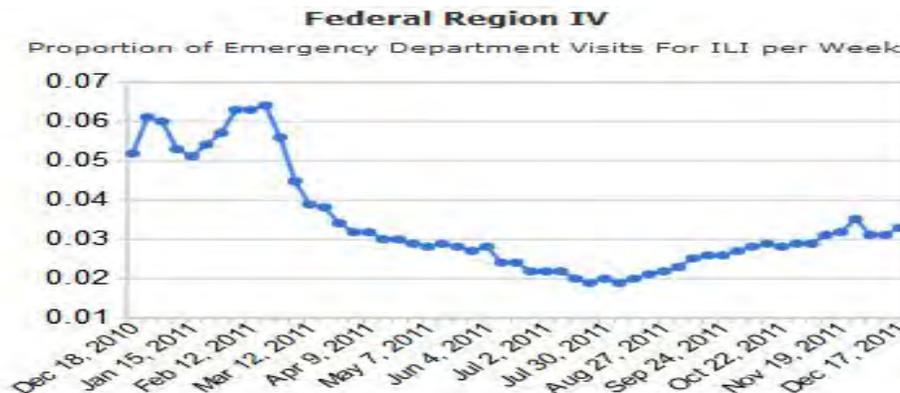
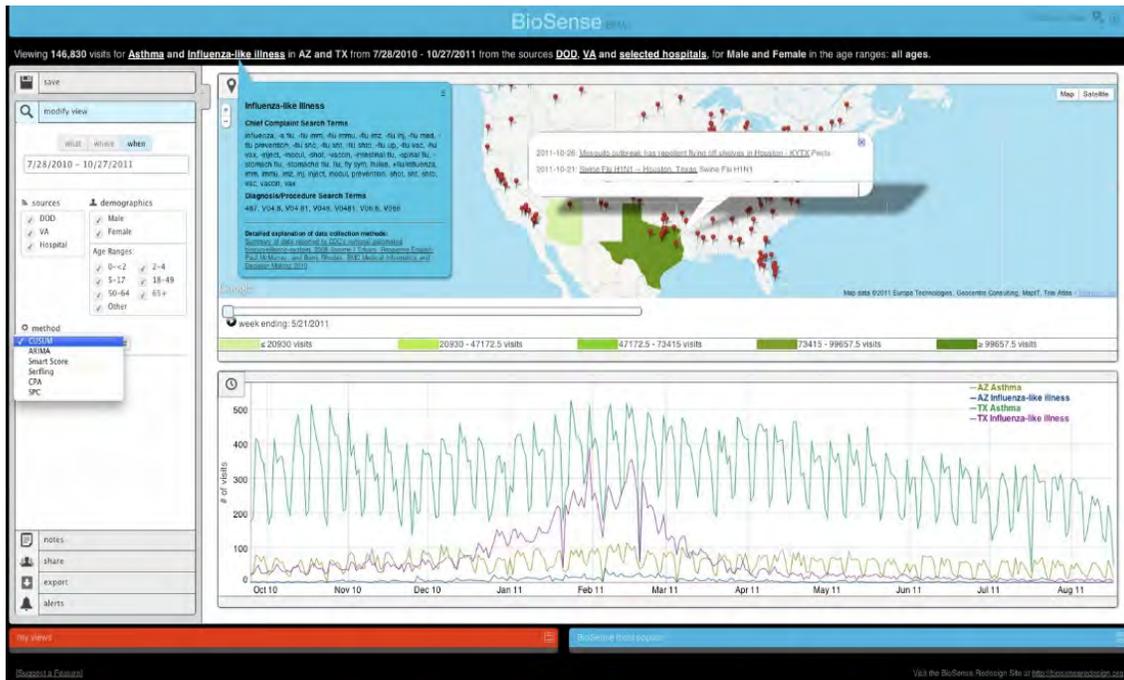


Figure 21.3: Data view in BioSense



BioSense

This is a CDC national web-based program to improve disease detection, monitoring and situational awareness for healthcare organizations in the United States by reporting emergency room, pharmacy and laboratory data. Participants include DOD (333), Veterans Affairs (770) and civilian hospitals (532) (2008 data). The program addresses identification, tracking and management of naturally occurring events as well as bioterrorism. BioSense is different from other automated syndromic surveillance programs in several ways.¹⁷ In 2010 BioSense was redesigned to integrate existing syndromic surveillance systems and allow for better regional sharing of information. The 2011 BioSense 2.0 allowed state and local health departments to access data that would support syndromic surveillance systems under meaningful use. A search engine can conduct a query by syndrome, location and date. De-identified data cannot be shared with any other entity, including the CDC without permission. The "data view" option will enable viewers to view data displayed in a variety of formats and will include basic statistical analysis. Figure 21.3

provides a screen shot of the data view. The goal is to provide a web based clearinghouse where data can be stored, searched and analyzed from and by multiple parties; decreasing the need for local health departments to purchase additional expensive information technologies.¹⁸ As of mid-2013 forty states or public health departments have signed data use agreements (DUAs).¹⁹ Clearly, the widespread adoption of EHRs and HIE adoption will assist this effort.

The Public Health Information Network

The Prevention and Public Health Fund, as part of the Affordable Healthcare Act of 2010, in conjunction with the Health Information Technology for Economic and Clinical Health (HITECH) Act allowed the public health infrastructure to move into the eHealth era. Driven by the mission to prevent, reduce and treat disease, these initiatives focus on developing interoperable public health information systems that are beneficial to the healthcare of all Americans.²⁰⁻²¹

The Public Health Information Network (PHIN) is a Centers for Disease Control and Prevention (CDC) initiative established to provide the framework for efficient public health information access, exchange, use, and collaboration among multi-level public health agencies and partners using a consensus of shared policies, standards, best practices, and services.²²

Establishing messaging and vocabulary standards is a key strategy for PHIN, allowing for consistent interoperability between local, state and national public health entities as well as other agencies. The PHIN Strategic Plan for 2011-2016 can be found on the CDC web site. The PHIN is currently working with the following standard development organizations (SDOs): Systematic Nomenclature for Medicine (SNOMED), Logical Observation Identifiers Names and Codes (LOINC), Health Level 7 (HL7), and Consolidated Health Informatics Initiative (CHI).²³⁻²⁴ For more information about these data standards, readers are referred to the chapter on data standards.

Meaningful Use and Public Health

The vision of the PHIN is similar to the vision of the nationwide health information network (NHIN). Both require standards, policies and procedures for secure transmission of healthcare data. Integral to that vision is the need for electronic health records and sharing of health information. Stage 1 and 2 Meaningful Use have several core and menu requirements for eligible professionals (EPs) and eligible hospitals (EHs) that impact public health:

- The capability to electronically transmit immunization data to immunization registries or immunization information systems. EPs or EHs must test the ability to transmit a HL7 message to a local public health agency.
- The capability to electronically transmit reportable lab results (as determined by state or local law). EHs only must use HL7 2.added a few words here.5.1 and LOINC to test the ability to transmit electronic

messages from the lab to public health agencies.

- The capability to electronically transmit syndromic surveillance data from an EHR. EPs and EHs must test the ability to transmit HL7 messages of syndromic surveillance data to public health agencies, which may include input into BioSense 2.0.
- The capability of EPs to report cancer cases to a state registry from a certified EHR.
- The capability of EPs to report specific cases to a non-cancer state registry from a certified EHR.²⁵

More public health reporting is likely as a result of Meaningful Use for EHRs but a broader approach would be aggregating EHR/data shared with a health information organization (HIO). For further information about health information exchange readers are referred to the chapter on HIE.

A recent article outlined use cases that demonstrate the utility of HIE in public health:

Mandated reporting of lab diagnoses: there is a predefined list of *notifiable diseases* (e.g. TB) that would benefit from electronic transmission to public health. In spite of that many states still rely on paper and results must be mapped to a standard vocabulary such as LOINC. A health information organization (HIO) could ensure proper identification, archiving and mapping. Mandated reporting could also trigger an alert of reportable diseases.

Non-mandated reporting of lab data: There are several infectious diseases of interest that are not on the notifiable list but ideally tracked by public health. Additionally, antibiotic resistance patterns should be reported and shared with public health. A community wide antibiogram could be developed to educate local physicians about optimal prescribing patterns.

Mandated reporting of physician-based diagnoses: physicians are separately required to report certain *notifiable diseases* but reporting is highly variable. This could be made easier with EHR reporting to the local HIO that

in turn reports to public health. Data standards would be essential and alerts to appropriate public health staff, infection control officers, etc. would be possible.

Non-mandated reporting of clinical data: syndromic surveillance will require symptom-related data from EHRs and emergency departments (EDs) to be sent and analyzed.

Public health investigation: public health officials could query the HIO for additional clinical or demographic (age, gender, location, etc.) information about a case of interest.

Clinical care in public health clinics: clinicians who treat patients in public health clinics could potentially benefit from access to a HIO.

Population-level quality monitoring: HIE has the potential to give public health officials a glimpse of the quality of medical care in their area without chart reviews, across multiple health care systems.

Mass-casualty events: HIOs might serve as a single point of contact for victims of a mass casualty. A record locator service might be able to keep track of admissions, discharges and transfer (ADT) data for the victims and their families.

Disaster medical response: HIOs have the potential to make available patient data during a disaster when paper records might be destroyed or unavailable.

Public health alerting - patient level: Theoretically, public health departments could alert all clinicians in a HIO about a case of TB where follow up is lost, for example. Public health officials could also warn hospitals about unique cases of highly resistant infectious organisms, particularly when patients tend to seek medical care at multiple institutions.

Public health alerting - population level: Clinicians could be warned about trends in the community, for example viral culture results or antibiotic resistance trends.²⁶

Geographic Information Systems (GISs)

Epidemiologists often characterize data by place, time and person. As early as 1855, Dr. John Snow created a simple map to show where patients with cholera lived in London in relation to the drinking water source in the Soho District of London. Using his hand drawn map and basic epidemiological investigation techniques, much of which are still used today, he determined the source of the epidemic to be a common water pump. Epidemiology, public health surveillance and indeed the field of public health have improved significantly since the pioneer work of Snow and others after him. Much of this transformation has been the result of the emergence and proliferation of advanced computing technologies, the internet and other automated information systems that have facilitated the amalgamation of large datasets to map out disease patterns.

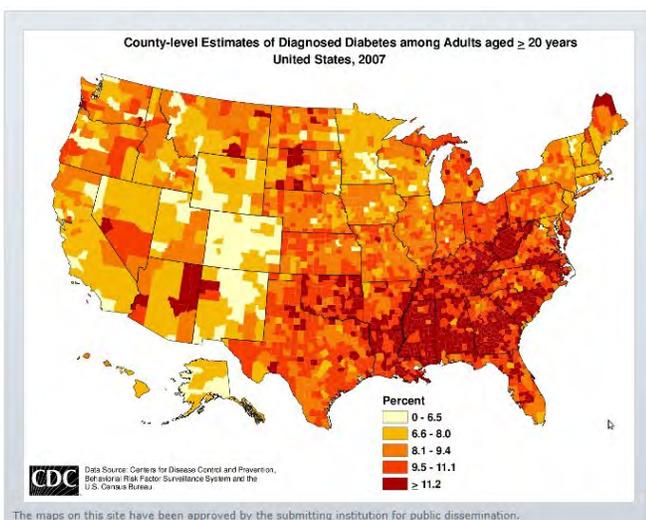
Modern geographic information systems (GIS) use digitized maps from satellites or aerial photography. A Geographic Information System (GIS) is a system of hardware, software and data used for the mapping and analysis of geographic data. GIS provides access to large volumes of data; the ability to select, query, merge and spatially analyze data; and visually display data through maps. GIS can also provide geographic locations, trends, conditions and spatial patterns. Spatial data has a specific location such as longitude-latitude, whereas attribute data is the database that describes a feature on the map.

GIS maps are created by adding layers. Each layer on a GIS map has an attribute table that describes the layer. The data can be of two types: *Vector* or *Raster*. *Vector* data appears as points, lines or polygons (enclosed areas that have a perimeter like parcels of land). *Raster* data utilizes aerial photography and satellite imagery as a layer. Using GPS and mobile technology, field workers can enter epidemiologic data to populate a GIS. This geospatial visualization has been useful in

tracking infectious diseases, public health disasters and bioterrorism.²⁷⁻²⁸

With the recent shift in public health focus to preventable chronic diseases, GIS has also been used to monitor chronic diseases and social and environmental determinants of health for public health policy. In early 2011, the Centers for Disease Control and Prevention launched a new project, Chronic Disease GIS Exchange. Designed for public health professionals and community leaders, GIS experts will use as an information exchange forum to network and collaborate with the goal of preventing heart disease, stroke and other chronic diseases. Data and information shared in this forum will be used in documenting the disease burden, informing policy decisions, enhancing partnerships and facilitating interventions from the use of GIS data.²⁹⁻³¹ Figure 21.4 shows a GIS display of diabetes incidence rates by State. The CDC has developed a specific tool known as the Diabetes Interactive Atlas that will display diabetes incidence by state or county from years 2004-2010 and produce a downloadable map similar to Figure 21.4.³²

Figure 21.4: GIS Map of diabetes diagnosis by county (Courtesy CDC Chronic Disease GIS Exchange)



Virtually all of the biodetection systems mentioned have a GIS component that allows for the mapping of disease outbreak events giving public health practitioners the ability to timely deploy resources to control the outbreak and prevent further spread. Key variables can be inputted by zip code, latitude, longitude, that help public health disease investigators narrow down the source of the problem.

HealthMap is a global project to integrate infectious disease news and visualization using an Internet geographic map. This program classifies alerts by location and disease. Users can select “malaria” and “global” and see if there were any reported cases in the past 30 days. “Mouseover” an icon and the user can see what is being reported in that area. A smartphone app “Outbreaks near me” details infectious disease outbreaks, e.g. H1N1 (swine flu), by locale, in near real time. Both the web-based and mobile app alerts the user of a local outbreak and allows the user to submit information about possible local outbreaks (crowdsourcing). The project also includes The Disease Daily that discusses infectious disease-related news around the world.³³ The open-source program was developed by the Harvard-MIT Division of Health Sciences and Technology, based on Google Maps and a more detailed explanation of the system and architecture is provided at this reference.³⁴ Figure 21.5 shows a GIS display of global avian flu outbreaks.

Asthmapolis is a GPS-enabled inhaler that can track compliance of rescue inhalers and syncs that information wirelessly to the user’s smartphone via Bluetooth. In addition, there is an electronic diary to track symptoms and compliance with controller/maintenance medications. Data on how often the inhaler is used and where is uploaded to a web portal that can be viewed by both the patient and the physician. Patients can receive weekly emails as feedback regarding trends. For example, they can view inhaler use based on day of week, night versus day, etc. They will see where inhaler use occurred and a statement whether their symptoms indicate good control, based on national guidelines. This approach provides

both a spatial and temporal view of where asthma symptoms occur (possible

environmental triggers) which may also benefit asthma research.³⁵

Figure 21.5: GIS display of global avian influenza outbreaks (Courtesy HealthMap)



Public Health Data Tools and Statistics

Central to public health and epidemiology is the need for high quality population data and the necessary analytic tools. Several new databases that are related to chronic diseases are included in the chapter on disease management. Partners in Information Access for the Public Health Workforce is a collaboration of US government agencies, public health organizations and health sciences libraries that hosts online a wealth of health data and tools. The following are categories under *Health Data Tools and Statistics* on the web site:³⁶

- County and Local Health Data
- State Health Data
- Individual State Data
- National Health Data
- Global Health Data
- Statistical Reports
- Demographic Data
- Geographic Information Systems (GIS)
- Training and Education
- Health Information Technology and Standards

- Tools for Data Collection and Planning

Other Public Health Data Sources include those administered by the Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS).³⁷ Some of these data sources have the unique advantage that they survey large samples of the US population.

The National Health Interview Survey (NHIS): Established in 1957, the NHIS is an annual surveillance tool that assesses the health status of Americans by collecting data on a broad range of health topics through personal and household interviews. Survey results have been instrumental in providing data to track health status, health care access, and progress toward achieving national health objectives. Statistics from 2013 are available on their web site.

The National Health and Nutrition Examination Survey (NHANES): The National Health and Nutrition Examination Survey (NHANES) is the most comprehensive survey system from the CDC and gathers data on the health and nutritional status of adults and children in the United States. Unlike most NCHS data survey instruments that only gather data based on interviews, NHANES combines interviews, laboratory, and physical examinations data. Data in NHANES includes infectious as well as chronic diseases allowing for more comprehensive analyses. The downside of this data source is that the sample

size tends to be smaller than that found in other NCHS data files.

The National Survey of Family Growth (NSFG) gathers information on family life, marriage and divorce, pregnancy, infertility, use of contraception, and men's and women's health on a longitudinal timeframe. The survey results are used by the U.S. Department of Health and Human Services and others to plan health services and health education programs, and to do statistical studies of families, fertility, and health. These data, unlike most NCHS datasets allows for trends analysis and is best suited for chronic disease surveillance and examination of trends in harmful health behaviors.

National Health Care Surveys are designed to answer key questions of interest to health care policy makers, public health professionals, and researchers. These can include the factors that influence the use of health care resources, the quality of health care, including safety, and disparities in health care services provided to population subgroups in the United States. Health Care Surveys collects from key health care providers and other public health entities that include:

1. Physician Offices and Community Health Centers
2. Hospital Emergency and Outpatient Departments
3. Ambulatory Surgery Centers
4. Hospital Inpatient Care
5. Nursing Homes
6. Nursing Assistants
7. Home and Hospice Care Agencies
8. Home Health and Hospice Aides
9. Residential Care Facilities

Project Tycho is a program hosted by the University of Pittsburgh Public Health department. They have digitized weekly disease surveillance reports for the United States from 1888-2013 for research purposes. After registration, users can access the data that are

associated with various filters. Several levels of data are available:

- Level 1 data includes 8 infectious diseases from 50 states during the time span of 1916-2009. They were able to show the benefits of immunizations and also demonstrated that some infectious diseases such as measles and pertussis resurfaced. Results were published in 2013³⁸
- Level 2 data includes 47 diseases from 50 states during the time span of 1888-2013. Figure 21.6 shows the history of pertussis reporting in the state of Florida from 1937-2013. Note there are gaps in the data.
- Level 3 data includes 56 diseases from 50 states during the time span of 1887-2013 but have not been standardized yet. They are available upon request³⁹

Public Health Informatics Workforce

As discussed, in order to most accurately and efficiently study the health of the population, information and communication technologies are essential to support the increasing demand for large public health research and evidence based public health practice as a result of the aging US population. These technologies also require a diversity of human expertise for management, analysis, and communication of public health data. The Association of Schools of Public Health (ASPH) estimates that the field of public health will require 250,000 more workers by 2020 to avert a national public health crisis.⁴⁰ The transition to eHealth requires all public health workers to have some knowledge of IT depending on the demands of their position. In anticipation of this need, the CDC in collaboration with the University of Washington's School of Public Health and Community Medicine's Center for Public Health Informatics developed a list of informatics competencies for public health workers to meet the needs of the evolving public health field as well as for the Public Health Informatician. A Public Health Informatician is "a public health professional who works in practice, research, or

academia and whose primary work function is to use informatics to improve population health.”⁴¹ In addition, the CDC now offers an applied two year Public Health Informatics Fellowship Program for professionals.⁴²

Global Public Health Informatics

Public health threats from chronic and infectious diseases, population health status, and health disparities within and across countries have gained global attention in part due to increasing personal mobility, economic globalization, and expansion of communication technologies. In fact, the global threat from chronic diseases was the focus of the 2011 UN General Assembly. Infectious diseases, such as influenza, polio, MERs, SARs and HIV/AIDS, can quickly spread across national borders and are best curtailed through international cooperation and timely information sharing. New or re-purposed health information technologies provide critical support in the identification, monitoring, alerting, and responding to emerging diseases, pandemics, bioterrorism, and natural disasters. Simultaneously, health informatics has also emerged as an important tool in addressing population health goals and as a means to reduce health disparities between *developed* and *developing* nations.

World Health Organization

The leading international public health entity is the World Health Organization (WHO). Organized in 1948 as an agency of the United Nations (UN), WHO directs and coordinates public health efforts worldwide. WHO and its 195 Member States collaborate with other UN agencies, nongovernmental organizations, and the private sector to:

Foster health security: Through its surveillance and disaster/epidemic response systems, WHO works to identify and curb outbreaks of emerging or epidemic-prone diseases. The revised 2007 International

Health Regulations address the major forces contributing to epidemics including urbanization, environmental mismanagement, food preparation, and the overuse of antibiotics.

Promote health development: Through this objective WHO works to increase access to life-saving and health-promoting interventions, particularly in poor, disadvantaged, or vulnerable groups. WHO’s health development efforts focus on the treatment of chronic and infectious disease (e.g. diabetes), prevention and treatment of tropical diseases (e.g. malaria), women’s health issues, and healthcare within African nations.

Strengthen health systems: In poor and medically underserved areas, WHO endeavors to strengthen and supplement existing health systems. Activities include providing trained healthcare workers, access to essential drugs, and assistance in collecting vital health information.⁴³

As discussed throughout this section, WHO increasingly relies on health information technology to carry out its objectives.

International Surveillance and Response Programs

The most visible role of WHO is to detect and respond to infectious disease outbreaks, pandemics, and disaster emergencies. Global surveillance of infectious disease, famines, and environmental disasters is implemented through a network of regional, national, and international institutes. Government organizations (e.g. CDC), military networks (e.g. US Department of Defense’s Global Emerging Infections Surveillance and Response System), and a host of public and private nongovernmental organizations (NGOs) (e.g. Google, HealthMaps) monitor and report infectious diseases to WHO. Additionally, internet sites such as Epi-X or Pro-Med maintain discussions on current infectious diseases.

A 2007 review of 15 international surveillance and response programs (ISRPs) classified their activities into four basic components:

surveillance, reporting, verification, and response.⁴⁴ The report found that the majority of these ISRPs focus on surveillance and reporting, while only six carry out all four activities. These six ISRP as well as other leading surveillance systems are described in the Appendix of this chapter.

Regardless of the surveillance component performed by an ISRP, these organizations have benefited from the expansion of health information technology into the surveillance arena. Over the past decade, WHO and ISRPs have embraced web-based computing, mobile applications, GIS, and even text messaging. The role of health informatics within the major global surveillance organizations are discussed below.

Global Alert and Response (GAR): GAR is the integrated infectious disease surveillance program within WHO. A network of national, regional, and international agencies, governmental organizations (e.g. CDC) and military networks (e.g. US Department of Defense's Global Emerging Infectious Disease), GARs primary function is the facilitation of epidemic preparedness and response worldwide. This body is also responsible for maintaining and enhancing the global outbreak and bio-risk operational platforms.⁴⁵ Global monitoring and coordination are increasingly important in light of recent public health challenges such as outbreaks of severe acute respiratory syndrome (SARS) and influenza A (H1N1), the AIDS epidemic, and emerging new diseases and pathogens. Electronic surveillance capabilities have greatly enhanced the ability of GAR and its component functions to identify and respond to public health emergencies. Subsidiary functions under GAR include:

International Health Regulations: 2005 revisions to WHO's International Health Regulations (IHR) are aimed at improving global public health security and collaborative response to natural disasters, biological or chemical agents, and radioactive material release.⁴⁶ This legally-binding agreement provides a framework for the management of international public health emergencies, while

also addressing the capacity of participating nations to detect, evaluate, alert, and respond to public health events. IHR specifies operational procedures for disease surveillance, notification and reporting of public health events and risks as well as for the coordination of international response to those events. The 2005 IHR allowed for the first time non-governmental sources to provide surveillance information to WHO. Participation by non-governmental contributors is as a positive step that pushes WHO to become more "dynamic, flexible, and forward-looking."⁴⁷

Early Warning Surveillance: GAR implemented an early warning and response network (EWARN) surveillance mechanism to effectively identify disease outbreaks and other health issues immediately following acute emergencies. An initial version of the system has been in use in Haiti since the 2008 hurricane and expanded following the devastating Haitian earthquake in 2010. The system monitored public health issues such as injuries, mental health concerns, TB and HIV treatment programs, and disease trends. Inconsistency of data reporting, lack of trained personnel for data collection and technological errors among other problems interfered with the project from the start.⁴⁸ One solution that was developed in response to these challenges was a "virtual Google group" set up to improve communication. In remote, undeveloped areas of the world, WHO has encouraged Member States to develop early warning systems that use a variety of media including fax, telephone, the internet, and SMS to connect district or national surveillance officers with field collection efforts.

Global Public Health Intelligence Network (GPHIN): GPHIN was developed by the Public Health Agency of Canada to electronically monitor infectious disease outbreaks. Approximately 40 percent of the outbreaks investigated by WHO each year come from the GPHIN. This network "is a secure, internet-based 'early warning' system that gathers preliminary reports of public health significance in seven languages on a real-time,

Malaysia: Early Warning And Risk Navigation Systems



eWARNS is Malaysia's Early Warning And Risk Navigation Systems for natural disasters including rainfall, flash flood, soil erosion, landslide, tidal wave, and forest fire. Remote Sensing and Transmission Units (RSTU) placed throughout the country are used to predict floods and other natural disasters. Each RSTU collects rainfall data, senses the impact of the rain, and transmits the data via the internet to a receiving unit. The RSTU also acts as a web-server allowing the 'remote panel' to be viewed via the internet. The system alerts the public to real time risk levels and forecasts via SMS text messaging on their mobile phones. Information on daily rainfall, erosivity index, and erosion hazards are also available on the website.⁵¹

24/7 basis.”⁴⁹ GPHIN “continuously and systematically crawls web sites, news wires, local online newspapers, public health email services and electronic discussion groups for key words.⁵⁰ Although originally developed to detect infectious disease outbreaks, GPHIN now scans for food and water contamination, exposure to chemical and radioactive agents, bioterrorism, and natural disasters. It uses automated analysis to process the gathered data to alert human analysts to conduct additional review of any serious issues or trends. These data are then made available to WHO/GOARN and other subscribers through its web-based Microsoft/Java application and to the public through the WHO web site. GPHIN's automated data has significantly accelerated global outbreak detection.

Global Outbreak Alert and Response Network (GOARN): The Global Outbreak Alert and Response Network was established by WHO in 1997. GOARNS has 420 global partners to collaboratively provide a rapid identification

and response to outbreaks and alert the international community. Collaboration is provided by organizations like the Red Cross, the United Nations, humanitarian and scientific institutions, technical networks, laboratories, and surveillance and medical initiatives.⁵²

Since 2000, GOARN has responded to more than 50 events worldwide, including SARS, Avian influenza and H1N1 influenza outbreak. Over one third of the surveillance information coming into GOARN is provided by GPHIN. Other surveillance information is provided by governmental agencies, universities, military agencies, and non-governmental organizations (NGO), such as the Red Cross and Médecins sans Frontières (Doctors without Borders). To facilitate global coordination, GOARN has established standardized operating procedures to be used by Member States and partnering organizations for identifying and responding to outbreaks. Features of the system include: alerts to the international community about outbreaks and technical collaboration on the rapid identification and response to outbreaks.⁵² WHO's state of the art IT and communications systems ensure secure timely communications within GOARN and between GOARN and Member States and partnering entities thus facilitating the quick response and control of disease outbreaks.

Effective communication and collaboration between local and global responders to public health crises, hazards, and pandemics, is critical to successfully address the complex and diverse needs of the population after a disaster or during a public health emergency. GOARN and other responders recognize the benefit of integrating information and communication technology (ICT) into current operations.⁵³ Although sharing protocols of ICT appear to be a challenge, the emerging field of community informatics seems to provide the potential for inclusion of local health providers in emergency response efforts coordinated by global public health agencies.⁵² Figure 21.6 depicts the complex and interdependent communication that must occur to ensure coordination of the

Figure 21.6: Coordination between local and global public health organizations



local and global public health entities involved in disaster or public health emergency response.

Other Global Public Health Activities

Surveillance and response to emergent health events maybe the most visible, but they are not the only functions of public health organizations. Public health is responsible for the prevention and control of disease, chronic and communicable diseases such as HIV/AIDS, TB, and polio and also plays a key role in health promotion and education. Historically, WHO and other public health organizations have struggled to provide even the most basic services to remote and poor areas around the globe. Health technology, particularly *mHealth*, has enabled public health agencies to reach out to isolated villages, connect with paraprofessional field workers, collect data, diagnosis disease, deliver disease management instructions, provide proficiency training to healthcare workers, and educate patients. Some of the organizations that deploy health technology in the fight to improve global health are identified in Table 21.2.

Global Health Information Technology Programs

Listed in alphabetical order below are a few of the premier organizations that facilitate the use

of health information technology for public health:

Center for Innovation in Global Health Technologies (CIGHT):

A component of the Robert R. McCormick School of Engineering and Applied Science at Northwestern University, CIGHT collaborates with other universities, global healthcare companies, and non-profit organizations on the research and development of innovative and affordable healthcare technologies. The program focuses on three areas that are of concern in developing nations: HIV and associated diseases, saving lives at birth, and training healthcare workers to supplement physicians and nurses.⁵⁵

FHI360-SATELLIFE: Created in 1987, SATELLIFE is a leader in using information technology to connect healthcare providers in developing nations to vital medical knowledge. Its GATHERdata™ project uses mobile devices to collect, report, and analyze real-time disease surveillance data.⁵⁶

Global Public Health Informatics Program (GPHIP):

The Centers for Disease and Control (CDC) established a Global Public Health Informatics Program (GPHIP) in 2008 to collaborate with WHO and other international partners. “The Goal of GPHIP is to improve domestic and international public health informatics programs and advance the best informatics science, principles, strategies, standards, and practices.” GPHIP assists CDC-

Table 21.2: Global Efforts to Improve Public Health through the use of Health Information Technology

Organization	Public Health Informatics Services
Cell-Life http://www.cell-life.org/	A not-for-profit organization that deploys mobile technology in the fight against HIV and other communicable diseases, primarily in South Africa. It has effectively used SMS to encourage HIV testing, to remind women to continue in prevention programs to curb mother-to-child transmission of HIV, increase antiretroviral therapy adherence, and provide family planning information.
Datadyne http://www.datadyne.org/	Datadyne offers applications for the use of cell phones to collect data, sending of mass SMS messages, and to provide continuing education to healthcare workers in remote areas through mobile devices.
Dimagi http://www.dimagi.com/	Dimagi is a for-profit company that builds custom mobile health and SMS solutions for resource-poor environments. It offers Windows Mobile 5 software devices to assist community health workers to screen HIV/AIDS patients, personalized SMS medication reminders to increase antiretroviral adherence in HIV patients, a mobile solution to improve home-based cancer care coordination, a portable web application for remote clinics to send cancer screening images to hospital-based physicians, SMS alerts for critical events, mobile applications for continuing education of remote healthcare workers, and a mobile application to increase compliance with WHO's Integrated Management of Childhood Illness program by remote health workers.
E Health Point http://ehealthpoint.com/?page_id=77	This project uses telemedicine to connect rural Indian villages to physicians and evidence based healthcare.
Mobile Alliance for Maternal Action (MAMA) http://www.mobilemamaalliance.org/	MAMA is a public-private partnership involving the US Agency for International Development, Johnson & Johnson, the United Nations Foundation, mHealth Alliance and BabyCenter. MAMA uses mobile phones to send audio and text health messages and reminders to new and expectant mothers.
mHealth Alliance http://www.mhealthalliance.org/	The mHealth Alliance is a public-private partnership between the UN Foundation, the Rockefeller Foundation, and The Vodafone Foundation. Its purpose is to harness the power of wireless technologies to improve health outcomes in low and middle income countries.

supported countries on developing and implementing innovative public health informatics solutions. Collaborative projects supported by GPHIP include a mobile-based

information system for use in health emergencies and for surveys in China, an electronic integrated disease surveillance systems (EIDSS) in cooperation with Armenia,

Azerbaijan, Georgia, Kazakhstan, Saudi Arabia, Ukraine, and Uzbekistan, and a national disease surveillance (NDS) and a health surveillance network (HSN) in Saudi Arabia.⁵⁷

Information and Communication Technologies for Public Health Emergency Management (ICT4PHEM): Established by GAR in 2009, ICT4PHEM “is a technical collaboration of existing institutions and networks that pool human, technical and technological resources together to provide enhanced ICT solutions to predict, prevent and support Public Health Emergencies.”⁴⁹ The objective of ICT4PHEM is to deploy ICT in the detection, assessment, verification and response to public health threats throughout the world. The initial meeting was held in April 2009 to discuss the need to develop, enhance and make available ICT tools to public health entities worldwide.⁵⁸

WHO Global Observatory for eHealth (GOe): In 2005, the 58th World Health Assembly recognizing the need to incorporate emerging health information technologies into WHO and Member States adopted an eHealth strategy resolution. That same year WHO established GOe to study the impact of eHealth. The GOe conducted a survey of members in 2005 to establish a benchmark for each nation on its eHealth; a follow-up survey was conducted in 2009. Information on their findings relative to mobile technology, telemedicine, safety and security and other eHealth issues are available on their website.⁵⁹

Wireless Reach™: Through its Wireless Reach™ program, Qualcomm works with global partners to bring wireless technology to poor and remote areas around the world. Wireless Reach™ addresses education, entrepreneurship, public safety, and environment in addition to health. Its projects tend to be telemedicine related, although some have public health applicability.⁶⁰

Recommended Reading

The following are samples of recent interesting articles related to public health informatics:

- *Automated Surveillance of Clostridia difficile infections using BioSense.* This article confirmed that BioSense could be used for automated reporting of a serious cause of hospital and community acquired diarrhea (C. difficile). Data was transmitted using HL7, established case definitions and data standards such as LOINC and SNOMED-CT. The researchers were able to show that this new system could generate rates of infection very similar to other studies and therefore show the feasibility of using BioSense for meaningful use reporting.⁶²
- *Participatory Epidemiology: Use of Mobile Phones for Community-Based Health Reporting.* Authors from the CDC discuss the new concept of obtaining public health information from mobile phone users, in contrast to the traditional submission of infectious disease information from public health departments, hospitals, etc. It forms the basis for the creation of Outbreaks Near Me discussed in the paragraph on HealthMap. It ties together this chapter and the chapter on mobile technology.⁶³
- *Integrating Clinical Practice and Public Health Surveillance Using Electronic Medical Record Systems.* The authors describe a new platform (ESP) that integrates with commercial EHRs to improve public health surveillance reporting. It is in use in Massachusetts and Ohio. The software (open source) contains complex algorithms to extract data for reporting. Capabilities include notifiable disease reporting and diabetes surveillance (similar to a disease registry). Authors discuss the potential of such a system, as well as known limitations.⁶⁴

Future Trends

At the core of public health informatics is surveillance, a practice that relies on near-real time, high quality data. Largely because of the increased global use of the Internet, there is an

increase in analysis of aggregated data collected by both public and private organizations such as Google and various social media sites like Twitter and Facebook. Google.org recently launched three Internet-based projects utilizing revolutionary technology for public health research and policy development: *Google Flu Trends*, *Google Dengue Trends*, and *Google Crisis Response*. *Google Flu Trends* and *Dengue Trends* use aggregated data based on Google search queries to estimate disease activity in real-time.⁶³ Correlating strongly with data from the CDC, *Google Flu Trends* data is estimated to precede CDC results by about one

week.⁶⁶ Ultimately, this methodology may be shown to be the most effective and fastest way to identify pandemic flu. Another venue for data aggregation analysis is social media. By examining data aggregated by user posts, researchers are gaining insight into health perceptions and behaviors as well as early detection of potential disease trends. Though criticized early on for the possibility of false reports and lack of specificity and sensitivity, social media's freely available, "real time" and statistically significant data is becoming an essential tool for disease surveillance.⁶⁷⁻⁶⁸

Case Study

Mobiles in Malawi was initiated in the summer of 2007, by Josh Nesbitt who was working with a "rural Malawian hospital that serves 250,000 patients spread 100 miles in every direction. To reach remote patients, the hospital trained volunteer community health workers (CHWs) like Dickson Mtanga, a subsistence farmer. Dickson had to walk 35 miles to submit hand-written reports on 25 HIV-positive patients in his community. The hospital needed a simple means of communication." Seeing the need Josh returned to the hospital the following year with mobile phones and a laptop running *FrontlineSMS*. In late 2008, *Mobiles in Malawi* merged with *MobilizeMRS*, an electronic medical records initiative that trained CHWs in structured data collection. The coming together of these efforts resulted in the creation of *FrontlineSMS:Medic* whose "mission was to help health workers communicate, coordinate patient care, and provide diagnostics using low-cost, appropriate technology...."

"In six months, the pilot in Malawi using *FrontlineSMS* saved hospital staff 1200 hours of follow-up time and over \$3,000 in motorbike fuel. Over 100 patients started tuberculosis treatment after their symptoms were noticed by CHWs and reported by text message. The SMS network brought the Home-Based Care unit to the homes of 130 patients who would not have otherwise received care, and texting saved 21 antiretroviral therapy (ART) monitors 900 hours of travel time, eliminating the need to hand deliver paper reports."

Frontline SMS:Medic has since been deployed in Haiti after the 2010 earthquake where it was used by frontline disaster relief workers to text message urgent needs. "Using crowd-sourced translation, categorization, and geo-tagging, reports were created for first responders within 5 minutes of receiving an SMS. Over 80,000 messages were received in the first five weeks of operation, focusing relief efforts for thousands of Haitians."

"In less than one year, *FrontlineSMS:Medic* expanded from 75 to 1,500 end users linked to clinics serving approximately 3.5 million patients. Growing from the first pilot at a single hospital in Malawi, they established programs in 40% of Malawi's district hospitals and implemented projects in nine other countries, including Honduras, Haiti, Uganda, Mali, Kenya, South Africa, Cameroon, India and Bangladesh."

Frontline SMS has developed other mobile tools including: *PatientView*, a lightweight patient records system, *TextForms*, a text-based information collection module, and a messaging module for *OpenMRS*. *FrontlineSMS:Medic* recently changed its name to *Medic Mobile*.⁶¹

Key Points

- Public health informatics is an important sub-category of health informatics
- Public health reporting will be part of meaningful use stages 1-3
- Public health surveillance is very broad and covers infectious diseases, epidemics, natural disasters and bioterrorism
- Geographic information systems provide a convenient display of medical information overlaid on geographical interface
- A myriad of new national and global public health informatics-related initiatives have been established

Conclusion

Public health is concerned with the health of populations, instead of individuals. In order to study large populations and track trends in health and other public health activities, paper-based reporting is no longer tenable. A robust public health network will require data standards, electronic health records and health information exchange. As a result of the HITECH Act and Affordable Care Act healthcare is moving closer to the ideal goal of almost real time public health surveillance and reporting.

Given the broad spectrum of health events, one of the major challenges for public health professionals in designing and implementing effective surveillance systems is the need for consistent case definitions for the disease being tracked. This may not be necessarily a major problem with infectious diseases which for the most part have one unique etiologic agent. Chronic diseases with multiple causative factors may present a challenge, in that different data systems would have different case definitions for the same disease.

APPENDIX 21.1

International Surveillance Systems and Platforms (Adapted from Castillo-Salgado, 2010)⁴⁶

Name	Institution	Website Address	Components	Description and Activities
BTRP (Biological Threat Reduction Program)	Defense Threat Reduction Agency (US DoD)	http://www.dtra.mil/Missions/Nunn-Lugar/BiologicalThreatReductionProgram.aspx	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting ✓ Verification ✓ Response 	Working with partner nations, BTRP's focus is to prevent the proliferation of expertise, materials, equipment and technologies that could contribute to the development of biological weapons.
EPR (Epidemic and Pandemic Alert and Response)	WHO	http://www.afro.who.int/en/clusters-a-programmes/dpc/epidemic-a-pandemic-alert-and-response.html	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting ✓ Verification ✓ Response 	EPR supports WHO Member States in the African Region to establish and implement functional integrated early warning and epidemic preparedness and response systems.
EUROFLU	WHO/European centers	http://www.euroflu.org/index.php	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Network of influenza morbidity and mortality surveillance reporting from health professionals in 53 countries and a laboratory network of European national influenza centers and two WHO influenza A/H5 reference laboratories.
GAINS (Global Animal Information System)	Wildlife Conservation Society with the support of USDA, USAID, FAO, and other agencies	http://www.gains.org	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Global initiative providing surveillance for influenza in wild birds. Collaborators in the GAINS network collect and analyze biologic samples from wild birds (which are caught and released), to identify locations of the avian influenza viral strain. The program disseminates information on avian influenza to governments, international agencies, and the public.
GDD (Global Disease Detection)	CDC	http://www.cdc.gov/globalhealth/gdder/gdd/	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting ✓ Verification ✓ Response 	GDD is CDC's principal program for developing and strengthening global capacity to rapidly detect, accurately identify, and promptly contain emerging infectious disease and bioterrorist threats that occur internationally.
GOARN (Global Outbreak Alert and Response Network)	WHO	http://www.who.int/csr/outbreaknet/ork/en/	<ul style="list-style-type: none"> ✓ Verification & Response 	The main surveillance network of the WHO with the collaboration of more than 140 institutions. Receives surveillance information from the GPHIN and official country sources. Its mission is the rapid identification/confirmation and effective response to disease outbreaks of international public health importance.

Name	Institution	Website Address	Components	Description and Activities
GEIS (Global Emerging Infections Surveillance and Response System)	US DoD	http://www.afhsc.mil/geis	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting ✓ Verification ✓ Response 	Designed to strengthen the prevention of, surveillance of, and response to infectious diseases that a) are a threat to military personnel and families, b) reduce medical readiness, or c) present a risk to U.S. national security. The DOD-GEIS mission is to increase DoD's emphasis on prevention of infectious diseases, strengthen and coordinate its surveillance and response efforts, and create a centralized coordination and communication hub to help organize DoD resources and link with U.S. and international efforts.
MedSys	European Commission	http://ec.europa.eu/health/ph_threats/com/preparedness/medical_intelligence_en.htm	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Surveillance system available only to European Union member countries. The system includes an information scanning tool to support the surveillance of communicable diseases and early detection of bioterrorism activities in Europe.
GPEI (Global Polio Eradication Initiative)	Public-private partnership; includes WHO, CDC, UNICEF, Rotary International, and national governments	http://www.polioeradication.org/	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting ✓ Verification ✓ Response 	The four cornerstones of GPEI's efforts to eradicate polio worldwide are: (1) routine immunization, (2) supplementary immunization, (3) surveillance, and (4) targeted "mop-up" campaigns.
GPHIN (Global Public Health Information Network)	Public Health Agency, Government of Canada	http://www.cdc.gov/globalhealth/GDD/gddoperation.htm	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Leading global web-based network providing surveillance information to WHO/GOARN and subscriber agencies. One of the first global monitoring systems using real time data from internet media sources to detect and report potential disease outbreaks.
HealthMap	Open-access GIS network supported by Google.org	http://www.healthmap.org/en	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Free internet GIS network collecting, organizing, and displaying infectious disease outbreaks. Integrates outbreak data of varying reliability, ranging from news sources to curated personal accounts (e.g. ProMED) to validated official alerts (e.g. WHO).

Name	Institution	Website Address	Components	Description and Activities
ProMED-mail (Program for Monitoring Emerging Diseases)	International Society for Infectious Diseases	http://www.promedmail.org/pls/apex/f?p=2400:1000	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Nonprofit, free email list network serving over 40,000 subscribers in more than 150 countries. Global electronic reporting system since 1993. One of the leading email surveillance-reporting systems.
Voxiva System	Private company	http://www.voxiva.com	<ul style="list-style-type: none"> ✓ Surveillance ✓ Reporting 	Electronic surveillance applications based on cell phones placed in remote places to report disease outbreaks. For use in low-resource environments.

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Chapter 22

eResearch

JOHN SHARP

Learning Objectives

After reading this chapter the reader should be able to:

- Understand the scope of eResearch and Clinical Research Informatics within the clinical research workflow
- Describe the use of EHR data in various phases of research including research originating from EHR data
- Conceptualize how informatics tools can be utilized in recruiting subjects for clinical research
- Detail how informatics supports the ongoing management of clinical trials
- Review the new trends in big data, real-time analytics and data mining

Introduction

Simply stated, eResearch refers to the use of information technology to support research. Within the past ten years, there has been a dramatic shift from paper-based records in research to almost completely electronic. Paper case report forms being transposed into spreadsheets or early database programs are rapidly disappearing. Now every aspect of clinical research is supported by informatics tools. Several factors enabled this rapid change: availability of open source programming, major support from the National Center for Research Resources of the National Institutes of Health for informatics, consolidation of field of clinical research informatics with the American Medical Informatics Association, and academic medical centers' move toward securing patient data as a result of HIPAA and HITECH. These forces accelerated the move toward informatics permeating clinical research. But

the most significant change is the adoption of electronic medical records. In a perspective from the New England Journal of Medicine titled "Evidence Based Medicine in the EHR Era" the authors give examples of how an electronic cohort of patient data in the electronic medical record (EHR) can be used in clinical decision support. They conclude: "the growing presence of EHRs along with the development of sophisticated tools for real-time analysis of de-identified data sets will no doubt advance the use of this data driven approach to health care delivery."¹ There is no doubt that health informatics and specifically eResearch will have a major impact on evidence based medicine in the future. In fact, there are now informatics solutions for every phase of the research process. This chapter will explore the current state of these tools and their usefulness in promoting clinical research.

Preparatory to Research

The first step for a researcher with a question is to research the literature. It has been well documented that the medical literature is growing at a rate which overwhelms the practicing physician and the clinical researcher. Informatics tools are increasingly needed to assist with sorting through the literature and creating a reasonable background for any study. Fortunately, PubMed offers an array of tools which can be utilized on the site or integrated into a website or application using web services and RSS feeds. Entrez Programming Utilities provide a catalog of XML scripts as well as Perl scripts and other tools for custom extraction of medical journal data. A mobile version is also available.² The National Library of Medicine sponsors App contests to improve searches and create visualizations to improve data analysis. Google Scholar provides a broader database search which includes PubMed but also other scientific and academic publications (scholar.google.com). Google Books provides access to excerpts of books and allows searches through published works as well (books.google.com). For more details on online medical resources and search engines, please see additional chapters.

ClinicalTrials.gov provides the researcher with a search of all registered clinical trials within the U.S. As with PubMed, ClinicalTrials.gov provides an open API (Application Programming Interface) for linking and XML for connecting through web services.³ For a wider search, the World Health Organization (WHO) provides a search tool which incorporates international trials.⁴ Both PubMed and WHO now have mobile versions of the clinical trial search tools.

Research collaboration networks have seen significant growth in recent years. Research networks are typically web-based applications which include features similar to other social networks, such as a personal profile, opportunities to connect with others with similar

interests and the ability to post status updates. Often research networks have personal profiles of researchers pre-populated with publications (thanks to integration with PubMed) and clinical trials (integration with ClinicalTrials.gov) and grants through the NIH Exporter.⁵ With these rich data sources, some research networks have created semantic connections between researchers (vivoweb.org). However, most research networks provide search tools to enable finding connections between those with common interests. Three tools stand out, although many have been developed:

- **Vivo.** An open source tool developed at Cornell University, Vivo is a semantic web application (common framework that allows data to be shared and reused across application)⁶
- **Harvard Profiles Catalyst.** This is an open source community of over 130 member institutions with built-in network analysis and data visualization tool⁷
- **SciVal Experts.** This commercial solution also has modules to find research funding and measure benchmarks⁸

Other available tools generate National Institutes of Health (NIH) biosketches and add publications and grants dynamically (see Figure 22.1). Since research networks are relatively new, there is not substantial evidence of their effectiveness beyond anecdotal examples.

In addition to finding collaborators, clinical researchers would like to know the feasibility of their studies before they initiate them. One approach enabled by electronic medical record data is doing queries to evaluate adequate pools of patients to be recruited into the study. This requires a clinical data repository from EHR data with a query tool to search de-identified clinical information. By modifying inclusion and exclusion criteria, a researcher can find the appropriate cohort for recruitment based on a reasonable recruitment rate. There are already successful examples of this that have saved years of unsuccessful or under recruited studies.

Figure 22.1: Example of a search from Harvard Profiles Catalyst

Harvard Catalyst Profiles

Search Results (12)

Click the **Why** column to see why a person matched the search.

Sort By: Query Relevance

Show (choose columns):

- Institution
- Department
- Faculty Rank

Search Criteria

- disease
- parkinson
- Pathology

Search Options

- Modify search criteria
- Restore default layout

Person Summary

Name
Mel B. Feany, M.D., PH.D.

Institution
Brigham and Women's Hospital

Department
Pathology

Title
Associate Professor of Pathology

Faculty Rank
Associate Professor

Query Relevance
Match score = 7.728
(Click Why for details.)

Name	Institution	Department	Why?
Mel B. Feany, M.D., PH.D.	Brigham and Women's Hospital	Pathology	
Bruce A. Yankner, PH.D., M.D., F	Harvard Medical School	Pathology	Why?
Pavan Kumar Auluck, M.D., PH.D.	Massachusetts General Hospital	Pathology	Why?
Matthew P. Frosch, M.D., PH.D.	Massachusetts General Hospital	Pathology	Why?
Rebecca Dunn Folkerth, M.D.	Brigham and Women's Hospital	Pathology	Why?
John Francois Staropoli, M.D., P	Massachusetts General Hospital	Pathology	Why?
Gilbert Gallardo, PH.D.	Harvard Medical School	Pathology	Why?
Richard Lawrence Kradin, M.D.	Massachusetts General Hospital	Pathology	Why?
Sandro Santagata, M.D., PH.D.	Brigham and Women's Hospital	Pathology	Why?
Tessa Hedley-Whyte, M.D., M.B.	Massachusetts General Hospital	Pathology	Why?
Antonio Rafael Perez-Atayde, M.	Children's Hospital Boston	Pathology	Why?
Jeffrey E Saffitz, M.D., PH.D.	Beth Israel Deaconess Medical C	Pathology	Why?

Per Page: 15

Page 1 of 1

Navigation: [Home] [Prev] [Next] [End]

Electronic grant submission is now common for government agencies. Through the Office of Extramural Research at the NIH, grant submission and award management are all web-based. Forms are completed online and uploaded to the site, email alerts are available about the posting of new grants, and grant awards are posted online at the site. In addition, some Clinical Trial Management Systems (CTMS) discussed later are integrated with the NIH electronic Research Administration Commons (eRA), which allows institutions to centrally manage grant submissions to the NIH.

Study Initiation

Informatics has a role in the initiation of studies as well. Volunteer recruitment can be enabled

over the internet. Two approaches to volunteer recruitment are ResearchMatch and TrialX.

ResearchMatch provides a way to connect patients seeking clinical trials and researchers seeking volunteers⁹ (see Figure 22.2). Volunteers can create an account and indicate what their health issues are that may match with clinical trials. Researchers from institutions affiliated with the network can enter the clinical trials and contact information by completing an online form. Then the researcher can search volunteers and email them an invitation to participate. The volunteer can accept or decline to receive more information.¹⁰ **TrialX** is a commercial venture which allows the volunteer to search clinical trials from ClinicalTrials.gov. Based on search terms, the user can see how closely their search matches available trials and then select a trial and email the investigator by

registering on the site. Researchers can also register to list their trials and organizations can partner with TrialX to create custom listings of their studies.¹¹ Yet another model is a social network built around volunteering for clinical trials. ArmyOfWomen provides that platform and has provided thousands of volunteers for dozens of trials, initially for breast cancer but now for a variety of conditions.¹²

Online recruitment of subjects using social media is an emerging trend. Information on clinical trials using major social media outlets like Facebook and Twitter are new ventures. A transition from traditional advertising to online promotion of clinical trials is growing but many Institutional Review Boards are unfamiliar with this approach and need education to promote acceptance and establish standards for appropriate use. Another promising use of social media is provider groups and researchers developing relationships with online patient networks. These groups of ePatients are receptive to clinical trials and partnerships with researchers. A successful partnership was

documented between women who have a rare cardiac condition and the Mayo Clinic. The women, whom already had an online community, were eager to participate in trials.¹³ Patient social networks are already collecting data on their treatments and so the word about new clinical trials travels quickly.¹⁴ Many healthcare organizations still caution patients and employees from using social media; in this context, patients should be cautioned that information on clinical trials communicated through social media must be evaluated like other online health content, with a critical mind.

Recruitment of subjects through the capabilities of the electronic medical record has two possible modes. First, the EHR can be used to find cohorts of eligible patients and create patient contact lists for recruitment.¹⁵ Second, clinical trial alerts can be embedded within the EHR based on diagnoses, lab tests or other patient characteristics. The alert would typically remind the provider that their patient may be eligible for a clinical trial and who to contact.¹⁶⁻¹⁷

Figure 22.2: ResearchMatch program (Courtesy ResearchMatch)

researchmatch

Have you seen this? As of right now there are:

volunteers	researchers	studies	institutions
47,746	1852	338	85 see more!

What is researchmatch?

A secure place for volunteers and researchers to get connected. Once you [sign up](#) and get added to our registry, a researcher will contact you if they think you'll be a good match for their research study. Find out more information [here](#).

Welcome to researchmatch!

ResearchMatch has a simple goal – to bring together two groups of people who are looking for one another: (1) people who are trying to find research studies, and (2) researchers who are looking for people to participate in their studies. It is a free and secure registry that has been developed by major academic institutions across the country who want to involve you in the mission of helping today's studies make a real difference for everyone's health in the future.

What's New

Dec 19 2013 [Food Allergy Sub-Registry Launched Today!](#)

Dec 15 2013 [Join RM for a Twitter Chat Tuesday, December 17 at 2p EST](#)

Nov 28 2013 [Happy MatchGiving!](#)

want to see more news? click [here](#).

[Sign up Now!](#) [Get More Information](#) [Sign up Later](#)

Study Management and Data Management

There are several informatics tools which support study management and particularly managing research data. Clinical trial management systems (CTMS) are now common in academic medical centers. The purpose of these tools is to manage the planning, preparation, performance, and reporting of clinical trials. A CTMS has multiple functions in study management including: budget management, study calendar of patient visits, and creating electronic case report forms (eCRFs).¹⁸ These tools can be open source or commercially available products.¹⁹ The Cancer Biomedical Informatics Grid (CaBIG) has developed a CTMS Workspace with “modular, interoperable and standards-based software tools designed to meet diverse clinical trials management needs.”²⁰ There is also a CTMS knowledge center which describes the NCI Clinical Trial Suite & Products.²¹

Some applications provide eForms or eCRFs with a focus on study data management. These tools enable the building of web-based forms for research without the support of programmers. Probably the most widely distributed tool is

Research Electronic Data Capture (REDCap), which was developed at Vanderbilt University. REDCap provides a secure, web-based application based on PHP and MySQL, which can be installed locally and provides an online designer for creating data collection instruments. REDCap also provides a method for controlling user rights and user access groups as well as maintaining an audit trail^{22, 23} (see Figure 22.3).

OpenClinica is another example of a data management system. It is an open source tool which provides the ability to submit and extract data, manage protocols and other study administration tools. It enables compliance with Good Clinical Practice (GCP) and regulatory guidelines such as FDA regulations for electronic databases. OpenClinica provides a free community edition and a licensed enterprise addition.²⁴ CAISIS Cancer Data Management System, developed at Memorial Sloan Kettering Cancer Center, is an open source .NET application which provides eForms for study data collection. CAISIS has an active open source community supporting and enhancing the application. There are also some tools within CAISIS to import data from clinical systems.²⁵

Figure 22.3: REDCap program (Courtesy Vanderbilt University)

The screenshot displays the REDCap web interface for a project at Vanderbilt University. The interface is organized into several sections:

- Header:** Features the Vanderbilt University logo and the text "Vanderbilt University" and "Vanderbilt Institute for Clinical and Translational Research".
- Navigation:** Includes "Project Home" and "Project Setup" buttons.
- Quick Tasks:** Contains two main tasks:
 - Export data:** "Export your data from REDCap to open or view in Excel or various stats packages."
 - Create a report:** "Build custom reports for quick views of your data, and export reports to Excel/CSV."
- Project Dashboard:** Provides general information:
 - Current Users:** A table listing users and their expiration dates.

User	Expires
site_admin (Site User)	never
 - Project Statistics:**
 - Records in project: 139
 - Most recent activity: 10/07/2011 3:45pm
 - Space usage for docs: 93.87 MB
 - Project status: Production
 - Upcoming Calendar Events (next 7 days):** A table with columns for Time, Date, and Description. One event is listed:

Time	Date	Description
	10/12/2011	K
- Left Sidebar:** Contains navigation links for "Data Collection" (Demographics, Baseline Data, Month 1-3 Data, Completion Data), "Applications" (Calendar, Data Export Tool, Data Import Tool, Data Comparison Tool, Logging, File Repository, Graphical Data View & Stats, Report Builder), and "Reports" (DMI report, MATest, Monocref Patient Compliance Data, Open cases, Withdraw reason, Missing Date of Consent, Test Report, Monocref Patient Compliance Data (copy), Monocref Patient Compliance Data (copy), hgmghm, m1 reporte colombia cali, reporte de no se nome impostsids).

Integration of EHR data into clinical trials provides an efficient method to add routine data into the study database. While this feature is rarely available within commercial EHRs, the data from EHRs or clinical data warehouses can be exported on study patients and then imported into study data management systems. The challenge is selecting the appropriate data, such as lab results from study visits, and exporting only that data. Some commercial data management systems have tools to automate this process.²⁶ An important part of secondary use of EHR data for research should include a validation process to ensure that data which was collected in clinical care is appropriate for a research study or registry.²⁷

EHR data can be used exclusively to produce a variety of study types. For instance, epidemiologic research, studying population characteristics or trends, can be extracted from EHRs containing large groups, such as, from regional or national health systems. Biosurveillance studies are also enabled by EHR data. With daily or near real-time data on large populations, outbreaks of new infections or other disease trends can be tracked. Biosurveillance using EHR data has also been shown as a method of diagnosing Strep in real time.²⁸

Identification of risk factors has been demonstrated through the use of EHR data. For instance a study from Harvard demonstrated the ability to rapidly identify risk of stroke associated with diabetes medication using signal detection analysis.²⁹ Another study, from Cleveland Clinic, used EHR data to predict six-year mortality risk in type 2 diabetes.³⁰ The Archimedes Model developed by David Eddy, provides predictive modeling for diabetes.³¹ In addition to predictive studies, EHR data has been used in identifying post-operative complications, medication adherence and triggered adverse event reporting.³²⁻³³ From these and other uses, it is clear that decision support is increasingly being supported by EHR data.

Comparative effectiveness research (CER) is of increasing interest related to healthcare reform

and research sponsored by the Agency for Healthcare Research and Quality (AHRQ).³⁴ EHR data can answer some questions that clinical trials cannot and can often do so more quickly. Hoffman and Podgurski propose using EHR data to develop personalized comparisons of treatment effectiveness, applying the rich clinical data to decision support in a personalized medicine approach.³⁵ Observational studies, which infer causation from EHR data, can examine large cohorts who received different treatments and then evaluate the outcomes and costs associated with each. A study of diabetes management of 27,207 patients demonstrated the comparative effectiveness of using EHRs as opposed to paper records; showing greater improvement in disease outcomes for those managed with EHRs.³⁶ The Institute of Medicine has developed a substantial workshop summary on the “Infrastructure Required for Comparative Effectiveness Research” which includes not only better research design, but a move from “siloed” evidence based medicine to “semantically integrated, information-based medicine” which requires “a substantial informatics platform to interpret, query and explore clinical data.”³⁷

What to do about data that is not routinely collected in EHRs? For instance, what about disease specific information which may be helpful in populating a disease registry? The solution is the use of smart forms within the EHR which are specific to a specialty clinic or treatment protocol. These forms must be designed with care to gather discrete clinical observations and judgments while being easy to complete in a busy clinical environment. Back-end integration with EHR data structure is essential.³⁸

Collection of research data using medical devices is another informatics challenge. With more medical devices being integrated with the EHR or generating their own data bases, a significant amount of new clinical monitoring data is available for research. Whether these are EKG monitors, automated anesthesia records, implanted devices³⁹ or activity sensors⁴⁰ data collection from medical devices provides a

method to quickly acquire research data for analysis.

Patient Reported Outcomes (PROs) is another area of growing emphasis in clinical research with the National Institutes of Health developing a program called PROMIS to focus attention on it. PROs “is the term used to denote health data that is provided by the patient through a system of reporting.”⁴¹ In the context of PROs, the use of tablet devices is gaining popularity as a method for collecting patient reported data at the point of care, such as, in the study of pain⁴² or cognitive impairment.⁴³ Tablets also have broader uses, including social networking and cataloging relevant articles for research.⁴⁴ Studies in patient reported outcomes are now being funded by the Patient Centered-Outcome Research Institute, a private organization funded by the U.S. government to promote outcomes research which includes PRO.⁴⁵

Data Management Systems for FDA Regulated Studies

The unique requirements of the Food and Drug Administration (FDA) for data management for studies of new drugs and devices present challenges for informatics. The regulation 21 CFR Part 11: Electronic Records, Electronic Signatures⁴⁴ sets a high bar for implementing data management systems and their validation. In addition to selecting a system which is compatible with the regulatory requirements, significant validation test cases must be developed and executed. While this area is typically the purview of drug/device companies or contract research organizations, academic medical centers often require this capability to support early stage, investigator-initiated studies. Commercial systems such as PhaseForward⁴⁶ and Oracle Clinical⁴⁷ dominate this market, but open source tools like OpenClinica can also be validated in compliance with these regulations. Remote Data Capture (RDC) is a term often used for these systems which enable secure data collection over multiple study sites for large clinical trials.

Interfaces and Query Tools

In recent years, Clinical Data Repositories and Registries using EHR data have been developed at many academic medical centers. A review by Weiner et al.,⁴⁸ discusses four such systems with a variety of features. One more broadly adopted tool, supported through the National Center for Research Resources (NCRR), is i2b2 (Informatics for Integrating Biology and the Bedside) which enables the secure storage and query of EHR and other data.⁴⁹ A query tool developed in the United Kingdom called TrialViz allows for searching by phenotype and data quality.⁵⁰

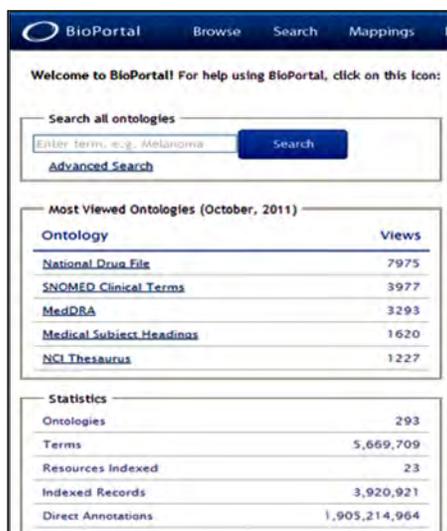
Stanford University is creating their own clinical data repository called STRIDE, Stanford Translational Research Integrated Database Environment.⁵¹ This repository has five functions: “Anonymized Patient Research Cohort Discovery, Electronic Chart Review for Research, IRB-Approved Clinical Data Extraction, Biospecimen Data Management, Data Management and Research Registries.” Registries will become an even more important tool to track patients with chronic and rare diseases. A white paper by RemedyInformatics points out the essential elements of electronic registries, including robust reporting for non-technical staff, flexibility to accommodate adaptive studies, data visualization and interoperability.⁵²

To support these large clinical data repositories, tools which support data mapping, semantic ontologies, and natural language processing have been developed. The National Center for Biomedical Ontology provides a repository of tools through its Bioportal for medical ontology standards and mapping (see Figure 22.4).⁵³

Wynden et al. note that the two main challenges in maintaining an integrated data repository for research are, “the ability to gain regular access to source clinical systems and the preservation of semantics across systems during the aggregation process.”⁵⁴ Natural Language Process (NLP) is required when one seeks to mine clinical text notes, such as encounter notes, operative notes, radiology reports and discharge summaries.

Many centers are developing such systems, such as cTAKES from the Mayo Clinic⁵⁵ and eNotes from Columbia.⁵⁶ Both examine notes and extract data elements based on structured vocabularies, such as LOINC® [Logical Observation Identifiers Names and Codes] for laboratory values.⁵⁷

Figure 22.4: Bioportal Ontology Search (Courtesy NCBO)



Health information exchange (HIE) is another technology which has potential for clinical research. Although developed primarily to enable care across health systems and states with various EHR implementations, it can be used in a de-identified mode to mine data for state or national trends including public health research. Health Query is a project of the Office of the National Coordinator for Health IT which is working on standards to develop a nationwide query capability.⁵⁸ If successful, it will promote epidemiologic research over broad patient populations.

Web services continue to expand in their support of many of the technologies noted above. For instance, the Columbia NLP tool utilized web services with “XML database storing documents represented using the Clinical Document Architecture (CDA) of Health Level 7 (HL7).”⁵⁹ At the Cleveland Clinic, a data warehouse and registry management tool are under development, utilizing RESTful web

services to update and map data into a standard format for queries.⁶⁰

The category of big data is now being defined in healthcare, not just business. Big data is typically defined in the multiple terabyte or petabyte range and creates unique management problems in traditional relational databases. Often, this scale of data requires cloud computing solutions for storage and analysis. A new focus on NOSQL databases and a group of tools developed by the Apache Foundation is called Hadoop. “The Apache Hadoop software library is a framework that allows for the distributed processing of large data sets across clusters of computers using a simple programming model.”⁶¹ While some of the initial applications of these NOSQL databases are in genomics, other research applications, such as, exploring PACS (radiology images)⁶² and multisite clinical trials may be future applications.⁶³ New analytic tools for large sets of EHR data are enabling data exploration. Explorys, a new spinoff company from the Cleveland Clinic using a Hadoop/MapReduce platform, is partnering with several health systems to store de-identified data for clinical exploration.⁶⁴ The practice of combining phenotypic from the EHR and genomic data is relatively new but shows promise is researching specific diseases with genetic markers.⁶⁵

Data Analysis

While Clinical Research Informatics has traditionally left the statistical analysis tools to their Biostatistical partners, with the wealth and volume of clinical data now available, some role in data analysis is appropriate. With tools like The R Project for Statistical Computing, an open source statistical package,⁶⁶ there is the potential for integration of the statistical package with the data repository.⁶⁷ Tools like REDCap provide access to their API (Application Programming Interface) to connect directly to statistical programs. SAS also provides for integration of patient data from a variety of sources with tools for data cleaning, standardization and exploration.⁶⁸

Data visualization has progressed beyond simple charts and graphs to a part of informatics which enables the researcher to see data patterns as part of data exploration and planning for analysis. Data visualization in research is in its early stages, so new approaches for how to visualize data need to be created and standardized. But when done well, visualization can help detect errors in the data and explore relationships.⁶⁹ The selection of visualization tools is key, and informaticists can aid in the selection of these tools as they do with other software. Tools like Tableau,⁷⁰ Aceso⁷¹ and functions embedded in statistical packages like SAS should be considered.

Real time analytics are also helpful tools for dealing with large datasets and clinical decision support. Real time analytics is the provision of analyzed data relatively instantly to support decision making. While this approach is relatively new in medicine, IBM's Watson project is proposing to provide this kind of service. This is closely tied to predictive analytics based on clinical data including discrete data, text and unstructured data.⁷²

Recommended Reading

The following articles are recommend for supplemental reading on e-research:

- *Evidence Generating Medicine: Redefining The Research-Practice Relationship To Complete The Evidence Cycle.* The authors review the technical, regulatory, fiscal and socioeconomic challenges facing clinical research. They maintain the relationship between clinical medicine and research be bi-directional. That is, not only should research results drive the practice of medicine but the practice of medicine should drive research.⁷³
- *Clinical Research Informatics: A Conceptual Perspective.* A conceptual model of clinical research informatics (CRI) is presented. The authors used the model to discuss 18 articles that were devoted to CRI in one issue of JAMIA.⁷⁴

- *Time To Integrate Clinical And Research Informatics.* The authors plead the case to combine clinical and research informatics in order to improve patient care and create a "learning healthcare system". They also outline known "bottlenecks" associated with the potential integration.⁷⁵
- *A Survey Of Informatics Platforms That Enhanced Distributed Comparative Effectiveness Research Using Multi-Institutional Heterogeneous Clinical Data.* Authors discuss what is needed in order for there to be effective comparative effectiveness research (CER) among disparate research organizations. They note that there are six large informatics platforms for CER being studied and they identified six steps towards successful CER among multi-institutions.⁷⁶

Future Trends

The future of eResearch is leading toward the nationwide learning healthcare system as described by the Institute of Medicine.⁷⁷ With the number of tools in active use as described in the chapter, further use and enhancement of these informatics resources combined with the broad adoption of EHRs, make huge amounts of clinical data available for analysis and further discovery. Research networks will enable collaboration that was not possible a decade ago. Research volunteer recruitment, which has been chronically low, can see new opportunities through web-based tools and social media. Study and data management, tied to paper records for so long, are now freed in a digital form for secondary use. Biosurveillance can detect new outbreaks in hours instead of weeks. Data poor registries now have the opposite challenge – large data and how to store and manage it. E-Research will enable researchers to reduce the time from "the creation and validations of new biomedical knowledge and translation of that knowledge into practice."⁷⁷

Key Points

- eResearch and Clinical Research Informatics have a role within every aspect of the clinical research workflow
- EHR data can be effectively utilized in clinical trials, registries, public health studies and can include research originating from EHR data
- Informatics tools are effective in recruiting subjects for clinical research
- Informatics supports the ongoing management of clinical trials including study calendars, data management, grant management and subject recruitment and consent.
- New trends include: big data, real-time analytics and data mining

Conclusion

The emergence of clinical research informatics as a field within bioinformatics has been made possible by major advances in technology and institutional support. Every aspect of clinical research now has a set of tools to support its processes. A mix of commercial-off-the-shelf tools, software-as-a-service applications (SaaS) and open source tools developed at academic medical centers have enabled this transformation. The growing availability of EMRs nationally is just beginning to make a contribution to clinical research and is poised to become a standard method for comparative

effectiveness and population-based research. New devices, such as, tablets and smart phones, and the ability to obtain data from medical devices, increase the amount of data available for research. Data analysis and visualization tools enable researchers to quickly turn the data into usable information. eResearch is now maturing as a field of informatics.

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INDEX

A

Absolute Risk Reduction (ARR) 329-30
ACA, *see* Affordable Care Act
Accountable care organizations (ACOs) 9, 31, 78, 147, 155, 157, 255, 351, 375-6, 385, 424, 434, 452
ACOs, *see* accountable care organizations
ADEs, *see* adverse drug event
Adverse drug event (ADE) 84-5, 87, 91, 124-5, 151, 362, 395, 398-9, 402, 411-12, 511
Affordable Care Act (ACA) 9, 351, 371, 373, 378, 382, 394, 424
Agency for Healthcare Research and Quality (AHRQ) 19, 22, 35, 38, 130-1, 342-3, 364, 366, 370-1, 383-4, 392-3, 433, 466, 505, 511
AHIMA, *see* American Health Information Management Association
AHLTA *see* Armed Forces Health Longitudinal Technology Application (AHLTA)
AHRQ *see* Agency for Healthcare Research and Quality
AI, *see* Artificial intelligence
AMA, *see* American Medical Association
American Health Information Management Association (AHIMA) 21, 26-7, 29-30, 132, 160, 252, 439
American Medical Association (AMA) 91-2, 224, 228, 239, 296, 331, 422
American Medical Informatics Association (AMIA) 21-2, 24-5, 29, 32, 35, 37, 59, 130, 223, 332, 397-8, 411, 413, 500
American Recovery and Reinvestment Act (ARRA) 15-16, 19-20, 22, 24, 34, 55, 60, 77, 102-3, 193, 197, 199, 428
American Telemedicine Association (ATA) 433
AMIA, *see* American Medical Informatics Association
ANI *see* Alliance for Nursing Informatics
APIs, *see* application programming interface
Application programming interface (APIs) 8, 190, 316, 501, 507
Application service provider (ASP) 81, 84, 97, 106, 113, 115
ARR *see* absolute risk reduction
ARRA *see* American Recovery and Reinvestment Act
Artificial intelligence 10, 89
ASP, *see* application service provider
ATA *see* American Telemedicine Association
Authentication 189, 200, 203

B

Bar coded medication administration (BCMA) 402

Bar coding 13, 413
BCMA *see* Bar coded medication administration
Bioinformatics 455, 469-70
Biomedical Informatics 29, 37, 470, 504, 510, 512
Biosurveillance 475, 505, 508, 510
Bluetooth 184-5, 187, 272, 425

C

California HealthCare Foundation 30, 125, 131-2, 176, 183, 191, 281, 284, 363-4, 368, 421, 436
CCD *see* Continuity of Care Document
CCHIT *see* Certification Commission for Healthcare Information Technology
CCR *see* Continuity of Care Record
CDA *see* Clinical Document Architecture
CDC, *see* Centers for Disease Control
CDR *see* Clinical data repository
CDSS *see* clinical decision support systems
CDWs, *see* Clinical Data Warehouses
Centers for Disease Control (CDC) 19, 138, 270, 473, 476-7, 479, 484-6, 488, 491, 493-4
Centers for Medicare and Medicaid Services (CMS) 19, 102, 369, 394
Certification Commission for Healthcare Information Technology (CCHIT) 15, 170
Chief Information Officer 27, 198
Chief medical information officers (CMIO) 27-8, 61
Claims data 145, 159, 342
Clinical data warehouses (CDWs) 46, 48-9, 354, 505
Clinical decision support 11, 79, 83, 87, 118, 124-6, 129, 342, 350, 399
Clinical decision support systems (CDSS) 83
Clinical Document Architecture (CDA) 507
Clinical practice guidelines (CPGs) 6, 83-4, 87, 89, 293, 295, 297, 323, 325, 336-43, 345, 348-9, 354, 371, 376
Clinical research informatics 46, 59, 500, 507, 509-10
CMIO, *see* chief medical information officers
CMS *see* Centers for Medicare and Medicaid Services
Coding 26, 92, 178, 275, 413
Computed radiography (CR) 444
Computerized physician order entry 15, 22, 47, 60, 83-8, 97, 124-5, 129-30, 355, 374, 397-9, 401, 411
Computerized physician order entry (CPOE) 83-4
Connecting for Health 15, 156, 251, 262
Consumer Health Informatics 242-3

Continuity of Care Document (CCD) 15, 84, 166, 252
 Continuity of Care Record (CCR) 84, 151, 166, 255
 CPGs, *see* clinical practice guidelines
 CPOE *see* computerized physician order entry
 CPT *see* Current Procedural Terminology
 Current Procedural Terminology (CPT) 92, 178, 364

D

Data standards 99, 124, 163-4, 170, 176, 466, 480
 DICOM *see* Digital Imaging and Communications in Medicine
 Digital Imaging and Communications in Medicine (DICOM) 167-8, 441, 446
 Direct Project 83, 141-2, 148, 152, 154-5, 252
 Disease Management (DM) 351-2
 Disease Management Programs (DMPs) 151, 249, 351-2, 360, 362, 364-5, 367, 426, 429, 456
 Disease registries 12, 351, 354, 362-3, 368
 DM *see* Disease Management
 DMPs *see* Disease Management Programs

E

E-prescribing 15, 150
 EBM, *see* Evidence Based Medicine
 EHR adoption 12, 80-1, 95-7, 106, 118, 129, 199, 370, 373, 382
 EHR-Lab Interoperability and Connectivity Standards (ELINCS) 170
 EHR vendors 16, 104, 106, 112-13, 115, 142, 147, 280, 364, 407
 EHRs *see* electronic health record
 Electronic health records (EHRs) 5-7, 9-12, 15-23, 46-9, 77-83, 85-91, 93-104, 108-18, 123-32, 165-8, 176, 249-53, 290-1, 342, 368-73, 465-8
 EMR *see* Electronic Medical Records
 Electronic Medical Records (EMR) 124-5, 127-8, 130, 225, 465, 471
 Electronic Prescribing 405
 ELINCS, *see* EHR-Lab Interoperability and Connectivity Standards
 EResearch 500, 508-9
 Ethics and Information Technology 238-9
 Evidence Based Medicine (EBM) 296, 323-5, 330-3, 336, 341, 344-5

F

Federal Communications Commission (FCC) 427

G

GANs *see* Global Area Networks
 Geographic information systems (GIS) 12, 20, 474, 481, 486
 GIS *see* Geographic information systems
 Global Area Networks (GANs) 189
 Global Public Health Intelligence Network (GPHIN) 486
 Google 40, 45-6, 197, 200-1, 291, 293, 302, 305-7, 310, 320-1, 464, 485-6, 491, 494, 501
 Google Scholar 306, 320, 501
 GPHIN *see* Global Public Health Intelligence Network

H

HAN *see* Health Alert Network
 HCPCS *see* Healthcare Common Procedure Coding System
 Health and Human Services (HHS) 16, 18, 20, 100, 117, 139, 153, 195, 197, 199, 205, 207, 342, 472
 Health informatics 1-2, 4-7, 14, 25-6, 29, 31-2, 217, 219, 223-4, 227-8, 232, 234-5, 455, 457, 485-6
 Health Information Exchange (HIE) 9-12, 14-15, 17-19, 26-7, 83, 134-6, 140, 145-7, 150-2, 154-5, 157-60, 371-6, 400, 446, 480-1
 Health information organizations (HIOs) 11, 13-14, 81-2, 134-41, 145-51, 153-9, 163, 176, 179, 182-4, 191, 416-17, 424, 452-3, 480-1
 Health information technology (HIT) 5-6, 11-22, 24, 29-32, 34-6, 39, 54-7, 59-60, 101-3, 159-60, 197-9, 369-71, 391-2, 408-9, 488-90
 Health Information Technology for Economic and Clinical Health (HITECH) 16, 202, 479
 Health Information Technology Standards Panel (HITSP) 138, 466
 Health Insurance Portability and Accountability Act (HIPAA) 16, 22, 34, 98, 100, 113, 168, 193-4, 197, 199, 202, 205, 443, 500
 Health IT Policy Committee (HITPC) 19, 117, 197
 Health IT Standards Committee (HITSC) 19
 Health Resources and Services Administration (HRSA) 20, 433
 Health Story Project 166
 HealthBridge 138, 147, 150-2
 Healthcare Information and Management Systems Society (HIMSS) 15, 27, 30, 35, 37, 99, 113-14, 126, 156
 Healthcare Information Technology Standards Panel (HITSP) 15, 138, 466
 HealtheVet 252

Healthfinder 248
 HealthGrades 382, 393, 397, 409
 HealthMap 482, 485, 494
 HealthVault 142, 249, 252-3
 Healthwise 248
 HGP *see* Human Genome Project
 HHS *see* Health and Human Services
 HIE *see* Health Information Exchange
 HIMSS *see* Healthcare Information and Management Systems Society
 HIOs *see* Health information organizations
 HIPAA, *see* Health Insurance Portability and Accountability Act
 HIT *see* health information technology
 HITPC, *see* Health IT Policy Committee
 HITSC, *see* Health IT Standards Committee
 HITSP *see* Healthcare Information Technology Standards Panel
 HL7 4, 163, 165, 168, 177, 477, 480, 507
 HRSA *see* Health Resources and Services Administration
 Human Genome Project (HGP) 11, 34, 455, 458-9, 463, 469

I

ICD-9 42, 45-7, 50, 84, 87, 115, 168, 175, 298, 342, 477
 ICD-10 98
 IEEE, *see* Institute of Electrical and Electronics Engineers
 IHIE, *see* Indiana Health Information Exchange
 Indiana Health Information Exchange (IHIE) 150-1, 161
 Instead 22, 24, 78, 82, 134, 136, 180-1, 198, 205, 324, 329, 332, 416, 419, 442-3
 Institute of Electrical and Electronics Engineers (IEEE) 171, 187, 189-90
 Institute of Medicine (IOM) 10, 13-14, 77, 82-4, 117, 324, 348-9, 351, 370-2, 389, 391-2, 398-9, 409-11, 414, 505
 Internet 29, 33-4, 38, 179-82, 185, 189-92, 195, 204, 238-41, 281, 346-7, 427, 475, 477, 482
 Interoperability 22, 32, 108-9, 163, 170, 177, 180, 189, 279
 IOM *see* Institute of Medicine
 iPad 114, 265, 270, 273, 275-6, 295, 343, 448-9, 454, 459
 iPhone 10, 108, 113-14, 273, 295, 343, 449, 451, 454, 459

L

LambdaRail 190, 192, 427, 434
 LANs *see* local area networks 179, 186
 Levels of Evidence (LOE) 328, 335, 339

Local area networks (LANs) 186
 LOE *see* Levels of Evidence
 Logical Observations: Identifiers, Names and Codes (LOINC) 151, 167-9, 177, 364, 373, 480, 507, 512
 LOINC, *see* Logical Observations: Identifiers, Names and Codes

M

Master Patient Index (MPI) 108, 140, 146-7, 182
 Meaningful Use 16-19, 99, 102-4, 106, 117-19, 134, 147-9, 152-3, 155, 157-8, 163-4, 199, 351, 363-6, 373
 MEDCIN 114, 168-9
 Medicaid 15-20, 35, 102-4, 106, 115, 118, 147, 153, 356, 366, 369-73, 376, 378, 384-6, 393-4
 Medical errors 13, 55, 80, 389-92, 397, 406, 408-9, 414
 Medical ethics 217, 219, 221, 223-5, 235, 239
 Medical home, patient-centered 375, 382, 384
 Medical informatics 21, 24-5, 27, 29, 32-3, 37, 59, 130, 220, 223, 236, 238, 241, 500, 510
 Medical Subject Heading (MeSH) 307-9, 317, 320
 Medicare 15-19, 102-5, 115, 117-18, 337, 355-6, 360, 366-7, 369-73, 376-8, 384-5, 393-4, 424-5, 430-1, 438
 Medication errors 84, 124-5, 398, 411
 MEDLINE 10, 275, 285, 293-7, 307-8, 315-16, 322, 324, 326, 336, 460
 MeSH *see* Medical Subject Heading
 MHealth 265, 268, 275-6, 280, 282, 489
 Microsoft HealthVault 142, 249, 252-3
 Mobile technology 10, 265, 269, 272, 275, 280-1, 448
 MPI, *see* Master Patient Index

N

National Center for Biotechnology Information (NCBI) 306, 315, 460, 469, 509
 National Committee on Vital and Health Statistics (NCVHS) 16
 National Coordinator for Health Information Technology 18, 21, 35, 136, 145, 160
 National Council for Prescription Drug Programs (NCPDP) 177
 National Guideline Clearinghouse 339, 342
 National Institute of Standards and Technology (NIST) 16, 19
 National Institute of Standards and Technology (NIST) 19
 National Institutes of Health 238, 458, 460, 463, 501, 506, 509

National Library of Medicine (NLM) 168, 306, 316
 Nationwide Health Information Network (NwHIN) 11, 19, 22, 118, 135-6, 159, 163, 199
 Natural language processing (NLP) 10, 47, 49, 59, 86, 114, 373, 477, 506, 511
 NCBI *see* National Center for Biotechnology Information
 NCPDP *see* National Council for Prescription Drug Programs
 NCVHS *see* National Committee on Vital and NeHC *see* National eHealth Collaborative
 Networks 2, 5, 145-7, 150, 153, 179, 181-91, 196-9, 423, 426-8, 433, 450-3, 465, 482, 485-6
 NIST, *see* National Institute of Standards and Technology
 NLM, *see* National Library of Medicine
 NLP, *see* Natural language processing
 NNH, *see* Number Needed to Harm
 NNT *see* Number Needed to Treat
 Number Needed to Harm (NNH) 330
 Number Needed to Treat (NNT) 298, 329-31, 336, 346, 430
 NwHIN, *see* Nationwide Health Information Network

O

OAT *see* Office for the Advancement of Telehealth
 Office for the Advancement of Telehealth (OAT) 433-4
 Office of the National Coordinator (ONC) 15-20, 24, 35, 99-100, 107, 117, 136-9, 149, 153-4, 159-60, 176, 356, 392, 507
 ONC, *see* Office of the National Coordinator
 Online medical resources 12
 Open source 142, 147
 Order sets 87, 89
 OVID 293, 315, 335-6

P

PACS *see* Picture Archiving and Communication Systems
 Patient-Centered Medical Home (PCMH) 375
 Patient education 247, 297
 Patient portals 250
 Patient safety 55, 79, 100, 124, 126, 129, 163, 176, 339, 386, 392-3, 395-8, 406, 408-14, 512
 Patient web portals 11, 250, 259
 Personal health records (PHRs) 12, 40-1, 77, 109, 137, 166, 242, 249-53, 259, 262-3, 295, 367, 371, 375-6, 466
 PHIN *see* Public Health Information Network

PHRs *see* personal health record
 Physician Quality Reporting Initiative (PQRI) 103, 377
 Picture Archiving and Communication Systems (PACS) 12-13, 22, 84, 186, 416, 419, 441-4, 446-8, 450-3, 507
 PQRI, *see* Physician Quality Reporting Initiative
 Public health informatics 474, 484, 488
 Public Health Information Network (PHIN) 19, 145, 473, 479-80, 494
 PubMed 11, 31, 52, 275, 291, 293-4, 297-8, 305-8, 310, 314-17, 320-2, 326, 335, 462, 501

Q

Quality improvement strategies 6, 48, 84, 356, 369, 371, 382, 390-1, 396, 424

R

Radio Frequency Identification (RFID) 13, 403-4, 413
 Radiologists 89, 451, 454
 REDCap, *see* Research Electronic Data Capture
 Regional extension centers (RECs) 17, 112, 136, 154
 Regional Health Information Organization (RHIO) 136, 150, 156, 160-1
 Registries 88, 332, 351, 362-4, 366, 368, 506, 512
 Relative risk reduction (RRR) 84, 329-30, 399, 402
 Research Electronic Data Capture (REDCap) 504, 507, 510
 RFID *see* Radio Frequency Identification
 RHIO, *see* Regional Health Information Organization
 RRR, *see* Relative risk reduction (RRR)
 RxNorm 168, 177

S

SDOs *see* standards development organizations
 Search engines 320
 Security 16-17, 19, 138-9, 156, 161, 185, 188, 194-9, 202, 204-5, 211, 224, 228, 230, 239
 Service oriented architecture (SOA) 139, 160, 182-3, 191, 451
 Simple Object Access Protocol (SOAP) 76, 94, 181-2
 Smartphones 10-11, 267, 281, 284
 SNOMED 4, 50, 84, 115, 163, 168-9, 177, 466, 480
 SOA, *see* service oriented architecture
 SOAP, *see* Simple Object Access Protocol

Standards development organizations (SDOs)
165, 169, 171, 480

T

Teledermatology 421
Telehealth 12, 275, 416, 426-7, 429, 433-7
Telehomecare 418, 423, 434
Telemedicine 16, 271, 280, 416-18, 425-6, 431,
433-9
Templates 79, 114

U

UMLS, *see* Unified Medical Language System
Unified Medical Language System (UMLS) 364
Uniform Resource Locator (URL) 181-2, 195,
315, 451
URL, *see* Uniform Resource Locator

V

VISICU 422-3
Voice over IP (VoIP) 108
Voice recognition (VR) 1, 5-6, 83, 94, 108, 112,
114-15, 132, 279, 419
VPNs *see* Virtual Private Networks
VR, *see* voice recognition

W

WANs, *see* Wide Area Networks
Web PACS 446-7, 453
Web services 181-2, 191, 507
Wide Area Networks (WANs) 189
WiFi 184, 187, 189, 191, 249, 267, 272, 425
Wireless 81, 184, 187-8, 191-2, 490
Wireless Local Area Network (WLAN) 187-8
WLAN *see* Wireless Local Area Network
Workflow 52, 92, 110, 113, 131, 454
World Health Organization 383, 473, 485, 501,
509
World Wide Web 10, 81, 179, 181, 191, 259,
302, 304

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