Chapter 1

Overview of Health Informatics

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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 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

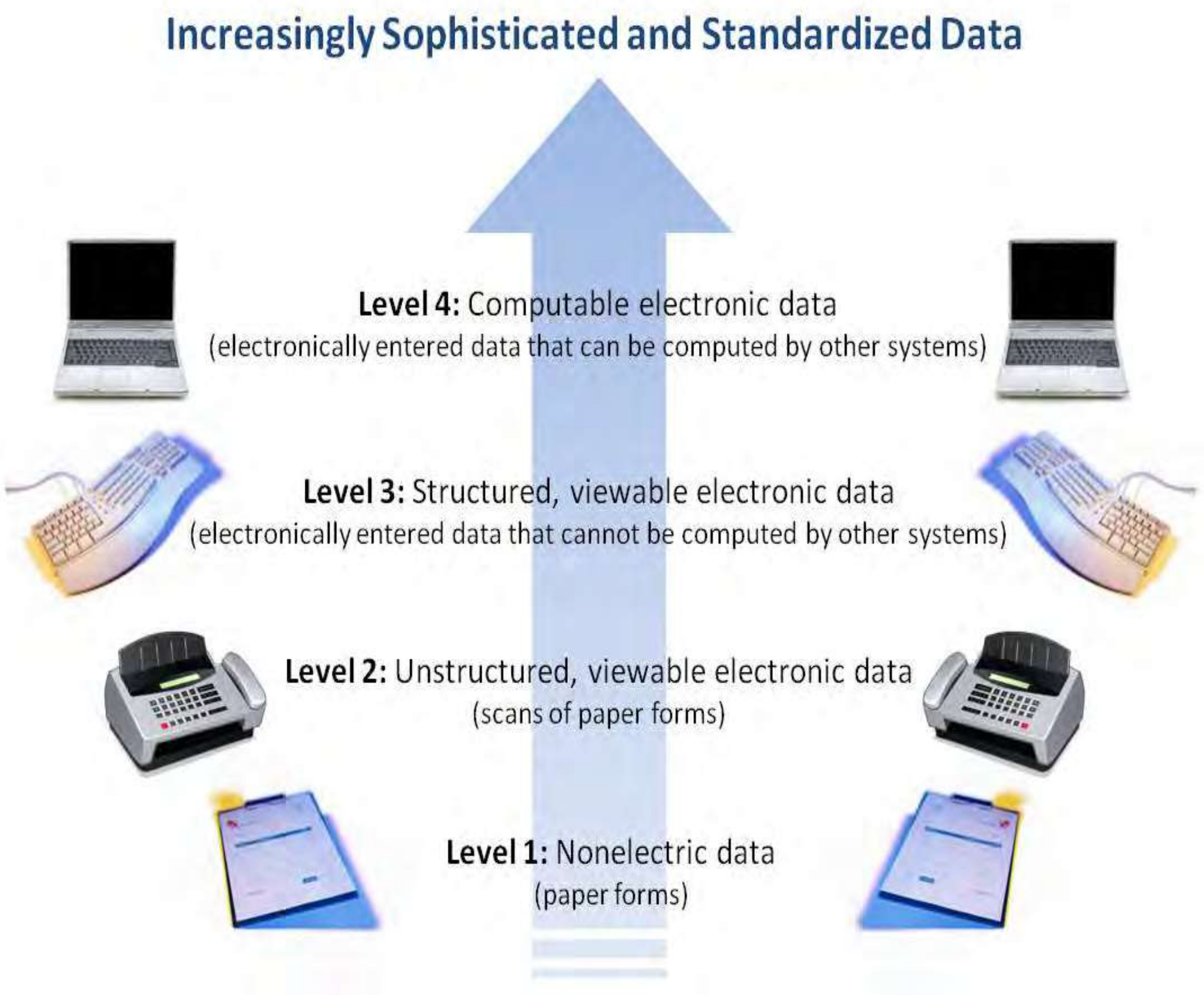
Health information technology provides the tools to generate information from data that humans (clinicians and researchers) can turn into knowledge and wisdom.[1-2] Thus, enabling and improving human decision making with usable information is a central concern of informaticians. This concept is discussed 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)

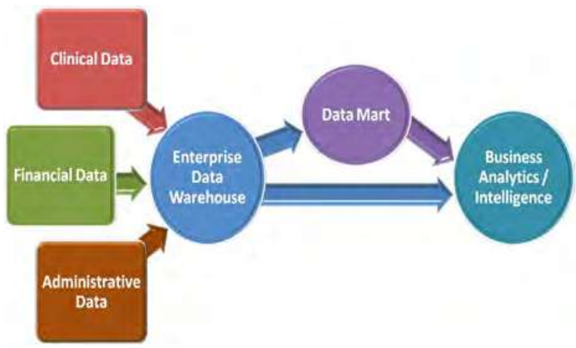


Informatics Definitions

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



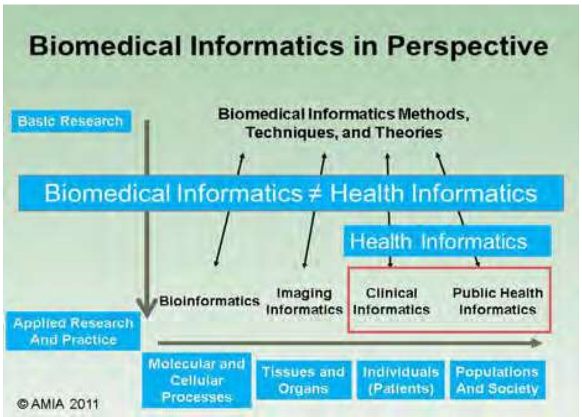
The definition of health informatics is dynamic because the field is relatively new and rapidly changing. The following are several definitions frequently cited:

- "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]

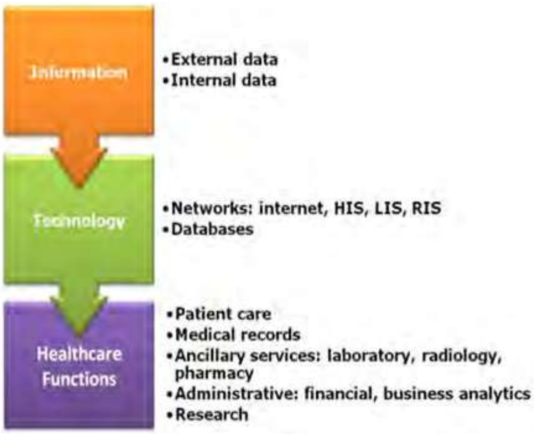
Background

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 tool[15]

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 test 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 teleconferencing, 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 financer 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 H IT 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:

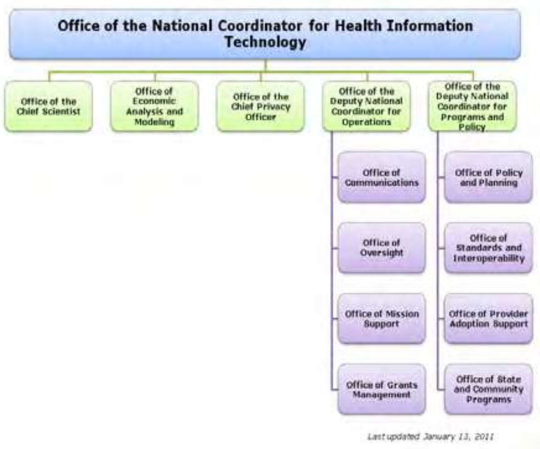
- Patient Centered Outcomes Research Institute that will fund patient-centered and comparative effectiveness research
- The CMS Innovation Center that will evaluate healthcare models such as the Accountable Care Organization (ACOs), discussed in another chapter
- The National Prevention and Health Promotion 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 advancement [55]

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 EHRs[61]

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.

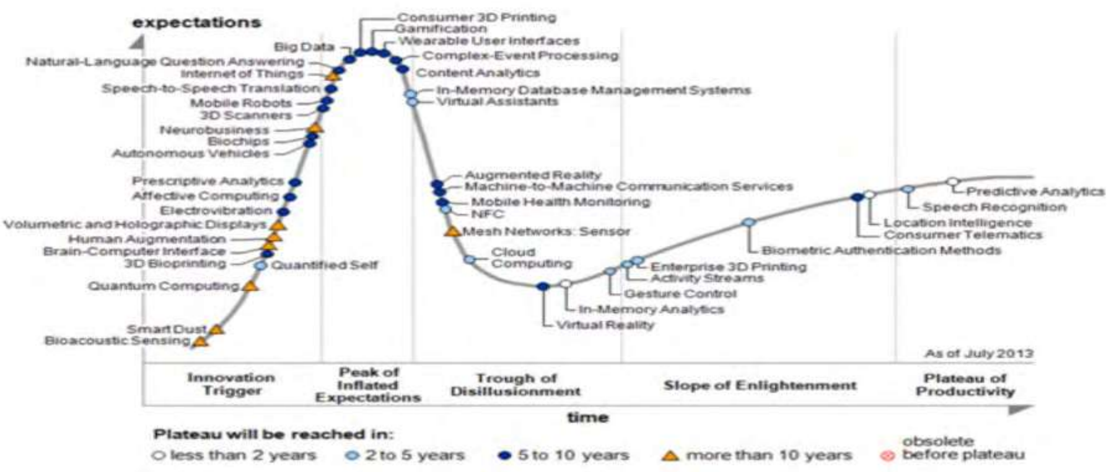
Behavioral change. Perhaps the most challenging barrier is behavior. In The *Prince* by Machiavelli, it was stated "there is nothing more difficult to be taken in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things."[77] 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 Federation[98]

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 cost[68]

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 tele-communications 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. 2009 [118]
- *Guide to Health Informatics*. Enrico Coiera. 2003 [119]
- *Biomedical informatics: Computer Applications in Health Care and Biomedicine*. EH Shortliffe and J Cimino 2006 [120]
- *Medical Informatics: Concepts, Methodologies, Tools and Applications*. J Tan. Four Volumes. 2009 [121]
- *Health Informatics*: *An Interprofessional Approach*. Nelson R, Staggers N. 2013 [122]

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]
- *HealthTechtopia* 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 blog[2] (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

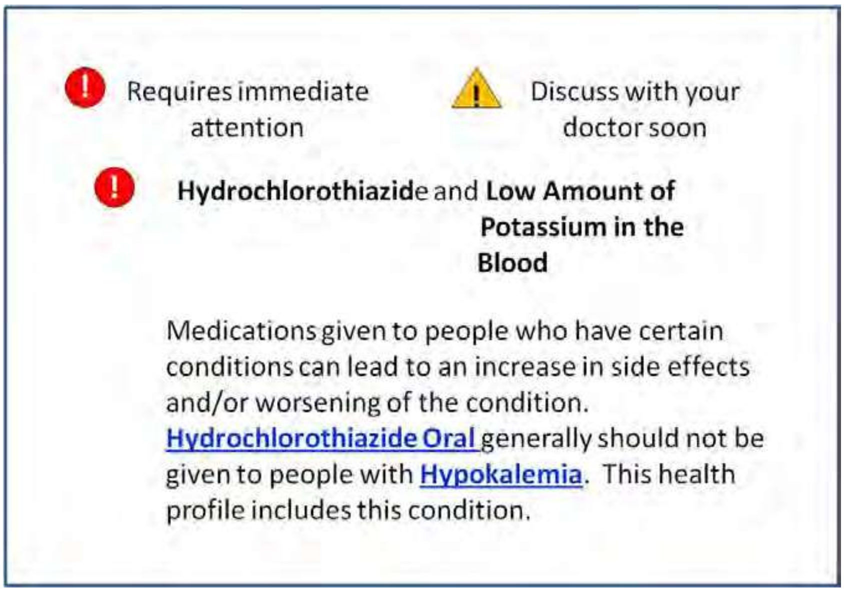


Figure 2.2: e-patient Dave's conditions as reflected in the newly-created personal health record (PHR)

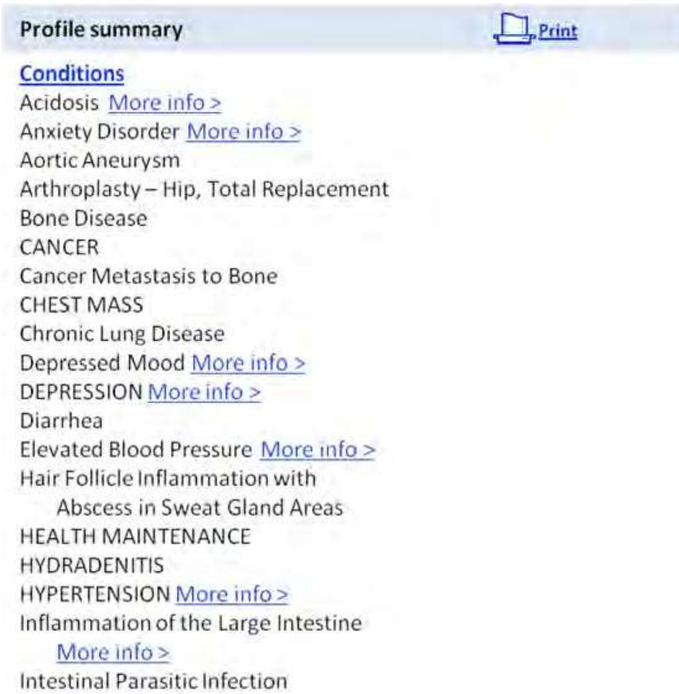
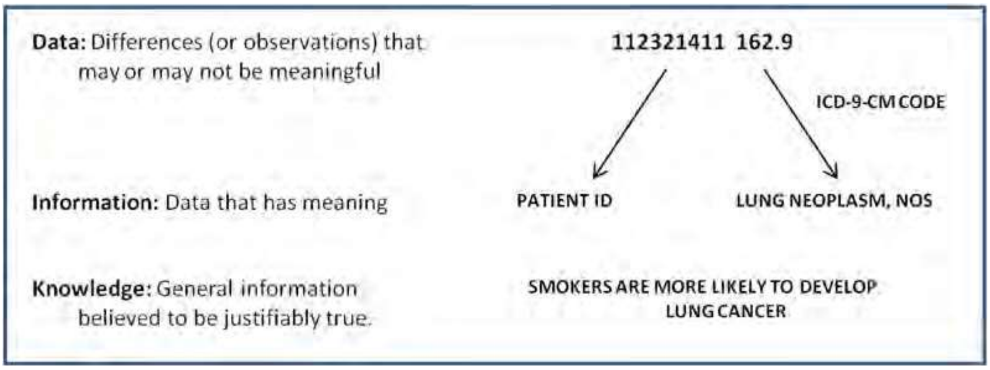


Figure 2.3: Data, information and knowledge



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.

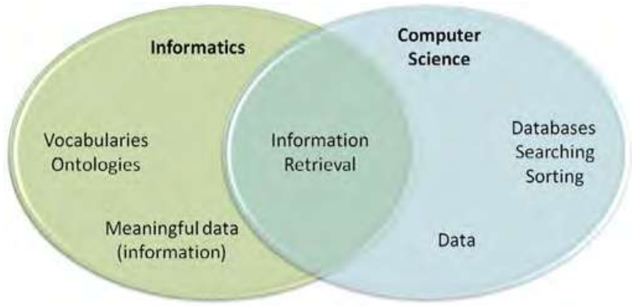
Though they may be motivated by specific applications, computer scientists typically develop general-purpose approaches to classes of problems that involve computation. For example, a computer scientist may design a memory architecture that efficiently stores and retrieves large data sets. The computer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

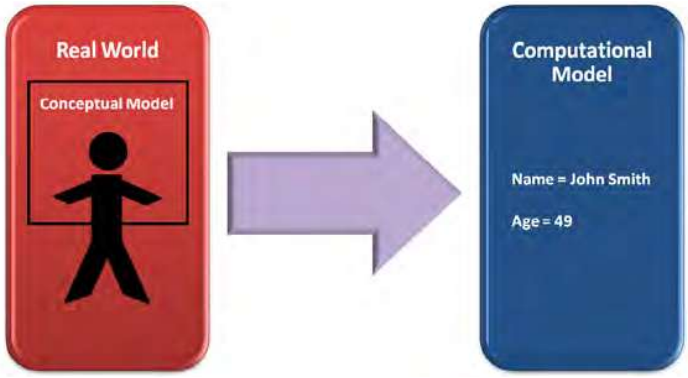
We live in the real world that contains physical objects (e.g., aspirin tablet), people (e.g., John Smith), things that can be done (e.g., John Smith took an aspirin tablet) and other concepts. In order to do useful computation, one has to segregate some part of the physical world and create a **conceptual 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 <u>information</u> that one wants to represent (e.g., whole numbers: 0, 1, 2, 3, ...). The **representing world** contains the <u>data</u> 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 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.

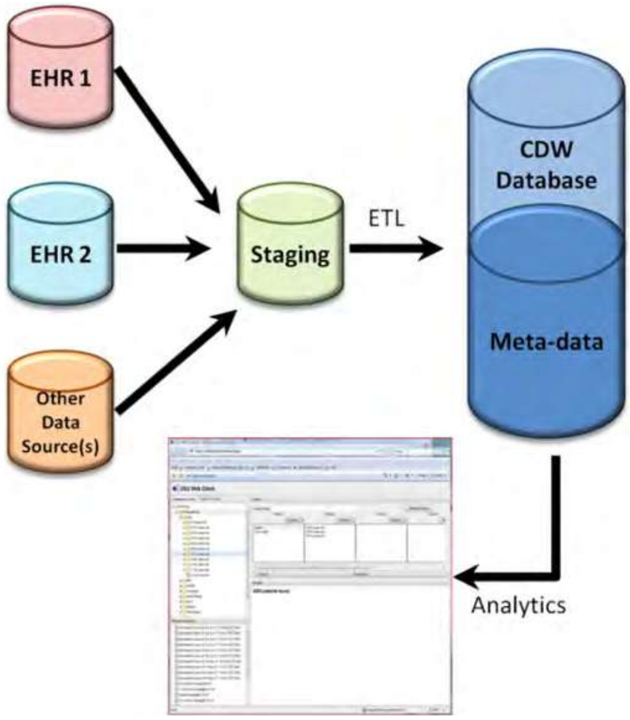
Free text, on the other hand, has the advantage of being able to express anything that can be expressed using natural language. On the other hand, it is difficult for computers to process. Indeed, the field of **natural language processing** (NLP) is an active area of research in both computer science 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

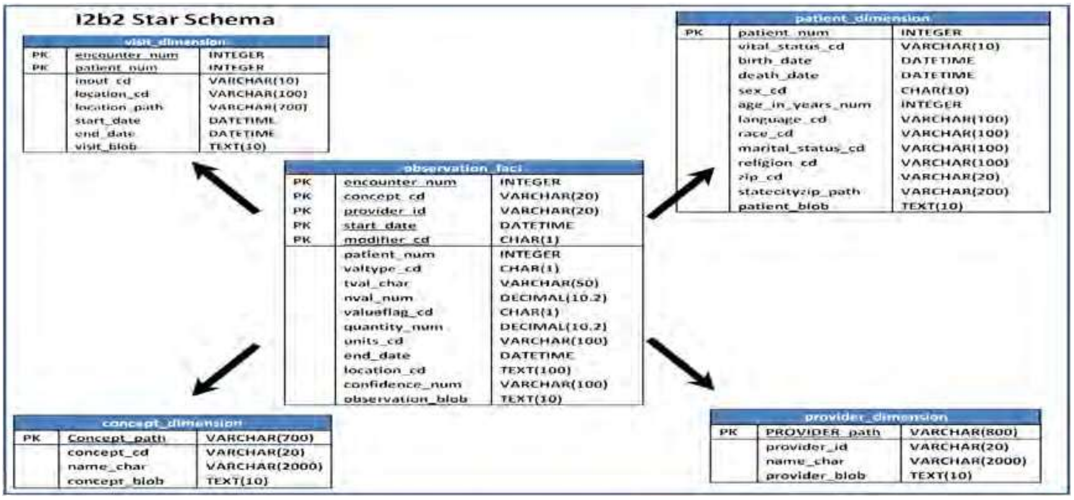
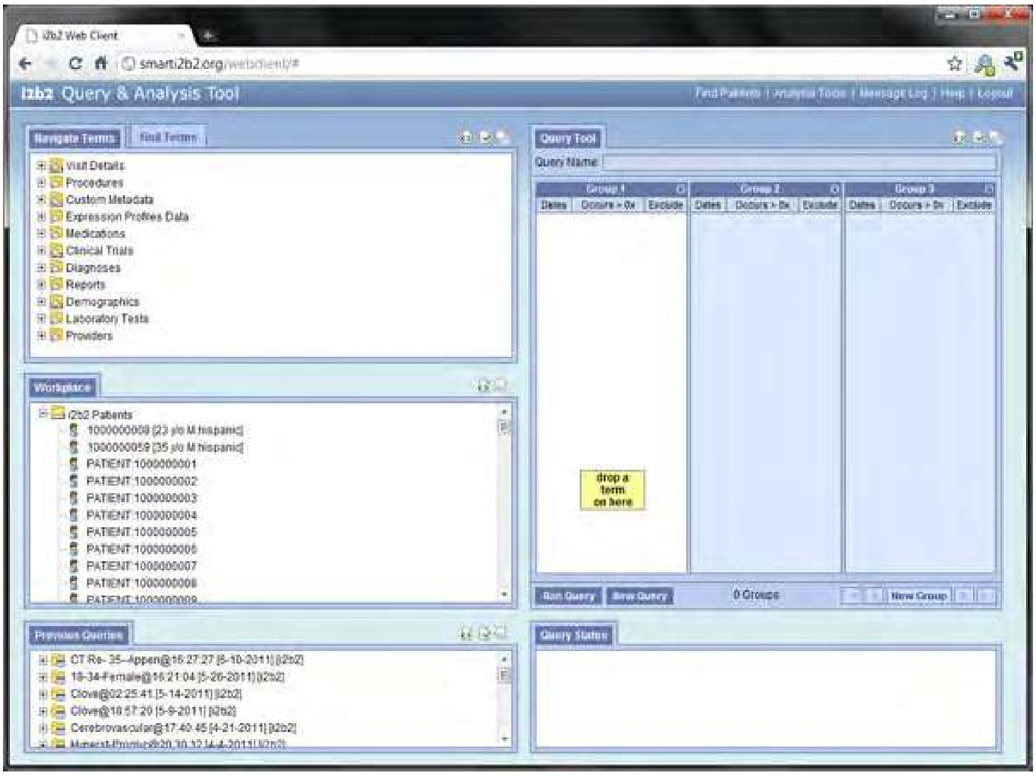


Figure 2.8: i2b2 screenshot



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 MetaMap[15] 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

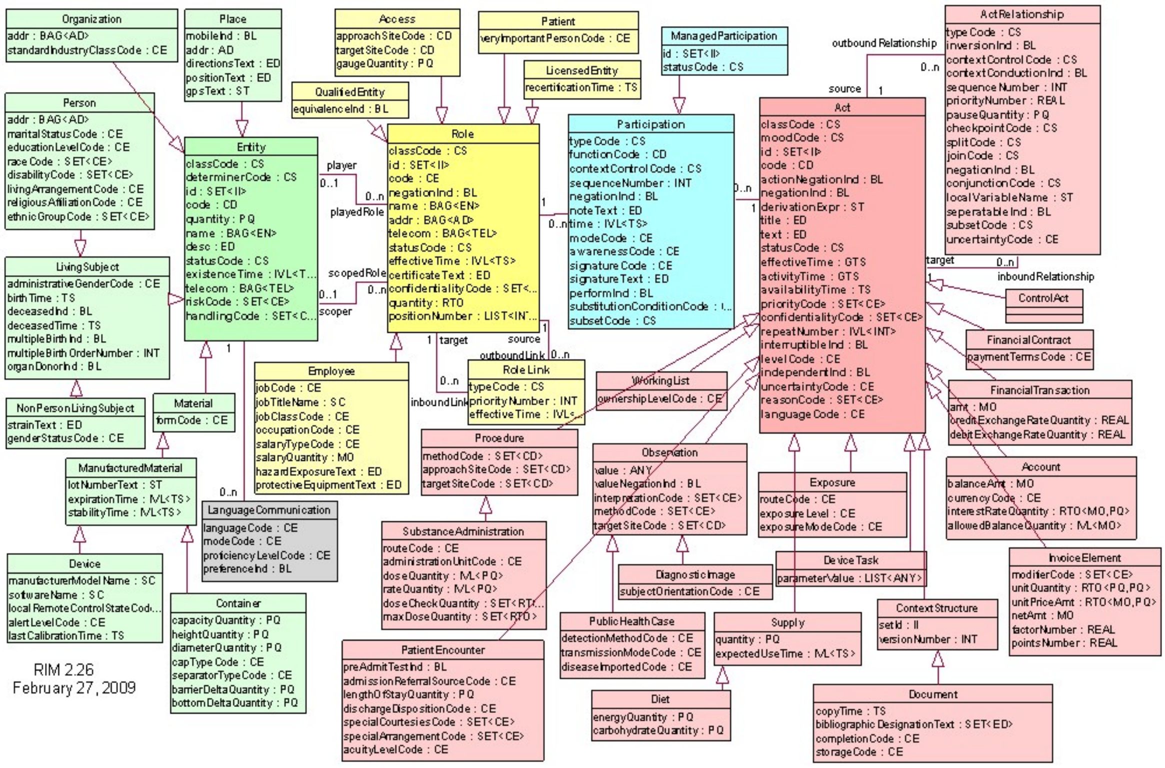
	Banking data	Health data
Concepts and descriptions	Precise *Example:* Account 123 balance = $15.98	General, subjective *Example:* sick patient
Actions	Usually (not always) reversible *Example:* Move money A → B	Often not easily reversible *Example:* Give a medication Perform procedure
Context	Precise, constant *Example:* US $	Vague, variable *Example:* Normal lab values differ by lab
User autonomy	Well-defined and constrained *Example:* What I can do with my checking account = what you can do	Variable and dependent on circumstance *Example:* 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 the real world concepts that affect an accurate account balance. On the other hand, in biomedicine these boundaries are often impossible to precisely define, so our conceptual and computational models are rarely complete and often lead to inaccurate results, such as was seen with e-Patient Dave.

Figure 2.9: Overview of the HL7 version 3 RIM (Courtesy HL7[24])



Complexity of Knowledge Models

Modeling health care is difficult but this has not stopped informaticians from trying. Notable modeling attempts include the HL7 Reference Information Model or RIM (see chapter on data standards). Work on the RIM started in 1997 and Release 1 was approved by the American National Standards Institute (ANSI) in 2003. The RIM is one of the major differences between the commonly adopted HL7 version 2.x that has been widely used for decades and version 3, which has yet not been as widely adopted.[23] One of the problems is that the RIM is very complex (see Figure 2.9) and does not necessarily match all health care environments. As of December 2011, the HL7 RIM remains somewhat controversial.

Biomedical informatics is also difficult because biomedical information can be imperfect in a number of different ways:

- Incomplete information: Information for which some data are missing, but potentially obtainable.
  - Example: What is the past medical history of an unconscious patient who arrives at ED?
- Uncertain information: Information for which it is not possible to objectively determine whether it is true or false. This can also be called epistemic uncertainty,

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 institution [35], 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

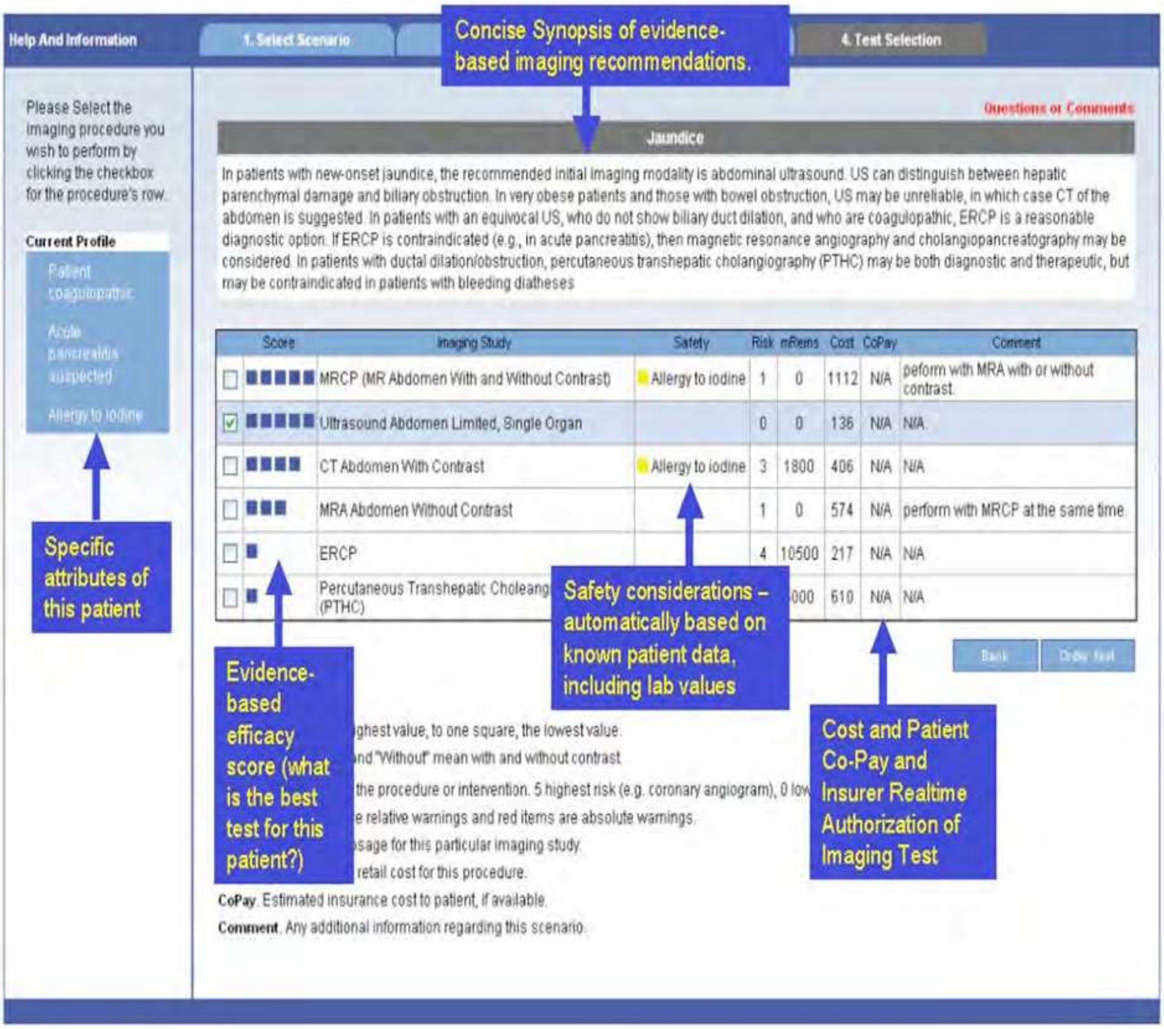
Researchers are exploring multiple promising paradigm-shifting ideas. Examples of approaches that address some of the fundamental problems described in this chapter can be provided.

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 EHR[48]



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

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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]

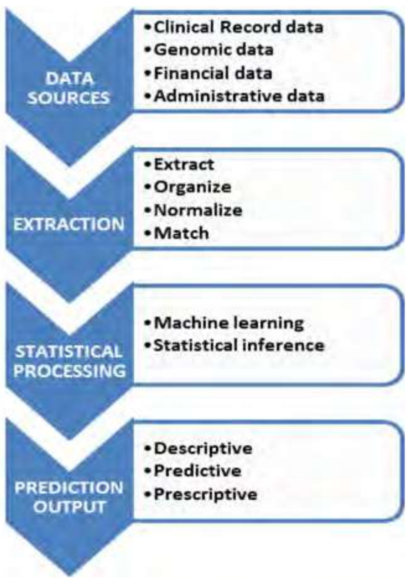
- Volume – ever-increasing amounts
- Velocity – quickly generated
- Variety – many different types
- Veracity – from trustable sources

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 inpatients[41]
- Identification of children with asthma[42]
- Risk-adjusting hospital mortality rates[43]
- Detecting postoperative complications[44]
- Measuring processes of care[45]
- Determining five-year life expectancy[46]
- Detecting potential delays in cancer diagnosis[47]
- Identifying patients with cirrhosis at high risk for readmission[48]
- Predicting out of intensive care unit cardiopulmonary arrest or death[49]

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 studies[50]
- Determining eligibility for clinical trials[51]
- Identifying patients with diabetes and the earliest date of diagnosis[52]
- Predicting diagnosis in new patients[53]

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 Initiative[56-57] 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 cancer[61] and gastroesophogeal 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 that 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 systematic 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]
- *Caveats*[33] *And Recommendations*[90] *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 University[3], 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.

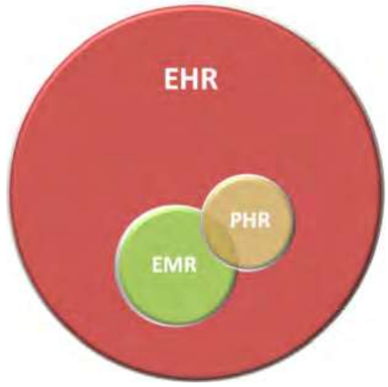
The authors will primarily discuss outpatient (ambulatory) electronic health records. Inpatient EHRs share many similarities to ambulatory EHRs but the scope, price and complexity are different. The logical steps to selecting and implementing an EHR are found later in the chapter.

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]

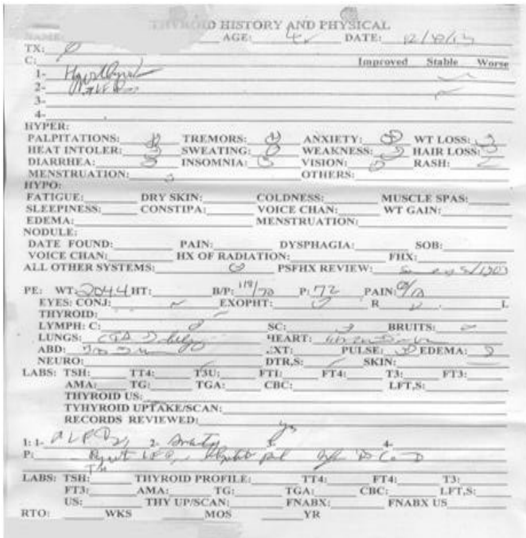
Need for Electronic Health Records

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


D HISTORY AND PHYSICAL
AGE: DATE:
TX:
C: Improved Stable Worse
1-
2-
3-
4-
HYPER:
PALPITATIONS: TREMORS: ANXIETY: WT LOSS:
HEAT INTOLER: SWEATING: WEAKNESS: HAIR LOSS:
DIARRHEA: INSOMNIA: VISION: RASH:
MENSTRUATION: OTHERS:
HYPO:
FATIGUE: DRY SKIN: COLDNESS: MUSCLE SPAS:
SLEEPINESS: CONSTIPA: VOICE CHAN: WT GAIN:
EDEMA: MENSTRUATION:
NODULE:
DATE FOUND: PAIN: DYSPHAGIA: SOB:
VOICE CHAN: HX OF RADIATION: FHX:
ALL OTHER SYSTEMS: PSFHX REVIEW:
PE: WT: HT: B/P: 119/70 P: 72 PAIN:
EYES: CONJ: EXOPHT: R L
THYROID:
LYMPH: C: SC: BRUITS:
LUNGS: HEART:
ABD: EXT: PULSE: EDEMA:
NEURO: DTR,S: SKIN:
LABS: TSH: TT4: T3U: FTI: FT4: T3: FT3:
AMA: TG: TGA: CBC: LFT,S:
THYROID US:
TYHYROID UPTAKE/SCAN:
RECORDS REVIEWED:
I: 1- 2- 3- 4-
P:
LABS: TSH: THYROID PROFILE: TT4: FT4: T3:
FT3: AMA: TG: TGA: CBC: LFT,S:
US: THY UP/SCAN: FNABX: FNABX US
RTO: WKS MOS YR

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 aweek 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 bioinformatics [26]
- 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 reviews [27]

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) option[36]

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)

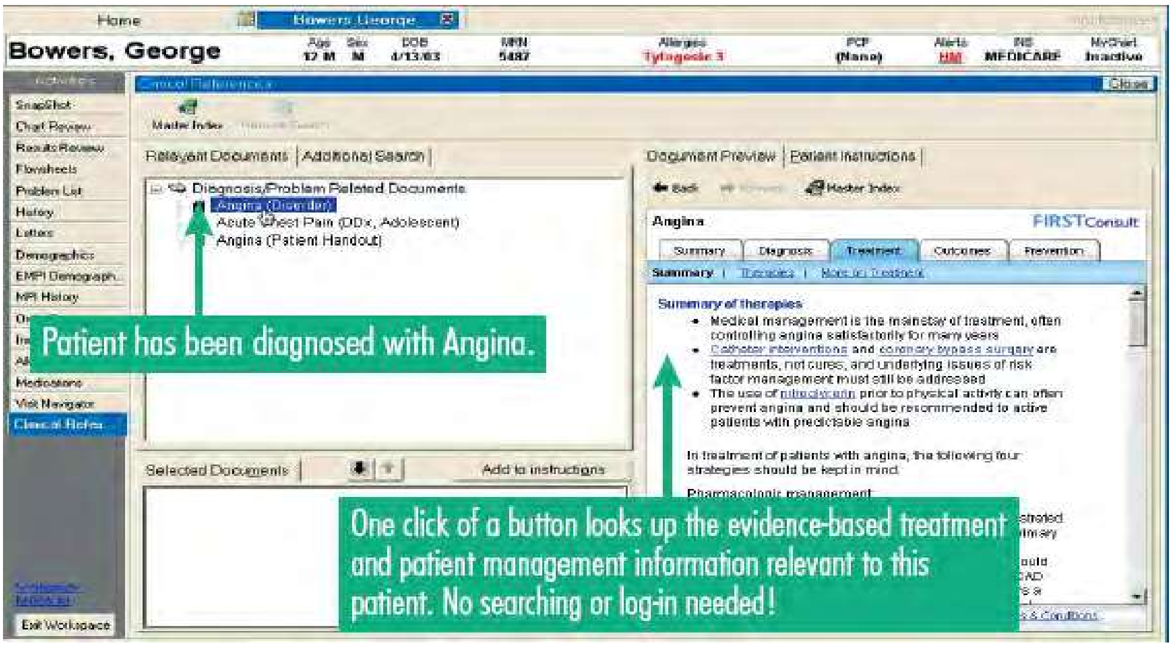
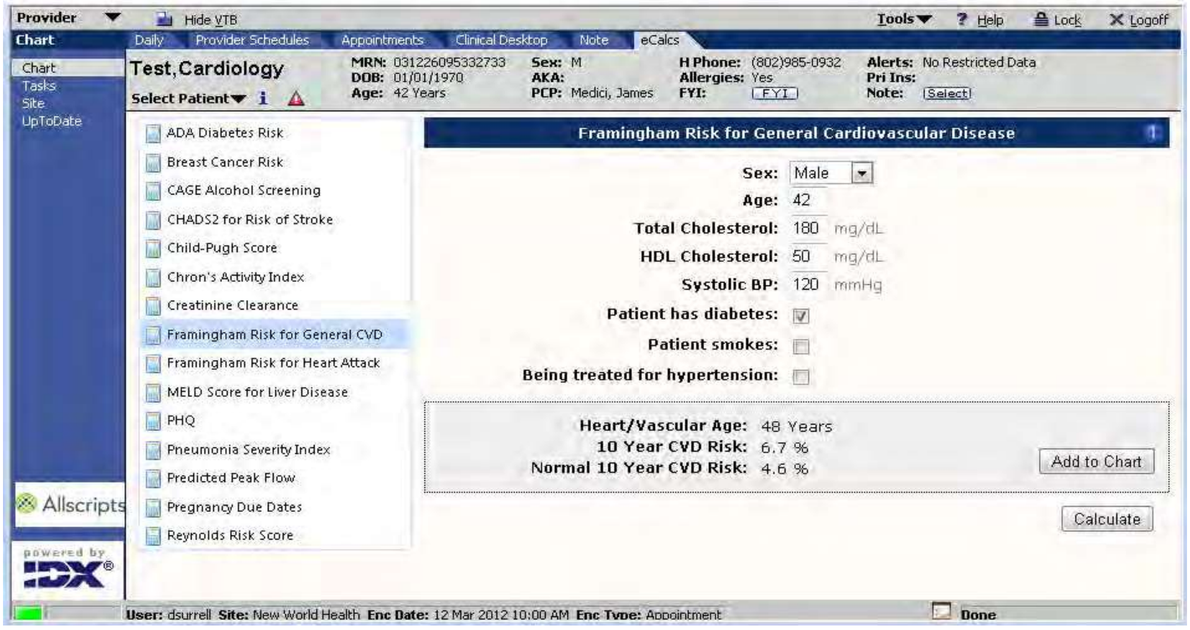


Figure 4.4: eCalcs (Courtesy eCalcs)



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. Dxplain 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.)

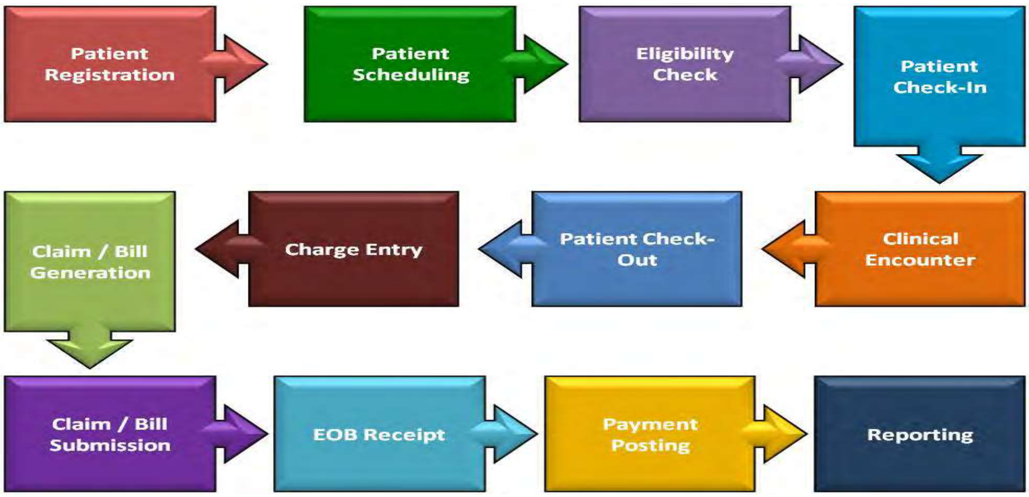
Additionally, a PM system provides routine and ad hoc reports so that an administrator can analyze the trends for a given practice and implement performance improvement strategies based on the findings. For example, a medical office administrator is able to use the PM system to compare and contrast different 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.

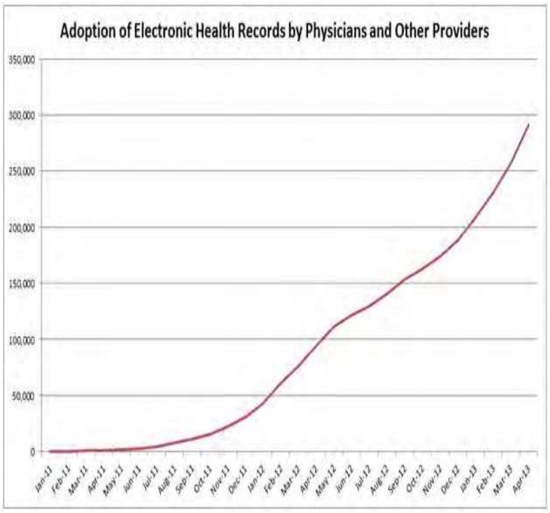
Electronic Health Record Adoption

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 plan[132]

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 heterogonous 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 implementtation 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

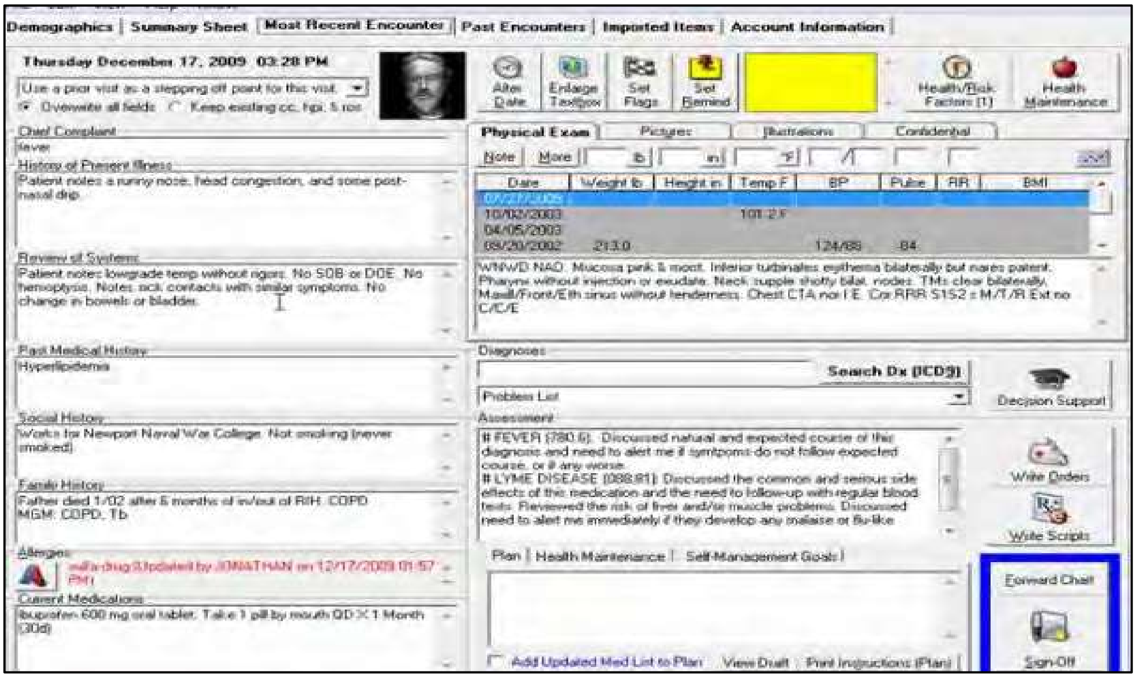
Amazing Charts: This simple and intuitive EHR is ONC ATCB certified and has scored high in usability by multiple reviewers which will be discussed later in the chapter. They offer a three month free trial which is unique among vendors. In 2013 they claimed more than 25,000 clinicians in 6300 practices.

- 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)

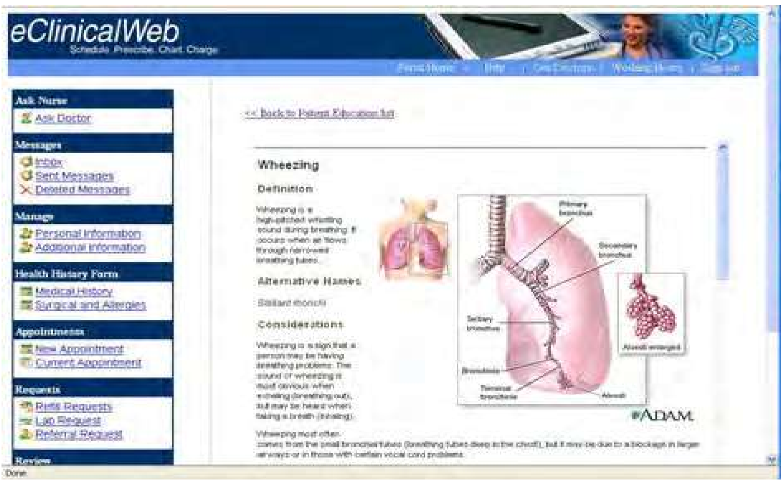


Medium Size Medical Practice

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 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 textbook[185-189]
  - Read important articles, monographs and surveys[190]
  - 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 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 research[231-232] increasing use of natural language processing[233] 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 pre-ventative/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 business days*.	> 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 though 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
All relevant data accessible through EHR CDS supports timely, effective, safe, efficient care and prevention CDS helps avoid inappropriate care. access to health information	Patients receive evidence based care Patients are not harmed by their care Patients do not receive inappropriate care
Provide patient and caregivers online access to health information Provide ability to contribute information in the record Patient preferences recorded and used	Patients understand their diease and treatments Patients participate in shared decision making Patient preferences honored across care teams
Relevant patient information is shared among healthcare team and patient, especially during transitions Goals, care plans, and interventions are shared and tracked	All members of a patients care team participate in implementing a coordinated care plan
Efficient and timely means of defining and reporting on patient populations to identify areas for improvement Shared information with public health agencies	Providers know the status of their patient's health Bidirectional public health data exchange
CDS support to avoid duplicative care CDS support to avoid unnecessary or inappropriate care	Eliminate duplicative testing Use cost-effective diagnostic testing and treatment Minimize inappropriate care (overuse, underuse, and misuse)
Patient conditions are treated appropriately (e.g age, race, socio-economic status, education, sexual orientation)	Eliminate gaps in quality of health and healthcare across racial, ethnic, sexual orientation and socioeconomic groups

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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. Secondarily, 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.

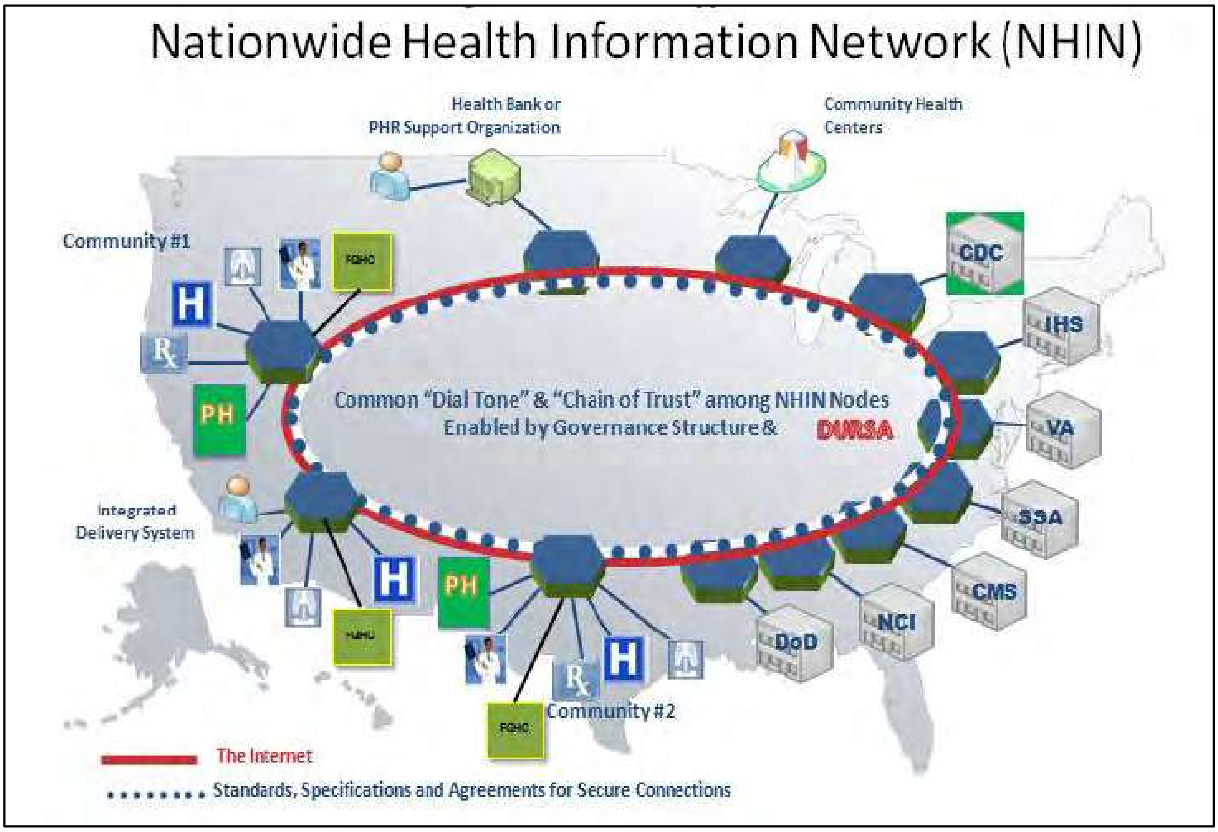
History of the Nationwide Health Information Network

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 R*equest 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 <u>not</u> 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.

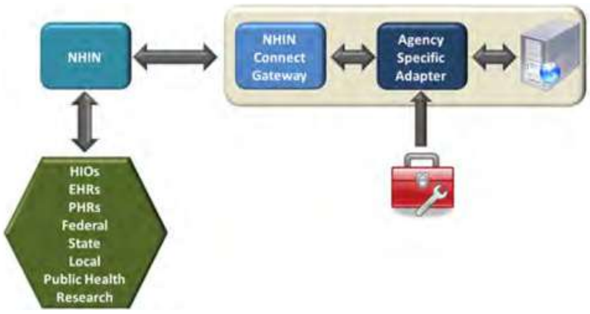
eHealth Exchange and HealtheWay

In 2012 the NwHIN Exchange was renamed the eHealth Exchange. Additionally, in 2012 a new entity HealtheWay was created to help direct the future of the NwHIN Exchange, discussed in the prior paragraph.. HealtheWay 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 ESC[16]

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.

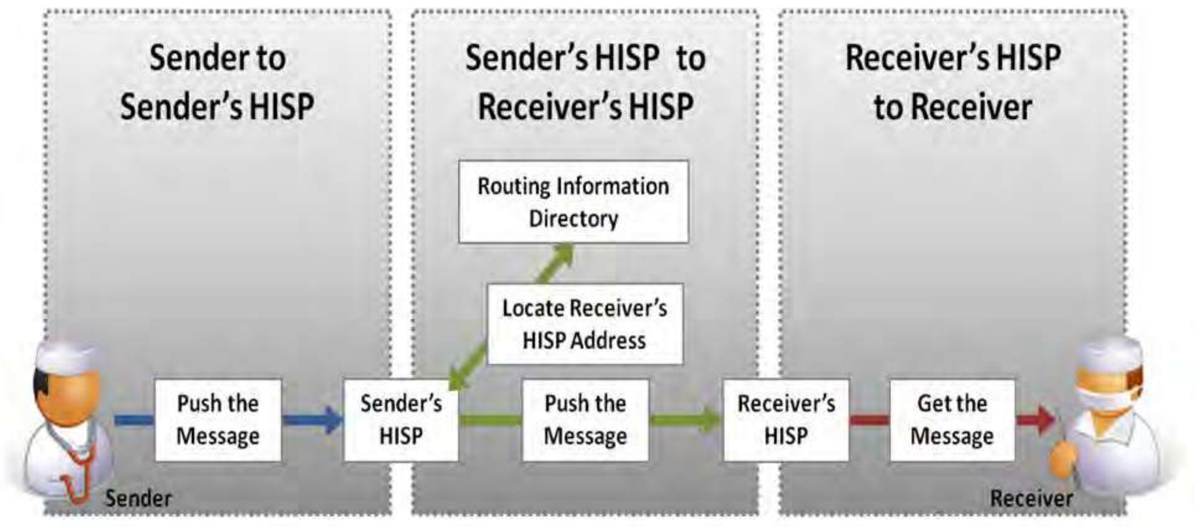
Launched in March 2010, NHIN Direct focused on the deployment of functionality using the lowest cost of entry from a technical and operational perspective. The purpose of NHIN Direct is to supplement traditional fax and mail methods of exchanging health information between known and trusted recipients 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 DURSAs 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

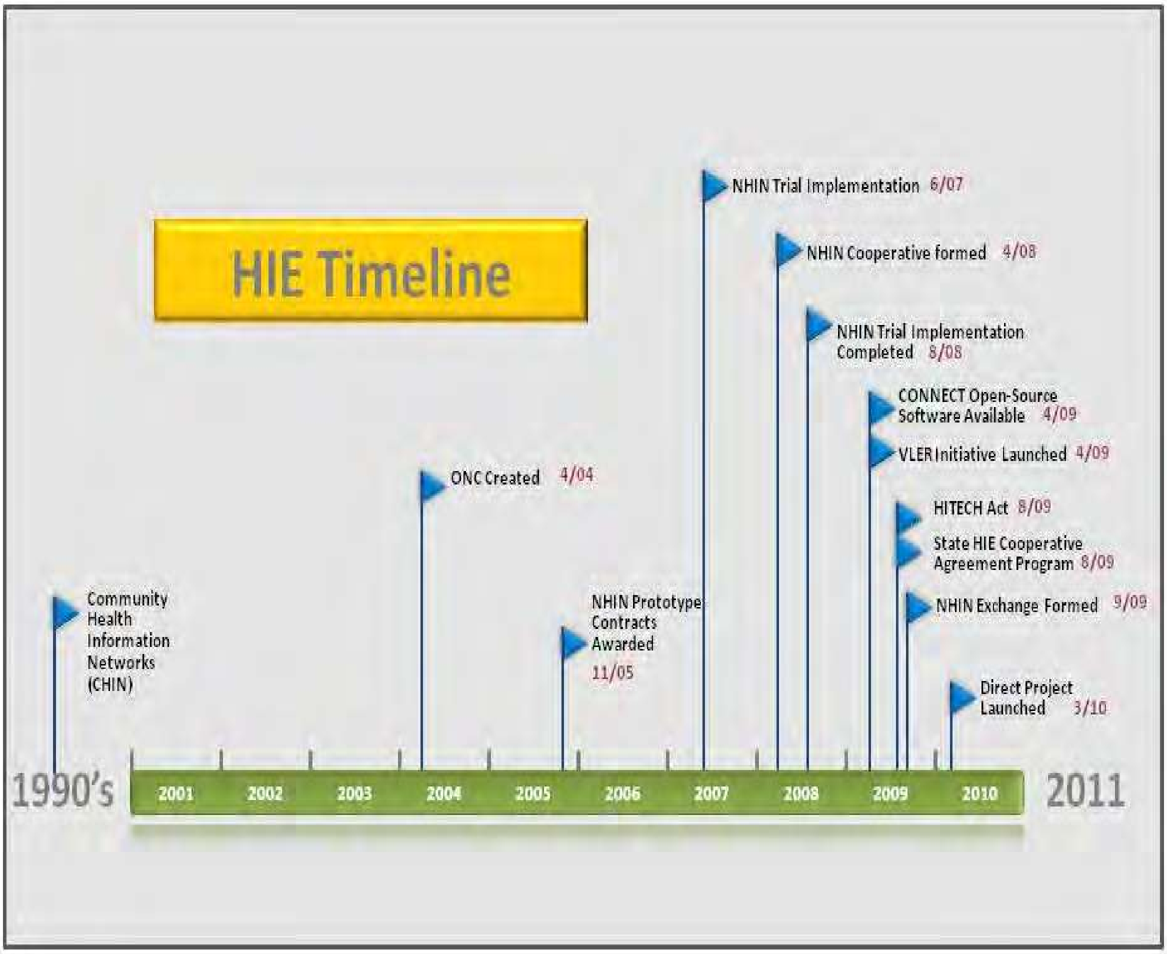


Table 5.2 HIE and Stage 2 Meaningful Use Objectives (EP =eligible physician, EH = eligible hospital)

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 authority[27]

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 Scalese[33])

	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.

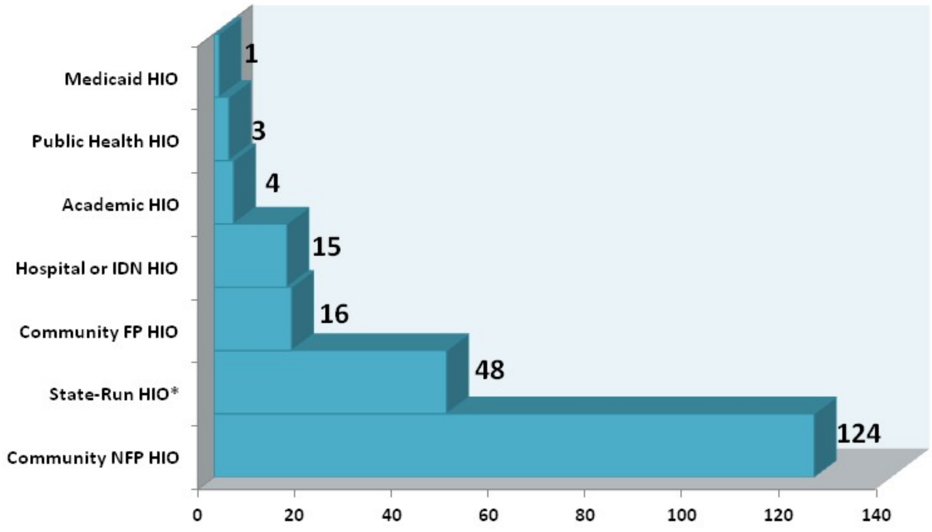
Furthermore, HIOs can be categorized based on ownership (see Figure 5.6)

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 included[42]

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 specifications[43]

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 services[44]

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 2015[45]

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 screening[46-49]

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]

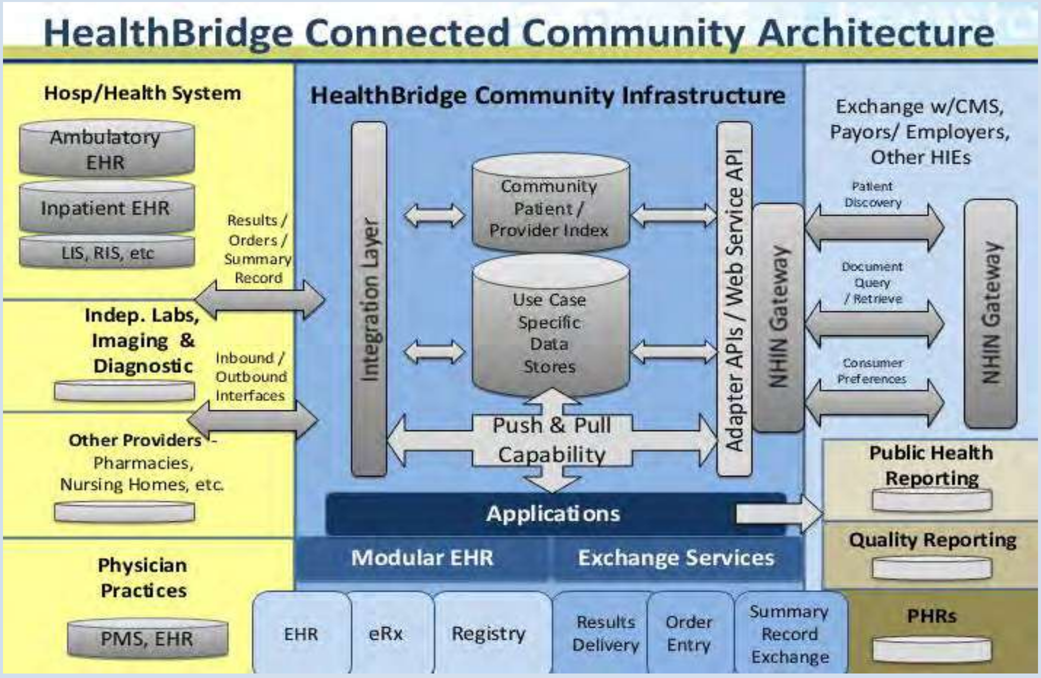
Claims-based HIOs

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 information[51]

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

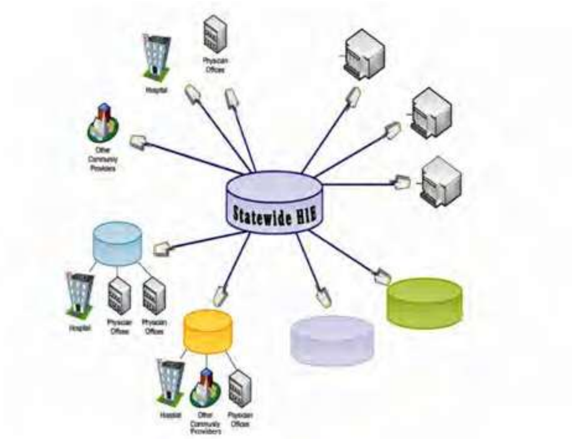
Statewide Health Information Exchange Cooperative Agreement Program (SHIECAP)

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 Program[52])



- 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 Health[52-53]

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 2006[61]
- 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 require-ments.[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 countries[78] 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 synomyms, 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|1999122271408|||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~PMA^^^^^^^^^^||||277^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)

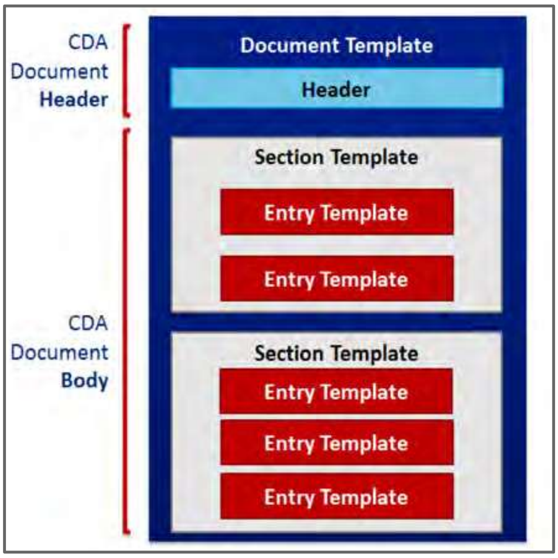
- In 2007 HL7 recommended the use of the Continuity of Care Document (CCD) standard. The CCD is the marriage of the Continuity of Care Record (CCR) (developed by ASTM International) and the clinical document architecture CDA (developed by the HL7 organization). The CCD has the advantage over CCR of being 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 Organization[8]



- 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 exit 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 inititiave 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 .

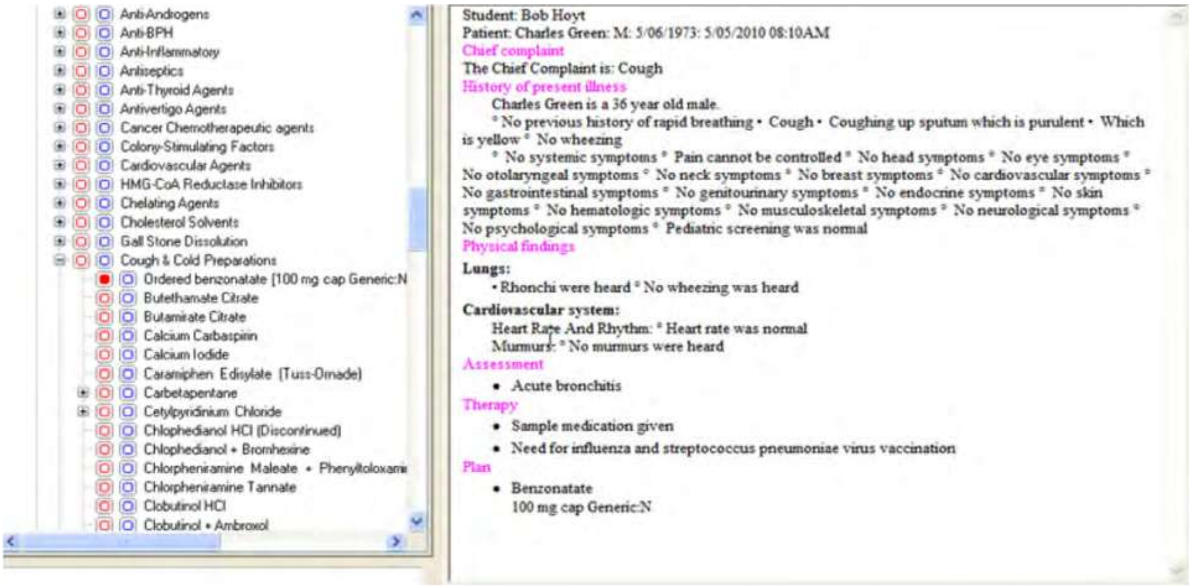
- SNOMED will be used by the FDA and the Department of Health and Human Services.
- SNOMED will be required for stage 2 meaningful use to record family history, smoking history, transitions of care, hospital lab submission of reportable cases to public health agencies and submission of cancer cases to 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 problems [20]
- SNOMED-CT Example: Tuberculosis
  - **D E – 1 4 8 0 0**
  - . . . .
  - . . . .
  - . . . 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 standard [24]

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:

- Certifed 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

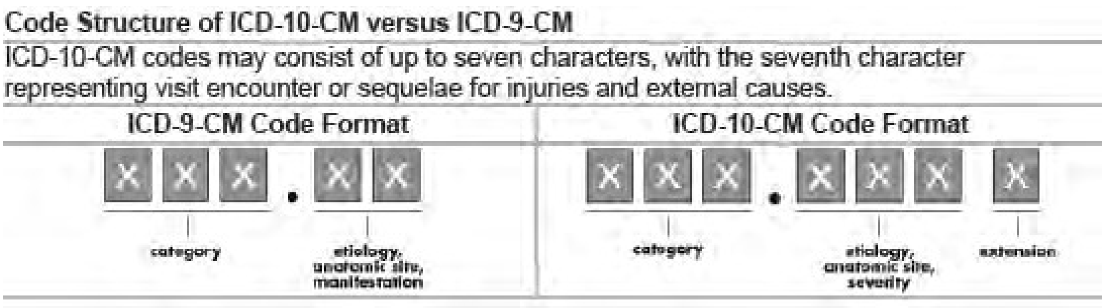


Table 6.2: ICD-9, ICD-10 comparision

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 hierarchial 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 7^{th} 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 physicians 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 procedures[31-32]

Healthcare Common Procedure Coding System (HCPCS)

HCPCS are codes used by CMS and contain two Levels:

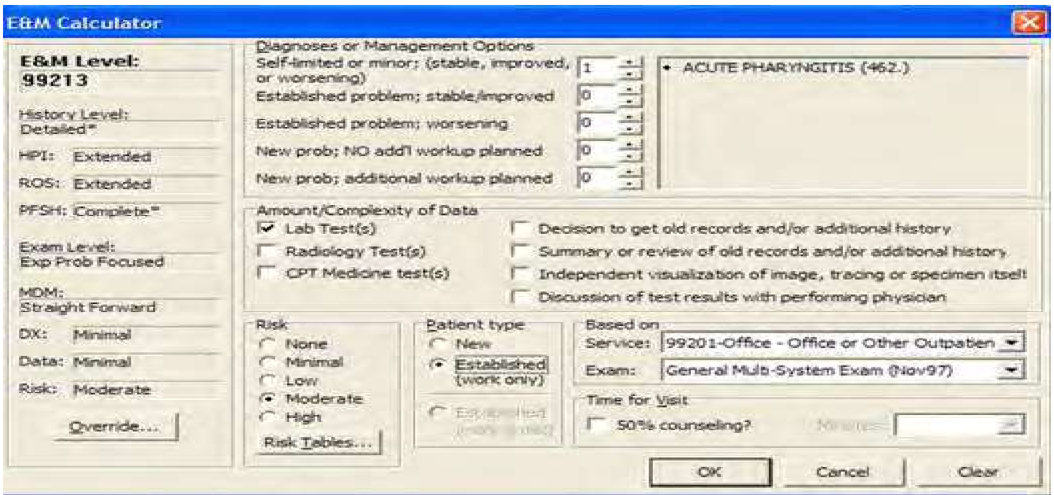
- Level I is CPT and purchased by CMS from AMA annually.
- Level II codes are used to obtain reimbursement for any procedure, service, supply, injectable or IV drip medication/nutrition, durable home medical equipment, orthotics, prosthetics etc.

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]

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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