Clinical Informatics Study Guide

Text and Review

John T. Finnell
Brian E. Dixon
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Contents

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Part I
Fundamentals

Chapter 1
Clinical Informatics: Emergence of a New Profession

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

Introduction

The roots of the applied informatics discipline date to the 1960s, when hospitals and other health-related entities first began to adopt the data processing capabilities that were taking hold in other aspects of business and science. Since the funds required to adopt such methods were substantial – this was the era of expensive mainframe computers before time-sharing or personal computers had been introduced – it is not surprising that the principal uses of computers were in large hospitals and that the applications were motivated either by clinical care or business operations. Thus the beginnings of clinical informatics can be identified some 50 years ago and the expertise in the area has had a half-century to evolve and mature – while it has also tracked the remarkable changes in technology as well as in the delivery and financing of health care that have occurred during that same period.

As growing numbers of individuals began to work at the intersection of computing and medicine, sometimes obtaining formal training in both areas, it became clear that a new profession was emerging – one that focused less on research and more on the effective practice of applied clinical computing and information management. Many questions arose regarding such individuals – questions that were vigorously discussed by early in the first decade of the new century. How might

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mid-career individuals get training in the area? Was it really necessary for them to go back to graduate school full-time? Was there a role for informatics as an area of subspecialty training for physicians who wanted to devote major portions of their careers to work in the area? How could an individual demonstrate to employers (typically health systems, hospitals, or other health-related entities) that he or she was qualified for a formal position in clinical computing, focused on practice, strategic planning, and implementation rather than on research? Might there be a suitable way to get certified in the area without needing to return to school to get a formal graduate degree?

Although these questions were asked by individuals from a wide variety of health professional backgrounds, they became especially pertinent for physician informaticians, driven in part by the creation of chief medical information officer (CMIO) positions occurring within a culture of recognized medical specialties. In this chapter we summarize what happened to address and answer these questions, culminating in the creation of a formal subspecialty for board-certified physicians through the American Board of Medical Specialties (ABMS). With that new subspecialty now in place, the need for formal training options has become more urgent. This volume is intended to help in the education of individuals who are preparing for their clinical informatics board examinations or who wish to refresh their knowledge of the field from time to time after they have been certified. Although the focus is on physicians who are eligible for formal ABMS certification, there are many other kinds of professionals who work in clinical informatics and the book will be valuable for them as well. Later in this chapter, we discuss efforts to create alternate certification pathways for individuals who work in the area but are not eligible to take the ABMS board examination.

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

Clinical informatics is an applied sub-discipline of the field of *biomedical informatics*, which has been defined by the American Medical Informatics Association (AMIA) as "the interdisciplinary field that studies and pursues the effective uses of biomedical data, information, and knowledge for scientific inquiry, problem solving, and decision making, motivated by efforts to improve human health" [1]. The term *clinical informatics* refers to practice in health care settings where the concepts of informatics are applied to the care of both individuals and populations. With the advent of widespread use of electronic health records (EHRs), it is now possible to manage populations of patients routinely, thus bridging a gap between personal and population health that has existed for over a century. This is one of the transformative aspects of clinical informatics as a discipline.

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

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

This volume, then, introduces and summarizes those concepts, methods, and tools, offering case studies and illustrations of both effective approaches and those that have limited the success of the field to date.

History and Development of Clinical Informatics as a Medical Subspecialty

Clinical informatics developed over a period of decades as computing and computer systems entered hospitals and clinics — primarily for billing purposes but also for laboratory results management and, in particular, for results reporting. A first-generation of clinicians emerged who were sufficiently interested in computing and computer science that they undertook formal study in these disciplines and then worked as researchers or practitioners at the intersection of computing and clinical care. By the early 1970s, the U.S. National Library of Medicine had begun to fund both research and the training of researchers in the emerging discipline. National meetings engaging those sharing these interests emerged during the late 1960s and 1970s. It was the introduction of an annual Symposium on Computer Applications in Medical Care (SCAMC), beginning in 1977, that served as a particularly important catalyst to the creation of a national community that, in time, became known as the *medical informatics* community. By 1984, the American College of Medical Informatics (ACMI) formed as an honorific society in which peers elected future members based upon their contributions to the field. Building on a smaller professional society known as the American Association for Medical Systems and Informatics (AAMSI), AMIA was formed in the late 1980s through a formal merger of ACMI, AAMSI, and SCAMC. AMIA quickly became the professional home where both senior and junior informaticians, including those focused on clinical care, could present their work as well as find out what was current in the field. Such informatics specialists were not necessarily physicians, however. From the beginning, AMIA welcomed all health professionals, and other scientists (e.g., computer scientists, decision scientists, cognitive scientists, sociologists) with an interest in

the application of computing and communications technology in health and health care. The term *informatics* was still new in the 1980s, and many workers in applied settings such as hospitals referred to what they did as "health information technology" (HIT or *health IT*). The HIT and health IT designations are still common today and at times have led to confusion regarding the relationships between clinical informatics and health IT. There has also been confusion at the international level in that most other countries have come to refer to HIT as HICT or health ICT, explicitly mentioning "communications" in addition to "information." Today the U.S. HIT community has a large trade organization known as the Health Information Management Systems Society (HIMSS), whose annual conventions often attract clinical informaticians who want to interact with colleagues and track the newest technologies and products. AMIA, with its own annual informatics meeting, has complemented and cooperated with HIMSS while attracting a more scholarly audience, including both researchers and professionals who look beyond the technology to educational needs and the conceptual underpinnings of knowledge and information management in health care settings.

Defining the Characteristics of the Profession

Following the release of a professional code for informaticians in 2004 [4], AMIA held a Town Hall meeting during its annual symposium to discuss the matter of formal training and certification in clinical informatics, regardless of one's area of clinical expertise or even one's previous health professional training, if any. The goal was to approach clinical informatics as an integrative discipline across all of health care. Further, the AMIA Board decided to begin its formal efforts with just one of the health professions rather than to try to mount a certification effort across all disciplines at once. The decision meant that AMIA would first pursue certification for physicians and then, with insights and lessons from that effort, pursue interprofessional certification for other clinical informatics experts (see the discussion of this topic at the end of this chapter). It made sense to start with MDs because many existing clinical informatics subspecialists were also physicians, board-certified in one of the major clinical specialties (e.g., internal medicine, surgery, pediatrics, radiology) and because the notions of specialist and subspecialist, and the processes for their certification, were familiar and well defined. A subspecialty, in this context, is a field of narrower concentration for someone who is already certified as a specialist. For example, cardiology is a subspecialty of internal medicine. As was successfully argued, clinical informatics can be viewed as a relevant subspecialty for physicians trained and certified in any of the standard specialties — i.e., they may appropriately work in clinical informatics regardless of their primary training and practice.

Any new discipline within the medical profession, seeking to obtain support for formal specialty or subspecialty status from medicine as a whole, must first convince other medical specialists and subspecialists that the discipline is worthy of

such designation. Thus three critical sets of players were involved in addressing the challenge that faced AMIA:

- First, clinical informatics needed to be viewed formally as a separate discipline by other medical specialty groups. Such recognition is evident when a nationally recognized organization that represents the rising discipline is elected to formal membership in an organization such as the American Medical Association (AMA) or the Council of Medical Specialty Societies (CMSS).
- Next, the subspecialty needs to be recognized by the American Board of Medical Specialties (ABMS). ABMS is an umbrella organization for the certifying boards in all the various specialties and subspecialties of medicine; it formally recognizes specialties and subspecialties and also, through its constituent boards, creates and maintains the certification examinations that attest to the competence of medical subspecialists.
- Third, the Accreditation Council for Graduate Medical Education (ACGME) must be engaged since the ACGME exists in large part to review and accredit training programs capable of preparing candidates to sit eventually for the certification examinations of the constituent boards of the ABMS.

Accordingly, the President of AMIA approached the officers of CMSS to determine if they would consider making AMIA a member of CMSS. CMSS is an organization whose purpose is to provide a forum for collaboration among medical specialty organizations to influence policy, medical education and accreditation from a broad, cross-specialty perspective. Within a few months, AMIA had been elected to membership in CMSS and its President, Don Detmer, was elected to serve as its Treasurer. He went on to participate actively at meetings of the organization.

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

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

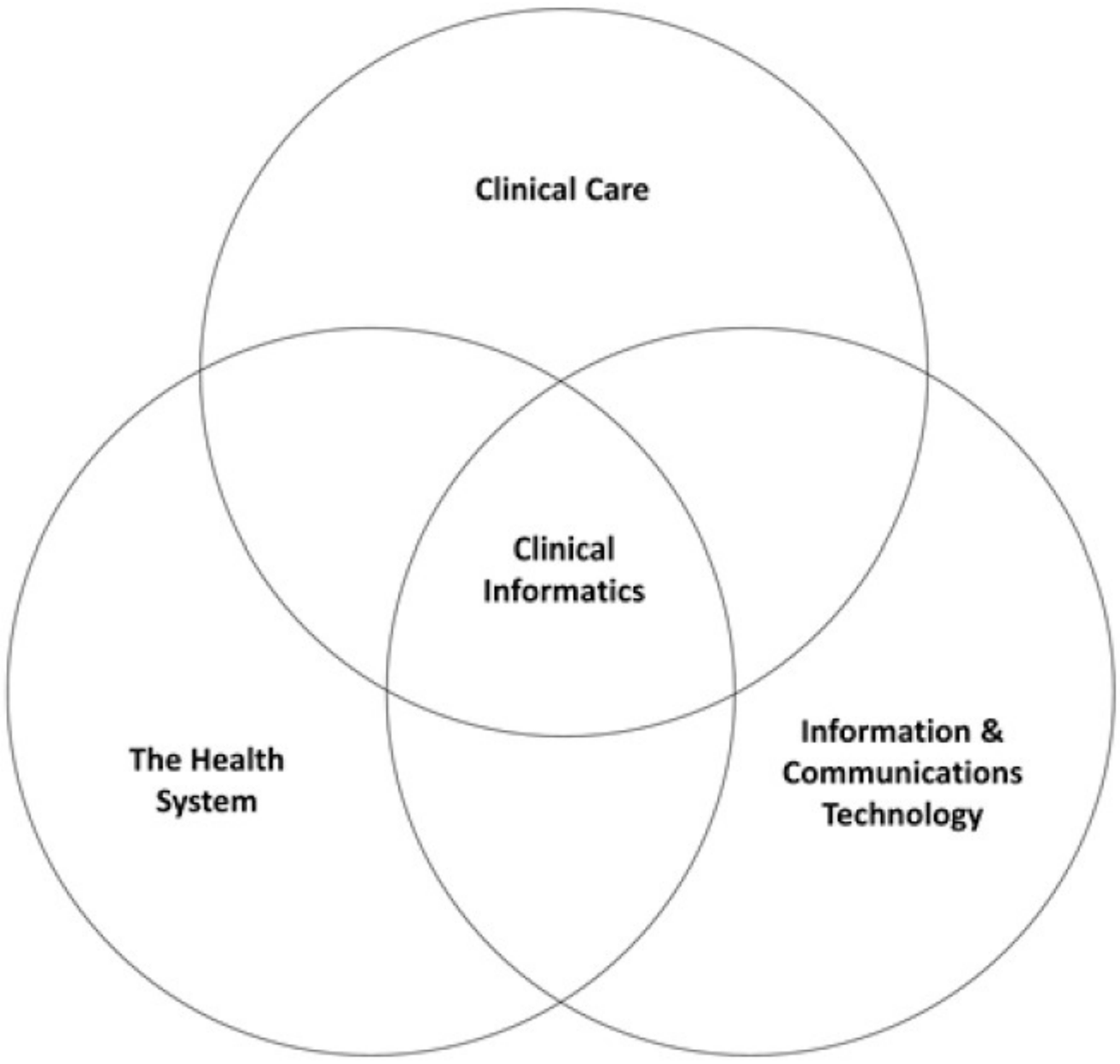

Fig. 1.1 Domains of clinical informatics (Reproduced from Ref. [2] with permission from the American Medical Informatics Association and the Journal of the American Medical Informatics Association)

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

Seeking Approval for the Clinical Subspecialty

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

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

Verbal support from other boards was helpful in reassuring ABPM that there was enthusiasm within ABMS for the creation of the new subspecialty and AMIA gathered suitable data to help to demonstrate the potential demand for such a certifying exam. In addition, in mid-2009 at the meeting of AMIA's Academic Forum in Colorado, Shortliffe invited a senior leader from ACGME to meet with informatics program directors who, up until then, were most familiar with requirements for graduate (MS and PhD) education and generally had less familiarity with formal fellowships that would need to be accredited if trainees were to become board-eligible within the ABMS certification model. The interactions at that meeting were crucial, not only because informatics educators began to understand the ACGME accreditation model but because ACGME leaders began to realize that, if they were involved in accrediting informatics fellowships, they would encounter many issues that had not arisen previously. There were, for example, questions of whether masters' degrees would be required or optionally offered to clinical informatics fellows in training and how or whether that option would be assessed by ACGME. Most fellowships have both clinical and research requirements, but what was "clinical time" for a clinical informatics fellowship? Perhaps it could be a service component that affected clinical programs at the affiliated medical institution? Unlike most fellowships, it was unclear what a "direct patient care" component would be. Since fellows could come from a variety of clinical backgrounds and specialties, it was not reasonable to expect the informatics fellowship formally to provide a panoply of direct patient-care opportunities in every specialty. In fact, ACGME began to realize that the creation of a clinical informatics subspecialty would require them to rethink the definition of the term "clinical". Shortly after the Colorado meeting, ACGME leaders began a discussion of this question, leading to the formal adoption of a new, expanded definition that was approved by their board and placed on the ACGME web site in 2009 [8].

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

This new definition became an extremely important factor in the subsequent discussions with ABMS as the subspecialty proposal was being considered.

By the autumn of 2009, the leadership of the ABPM had approved a plan to propose the new subspecialty to ABMS. As is customary for new subspecialties, there was to be a 5-year "grandfathering" period during which active clinical informaticians who were also ABMS-certified physicians could apply to be deemed board

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

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

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

The Clinical Informatics Subspecialty in the Context of ABMS Evolution

The subspecialty of clinical informatics occupies an interesting space within ABMS. In 1972 ABMS initiated the process of approving new subspecialties [9]. American medicine was early in the process of practice differentiation. Except for the surgical specialties, graduate medical education beyond a 1-year rotating

internship was uncommon. The American Boards of Pathology, Internal Medicine and Pediatrics had begun to develop subspecialties and nine were created. Each of these subspecialties had a direct relationship to one primary board (e.g., cardiology, gastroenterology, forensic pathology, hematology). The certificates were each issued by their primary board.

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

The 1980s brought the first discussions among ABMS boards about a subspecialty that might cross primary specialties and therefore require a different approach to examination development and administration. During this decade ABMS also produced 21 new subspecialty certificates.

When a subspecialty is associated with only one primary board, the lines of responsibility are very clear. That board sets the policies, develops and administers the examination, and issues the certificate. With a subspecialty area that has common training standards but involves fellows from more than one board, and with more than one board issuing a certificate, the process became more complex. An example of this new approach was geriatric medicine. Both the American Board of Internal Medicine (ABIM) and the American Board of Family Medicine (ABFM) issue subcertification in geriatric medicine. Both boards participate in the development of the examination but ABIM takes responsibility for formal examination administration.

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

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

Between 2000 and 2009, ABMS approved 34 subspecialty certificates. This number was significantly influenced by two new subspecialties, (a) hospice and

palliative medicine and (b) sleep medicine. Hospice and palliative medicine has ten co-sponsors; sleep medicine has six.

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

Creating and Offering the Board Examination

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

Once ABMS gave approval to ABPM to issue subcertification in clinical informatics, the process moved to ACGME. As was mentioned earlier, ACGME is the organization responsible, in the United States, for the accreditation of graduate medical education programs in all medical specialties and subspecialties. During the entire development process the AMIA leaders involved kept continuous contact with ACGME to assure that they were well aware of the process that was proceeding through the ABMS.

In 2011, ACGME appointed a Residency Review Committee (RRC) group to develop the new program requirements and recommend them to the ACGME Board. The committee was composed of graduate medical education experts in clinical informatics. The review committee began with the Draft Training Requirements developed and published by AMIA [2, 3]. The review committee also requested feedback from the clinical informatics community and, on the basis of that feedback, developed a recommendation that was submitted to the ACGME Board and approved in February 2014.

As a parallel process, the ACGME staff began the construction of the Program Information Form (PIF) to be used by programs to apply for ACGME accreditation. This PIF was made available to potential applicant programs in May 2014.

During the construction and approval of the necessary ACGME documents, another interesting issue surfaced. Although ABPM is the administrative primary board within the ABMS structure, with ABPath as co-sponsor, the intent of the fellowship training process was to avoid limiting sponsorship of fellowship programs exclusively to departments of preventive medicine or pathology. It was always envisioned that many other primary specialties would be interested in sponsoring fellowship programs and therefore local medical school and teaching hospital departments from a wide variety of specialties would submit applications to ACGME.

When the original Program Requirements were approved and distributed the list of primary specialties that could sponsor an ACGME fellowship program was limited. The reaction to this list was immediate as several of the larger primary specialties, such as internal medicine, pediatrics, and family medicine were not included. The ACGME understood the issue and worked with AMIA's graduate medical education leaders to raise the issue with the leaders of the missing primary specialties. AMIA leadership coordinated a series of conversations between the informatics faculty in the appropriate primary specialties and the leadership of the target RRCs to explain the concern and to seek their support for allowing their RRCs to be involved in the accreditation process. A primary concern from the RRC leaders was the lack of expertise in clinical informatics among their RRC members. It was also clear that the interest of individual primary specialties at the local departmental level is often not available to the leadership of such national organizations. As a result of this process the program requirements for clinical informatics, approved in 2014, allow for sponsorship by departments of nine primary specialties (anesthesiology, diagnostic radiology, emergency medicine, family medicine, internal medicine, medical genetics, pathology, pediatrics and preventive medicine).

The RRC leaders' discomfort was greatly mitigated by the presence of the Clinical Informatics Review Committee (CIRC) that had been approved and appointed by the ACGME. The CIRC provided a structure through which applications from clinical informatics fellowship programs could be pre-reviewed by a panel of experts with a recommendation provided to the RRC responsible for the decision. That group of reviewers continues to function as initial reviewers of all incoming applications for the accreditation of clinical informatics fellowships by ACGME.

Initial Development of Fellowship Programs

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

like the proposed ACGME fellowships and others that had many years of experience and funding but were blends of degree and certificate programs. A good number of the programs on the list were located in medical schools or had existing faculty relationships with one. Many were also funded by the National Library of Medicine and had been in operation for many years. One of the assumptions in the subspecialty application was that a significant number of the existing programs would move to create a parallel program that would train physicians using the ACGME program requirements.

In 2014 the first applications were submitted to the ACGME, were reviewed by CIRC and recommendations were sent to the appropriate RRCs. In late 2014 the first set of ACGME-accredited fellowship programs in clinical informatics was approved [10].

Career Options for Clinical Informaticians

Career options as well as job opportunities are expanding rapidly for trained and experienced clinical informaticians, particularly within healthcare delivery systems. As previously noted, the most likely title for an experienced clinical informatician is *Chief Medical Information Officer* (CMIO). This position in a healthcare organization is at a senior level within the executive structure and typically reports to the chief executive officer (CEO) or the chief medical officer (CMO). The role enjoys close interactions with the chief information officer (CIO) as well as the rest of the senior management team. Principal responsibilities relate to serving as the primary point of contact between the medical staff and the institution's clinical information systems, e.g., electronic health records, data exchanges, and data repositories, as well as systems to address clinical performance, such as quality and safety. When the notion of a CMIO was first introduced, these positions had tended to report to the Chief Financial Officer (CFO) or the CIO and had focused more on information technology as infrastructure rather than as a strategic asset. The role, with its new reporting structure, has evolved to be a strategic as well as operational position. Although the trend today is for the CMIO to report to the CEO or CMO, there is substantial variation. Furthermore, based upon one's personal attributes, experience, and aspirations, some clinical informaticians are beginning to find themselves pursued for the CIO, CMO, or even CEO roles. Looking forward it is likely that clinical data analytics, with an emphasis on clinician performance, quality, safety, and external reporting relating to these matters, will play a larger role in the CMIO job description.

As the numbers of trained clinical informaticians increase in the future, it is also possible that all major departments and/or units in major healthcare delivery systems may have a "Chief Surgical IO", a "Chief Pediatric IO", and other such individuals who work across the major departments and also link to other health professionals such as nurses, pharmacists, etc. Chief Nursing Information Officers (CNIOs) are already becoming common in larger health systems, as are Chief Research Information Officers (CRIOs). The Veterans Health Administration in the U.S. includes Chief Health Informatics Officers (CHIOs) within many of its medical centers, who

represent a variety of clinical backgrounds. The role of such individuals is to serve as members of a clinical informatics team whose job is to assure that HIT systems meet growing strategic goals – supporting clinical operations, as well as research, while engaging patients, community resources, and other relevant entities both near and far.

A recent movement among a number of state departments of health is to create an equivalent position of CMIO to offer strategic advice and to provide oversight of public health considerations, linking with other health data experts in the state (including CMIOs in healthcare delivery systems). The fact that ABPM also deals specifically with the care of populations makes this newly emerging position a good fit with the ABPM and its administrative oversight of the clinical informatics subspecialty and design of the board examination.

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

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

Current Challenges for Clinical Informatics

Addressing the Training of Clinical Informaticians

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

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

Early steps in the creation of fellowships suggests that some will arise from within specific specialty units or clinical departments within hospitals or medical centers. As was discussed earlier, those programs will need to partner with one of the nine primary specialty programs through which the ACGME accreditation process will be carried out by the RRCs. Complex relationships and partnerships will need to be created if the fellowship "home" is not in one of the nine specialties. Furthermore, there are questions about whether and how the RRCs will standardize the way in which they evaluate the clinical informatics fellowships. Will there be uniformity in expectations across the specialties, deferring to the CIRC review, or will fellowships evolve to take on an emphasis related to the specialty group with which they are partnering [11]? As this volume emphasizes, clinical informatics is viewed as a broad and integrative discipline. Unintended evolution of sub-subspecialty programs (e.g., *anesthesia informatics*, *pediatric informatics*, *radiology informatics*) would run counter to the intentions of AMIA, ABPM, and ABMS when they approved the subspecialty. Those completing fellowships need to have a broad knowledge of the field, regardless of their primary specialty or the "partnering" specialty responsible for the ACGME accreditation of their training program.

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

As with most fellowships, the program director for a clinical informatics fellowship is expected to be board-certified in the subspecialty. This creates start-up challenges for institutions that may not have such expertise in house. Furthermore, the fellowships require additional faculty who can define the curriculum, offer it to

trainees, serve as mentors, and oversee projects. Thus we can anticipate substantial needs for new faculty at many institutions that would like to offer fellowships. Accreditation of their program will clearly require that they have the required local expertise. Given the potential shortage of board-certified subspecialists, especially starting in 2018, this could be a great challenge as the discipline seeks to increase the available fellowship training opportunities.

As organizations and institutions seek to find qualified individuals, they are faced with a dizzying array of credentials. There are multiple organizations in the informatics certification field. These credentials cover a wide range, including basic certificates, degrees from academic entities, and training and certification based on accredited programs [12]. Employers looking at this landscape have a difficult time identifying the training and skill base represented by each option [12]. ABMS certification in clinical informatics is, of course, intended to help with this problem. By establishing an official subspecialty, ABMS and ABPM have sought to offer a credible reference certificate to employers who seek to engage physicians in their clinical informatics processes. But, as with any certificate, ABMS certification in clinical informatics cannot address every employer's needs, especially in the short term. The implementation of the ACGME-accredited training programs will take several years and physicians holding that certificate will not fill every position. What has been put in place is a credible training and certification system based on a public core content of skills and knowledge.

In addition to the "supply" concern just outlined, there are questions regarding demand. Physicians in the informatics community have been decrying the lack of informatics content in the medical school curriculum for some time [13, 14]. Until recently there have been very few role models for medical students who might develop an interest in clinical informatics, and there is accordingly hope that the creation of the formal ABMS subspecialty, plus the introduction of fellows and faculty who have expertise in the area, will increase the credibility of this training option and draw more physicians into the discipline. The challenge, of course, will be to match the supply and demand so that there are not only applicants to fill the available fellowship positions (which does not currently seem to be a problem) but also enough positions to match an increasing number of residents who wish to pursue subspecialty training in clinical informatics.

Another dimension of importance with respect to board certification is the issue of maintenance of certification (MOC). This aspect of the current specialty certification landscape is particularly rocky at present, with rising concerns from specialists and others about a number of issues relating to MOC, including costs, relevance to actual competence on the job, and current professional practice profiles, among others. Since clinical informatics is such a new entrant to formal recognition as a subspecialty, further discussion of this issue will not be discussed here except to acknowledge that it will be an important issue for AMIA and ABMS in the years ahead. There is a movement in medical education to transition from "time in seat" to competency-based education wherein the criteria for professional performance are explicit and learners can advance based upon their individual pace, as evaluated by both written exams and observed demonstrations of knowledge and skills. Many

hope that MOC will also eventually adopt this approach, both for clinical informatics and more broadly. However, there are major pedagogical, administrative, and political aspects that will need to be accommodated before such new approaches will be adopted for both specialty education and MOC.

Interprofessional Certification

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

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

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

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

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

Population and Global Health

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

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

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

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

Concluding Remarks

The details of the clinical informatics certification process we have outlined in this chapter are arguably less important than the larger lesson: despite a 50-year history, clinical informatics is young and only now coming into its own as a broadly recognized professional discipline. The steps required to advance the cause were time-consuming, arduous, and met by setbacks along the way. But the dominating logic of recognizing the importance of informatics to our health and health care systems has both inspired persistence on the part of the prime movers in the process and influenced the reception that the field has garnered as more people learn about its substance and strategic importance. Its broad interdisciplinary nature, coupled with a commitment to interprofessional training and exchange, is a model for others to follow as many people in health and medicine strive to break down traditional silos and to promote inclusiveness and openness – not to be politically correct but because it clearly makes sense for the health of our people and the future of our world.

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Chapter 2
The U.S. Health System

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Learning Objectives

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

- describe components of the health care delivery system
- summarize the state of health care delivery in the United States
- explain the role of data in health system planning and policy making

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Core Content

The following core competencies are covered in this chapter:

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

Case Vignette

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

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

The patient is moved into a special isolation room where he is hooked up to a variety of monitors to track his vital signs, and the doctor suits up to perform a complete assessment. The doctor notes that the patient also has a stiff neck and as his headache has grown worse, he has begun complaining about the lights being on in his room. After finishing his exam, the doctor documents his new findings in the EMR and reviews the patient's past medical history, current medications (verified earlier with the patient by the inpatient pharmacist), and checks for any allergies entered earlier by the nurse. Based upon these findings, the doctor locates the appropriate Order Set for working up his patient, and looked through the list of testing options, leaving all of them checked—multiple types of bloodwork, a spinal tap and a few other tests. He then looks at the choices of pain medications listed in the order set and chooses one for now and a stronger dose, if needed. He leaves the rest of the orders as they are written for the nurses to follow in their daily care of the patient. He thinks of how good it is that they now have these standardized Order Sets created, so that they know they are delivering consistent, evidence-based medicine.

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

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

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

fiable" disease per the Centers for Disease Control (CDC) National Notifiable Diseases Surveillance System (NNDSS). Per protocol, the State Health Department then notifies the CDC of this patient through the same electronic tracking system.

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

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

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

As the nurse is preparing him to be discharged, she goes over a set of post-discharge instructions with him. Then, she asks him if he is familiar with the patient personal health portal that is available for him within the EHR. He is not sure, so she shows him how to set up his account, and get logged in, then she goes over how to send secure messages to his caregivers, look at past lab results, radiographs, and other diagnostic tests. She also shows him how to review and download summaries of his clinic visits and hospital stays if he needs them for future doctor visits out-of-network or for other reasons. She reminds him that as a part of his follow-up instructions he is to schedule an appointment with his primary care provider in clinic in 2 weeks. She shows him a scheduling tool in the portal where he can do this on-line if he would like. She also lets him know now that he is signed up for the portal, he will get an email reminder to schedule his appointment if he hasn't done so in a week.

Throughout the patient's stay, charges for all of the testing, supplies, and daily care he received from the hospital were entered into the hospital's billing system through his EMR. At the end of his stay, these charges were submitted electronically

to the insurance company on file. The summary data from his hospital stay was copied to the hospital's data warehouse, to be utilized for quality review and other internal projects, and it was copied to the state Health Information Exchange (HIE), to make it available to physicians at out-of-network hospitals who might treat the patient in the future.

Introduction

The U.S. Health System is composed of a highly complex network of organizations, institutions, and resources focused on the monitoring, maintaining, and improving the health of individuals and populations. Health care delivery, public health, clinical research, education and health professionals, and personal health are all domains of the health system. Health information has a specific and important role in each of these, as do health policies and economics. Understanding the basic structure and function of the health system and the flow of information (data) within and between its various domains is critical to the field of clinical informatics. This chapter will examine the various domains of the health system and serve as a foundation to understanding the role of clinical informatics in this intricate and complex system. We begin by considering the concept of health as an individual and population characteristic in order to provide a frame of reference for studying the health system.

Health

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

The determinants of health do not exist within a vacuum, they are intertwined and interdependent. Genetics are the foundation of human health. Genes are responsible for basic level of health at birth and determine risk for certain diseases [2]. Beyond genetics, however, individual and environmental factors also have a large influence on human health. Poverty, for example, is a social factor commonly associated with health and also related to physical environment, another determinant of health. People living in poverty are more likely to reside in low-income communities where health care resources are scarce and difficult to access.

Regardless of their genetics, poor individuals living in low-income communities are more likely to experience barriers to access health care services than their more affluent counterparts. This simple example illustrates the complex nature of human health and those dimensions beyond the bounds of health care delivery.

Individual Versus Population

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

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

Individual health information has been part of health care delivery from its start, as a tool for practitioners to document and monitor the patient health. Historically, data were documented in record books by hand. Handwritten records evolved into patient charts, which are now health information systems employing sophisticated technologies. Health care providers gather health information to determine patient's health status and inform diagnoses and treatment planning, but individuals are increasingly monitoring their own health. New and emerging technologies empower individuals to collect and monitor their health. These technologies and their role in personal health are explored later in the chapter.

Population health information has also been recorded for many years. The earliest population health information includes mortality records and recordings of major epidemics that occurred throughout history. The 'Bill of Mortality' from 1665 depicted in Fig. 2.1 demonstrates how early data on cause of death were recorded and reported. The first documented recording of population health data to monitor trends in health and disease to determine the source or causation were done by the British physician John Snow. Snow, a nineteenth century anesthesiologist from London, England, is credited with systematically studying a cholera epidemic in his community and identifying polluted drinking water as the source. This study of an epidemic and subsequent intervention, removal of the water pump handle to the contaminated drinking water supply, were successful in stopping the cholera epidemic [4].

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

The Diseases and Casualties this year

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

Fig. 2.1 Bill of mortality from 1665. The 'Bill of Mortality' from 1665 demonstrates how early data on cause of death were recorded and reported

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

The Right to Health

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

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

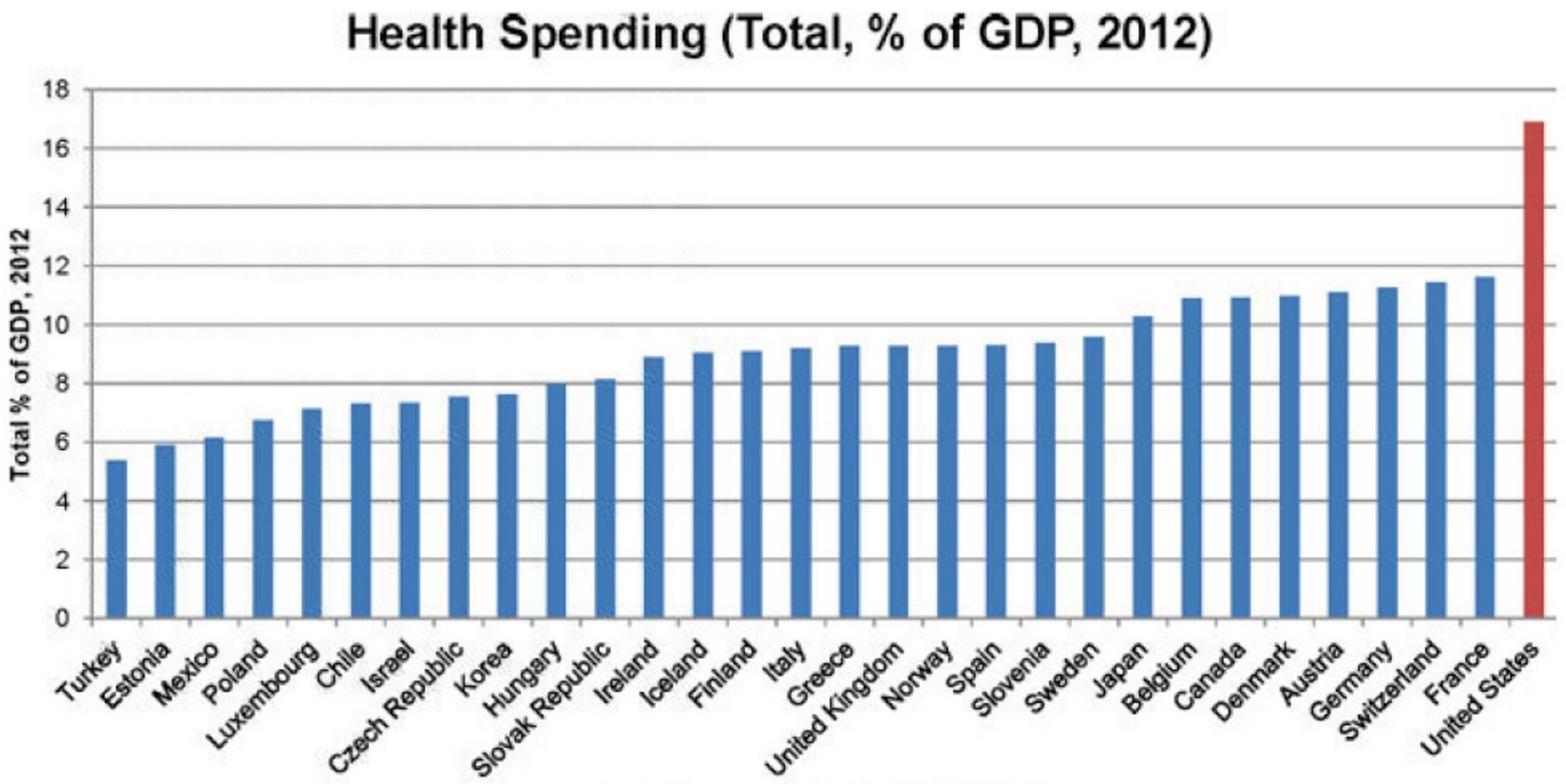

Fig. 2.2 Health spending among OECD (Organization for Economic Co-operation and Development) countries. This figure shows the United States' health care spending relative to other OECD countries (Data source: OECD Health Data 2012)

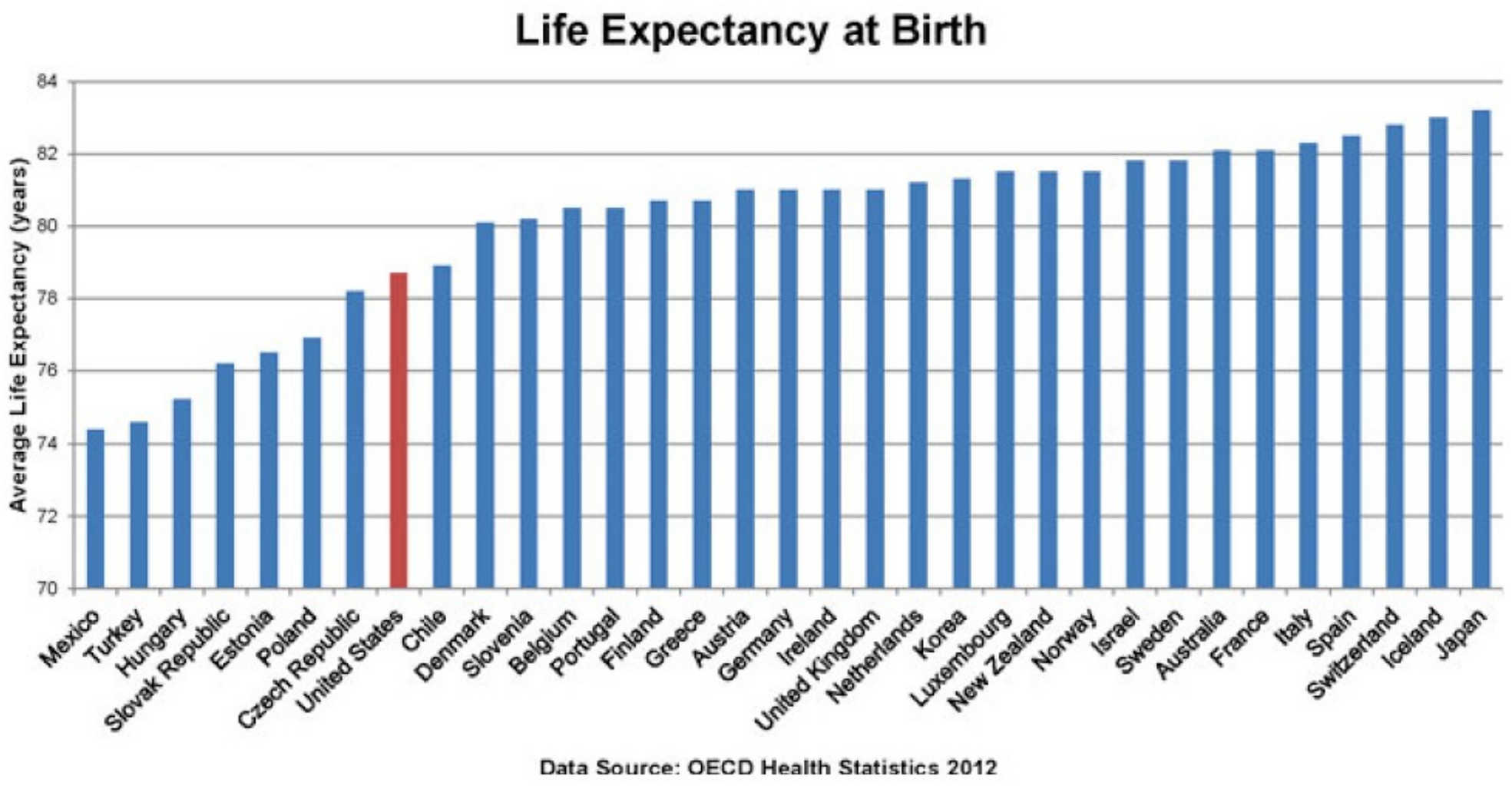

Fig. 2.3 Life expectancy at birth for OECD (Organization for Economic Co-operation and Development) countries. This figure shows the United States' life expectancy relative to other OECD countries (Data source: OECD Health Statistics 2012)

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

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

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

Summary

Health is a defining human characteristic and a basic human right. Many factors interact and influence health, including genetics, social and physical environments, medical care, and behavior. The 'right to health' is almost universally recognized. Although the United States reports the highest percentage of GDP is spent on health care, its population lags behind other developed countries in life expectancy and other population health measures. Contributing to this is an inefficient disease focused health system.

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

Where genetics are the foundation of human health, information is the foundation of the health system. The next sections of this chapter review the major domains of the U.S. health system and explores the flow of data throughout it.

The United States Health System

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

Health Care Delivery

Health care delivery *generally refers to the resources and processes which enable people to receive health care services* [7]. The United States has the most expensive, highly complex system of health care delivery in the world. Its complexity may be summarized into four broad components: providers, payers, suppliers, and regulators.

Health Care Delivery: Providers

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

In addition to organizations, the workforce of health professionals that deliver health care services is also a major component of health care providers. This workforce includes licensed health professions such as physicians, nurses, dentists, therapists, and many other health professionals. In addition to the professionals traditionally thought of as "health care providers," many others professionals support the delivery of health care services. Community health workers, for example, are increasingly being used to support health care delivery and build additional capacity or manage care and care transitions, especially among vulnerable populations [8]. In addition, practitioners in clinical informatics may also be considered a provider as they play a critical role in health care delivery process. This is especially true as newer health care delivery models which rely heavily on clinical information technologies, such as tele-medicine, are more widely utilized.

As the point of intersection between medical sciences and health care delivery, the healthcare workforce has a large role in the health care system. This workforce oversees the collection and recording of patient health information and leverages it to inform patient care. Additional information on the education of health professionals is explored later in the chapter.

Health Care Delivery: Payers

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

Health insurance is the foundation of the health care financing in the United States and is also the most common mechanism. Insurance is grounded in two basic principles: Risk Spreading and Cost Sharing. **Risk spreading** is *the process of minimizing the chance of major losses to the payer*. This is typically accomplished by setting insurance premiums concordant with a patients, risk level, selectively denying coverage based on risk, or increasing the rate of cost sharing. **Cost sharing** is *a financial risk-management strategy that requires patients to share in a portion of*

healthcare costs. Common cost sharing mechanisms include premiums, deductibles, copayments, coinsurance, or benefit limits. Due to the high costs, few individuals pay the entire cost of health care services out of pocket. This system of health care financing is unique to the United States, represents a major source of inefficiency, and is a threat to equity within the system. Understanding how this system evolved is important.

Although health insurance is the primary mechanism for financing health care today, this was not always the case. Health insurance has only been in existence since the mid-twentieth century when major automotive manufacturers began to offer health benefits to employees as an incentive to offset the cost of health care [9]. Employer-based health insurance expanded throughout the latter half of the twentieth century and became a major recruiting incentive for employers. During this same time period, incredible advancements in medical science were also being made. Advancements led to the development of technologies and treatments for many conditions that were previously untreatable and/or incurable. These innovations came with a high price tag, but patients were largely unaware of the cost as most services were reimbursed, on their behalf, through their health insurance program. Cost-sharing, described earlier, was introduced more recently as an effort to increase patient awareness regarding the cost of health care.

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

Financing of heath care in the United States largely determines who has access to health care and who does not [10]. **Access** *refers to the ability of an individual to obtain health care services when needed* [7]. Individuals typically must be able to finance health care through one of the following mechanisms in order to have access to care.

1. They must have health insurance through their employer
2. They must be covered under a government health care program
3. They must be able to afford to buy insurance with their own private funds
4. They must be able to pay for services privately [7].

The ability to finance health care services through one of these means does not guarantee access. In addition to the 'ability to pay' for health care, an adequate supply of health care providers (organizations and professionals) is needed to ensure access to health care services. Unfortunately, health care providers are not evenly distributed across the population.

Health care financing has a large influence on the supply and distribution of health care services. Health care providers are clustered in metropolitan areas with high population densities in which greater proportions of the population have health insurance coverage. Rural communities with small populations and low-income urban communities with less robust financing mechanisms are more likely to experience shortages of health care providers and associated health services.

In addition to its influence on the geographic supply and distribution, financing has also had a large role in shaping providers in the current health care delivery system. For example, historically **fee-for-service** (FFS) **payments**, *or payment of a fee for each specific health care service or visit,* were the major form of reimbursement to health care providers. FFS payments are issued to providers retrospectively after the service is provided. Advanced and specialty health care services requiring greater expertise and more resources were reimbursed at higher FFS rates while primary health care services focused on disease prevention and health promotion were reimbursed at lower rates. Under FFS reimbursement, health care providers are incentivized to increase the volume of specialty services. Over time, the culture favoring high cost specialty services became embedded into the fabric of health care delivery in the United States.

Health Care Delivery: Suppliers

Healthcare suppliers are *organizations which provide resources to the health care delivery system*, such as pharmaceutical companies and medical equipment manufactures. Suppliers are a diverse group ranging from large pharmaceutical firms and durable medical equipment manufacturers to small companies that produce hospital linens and medical uniforms. In addition to organizations that supply medications and materials, organizations that supply services such as biohazardous waste disposal companies, medical laboratory courier, and health information technology companies are also included in this category. Basically, any industry or organization that provides goods, materials, or services which directly or indirectly support health care delivery are considered suppliers.

Health Care Delivery: Regulators

Because of its substantial impact on human health, health care delivery is the most regulated industry in the world. Regulation occurs at all levels within the health care delivery system. **Regulators** primary responsibility is to *direct or influence the actions, behaviors, or decisions of the providers, suppliers, and payers of the health system to ensure safety and to balance the objectives of enhancing quality, expanding access, and controlling costs* [11]. Currently, the majority of regulation occurs within the various sectors (providers, supplier, and payers) through governmental and private agencies that develop and oversee guideline and policies around cost, access, and quality. Table 2.1 summarizes the regulation occurring within each healthcare delivery sector and provides examples of the most prominent regulators within those sectors. It is important to understand that many of these regulators span multiple or all of the healthcare delivery sectors although their primary responsibility may lay within one of the three sectors. Although a large number of entities are engaged in regulation, their efforts are not currently coordinated. Ensuring access to high quality, low cost care in the United States requires system level and

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

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

[a]Health Insurance Portability and Accountability Act of 1996

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

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

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

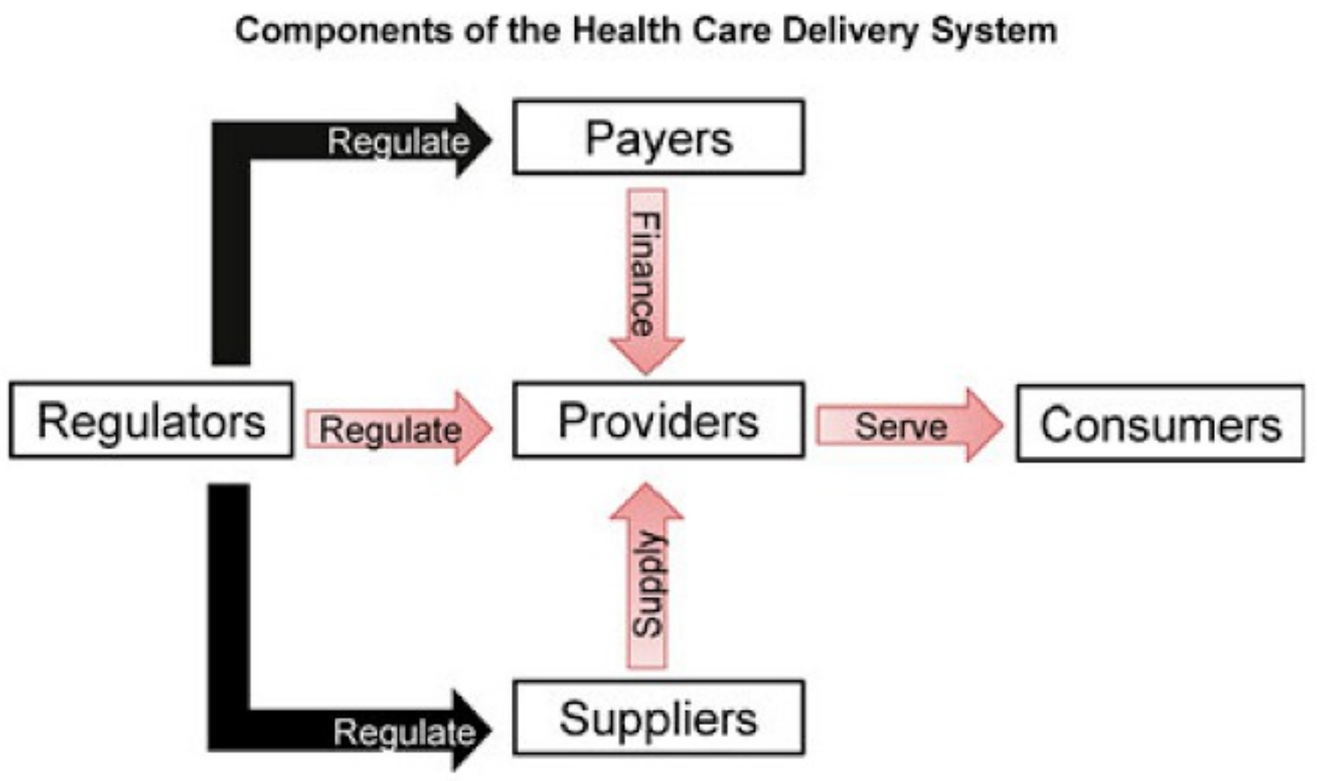

Fig. 2.4 Components of the United State health care delivery system. This figure identifies the relationship between the four major components of the health care delivery system: Payer Providers, Regulators, and Supplies

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

Regulators are largely responsible for patient safety and health system quality and efficiency. Unfortunately, health care delivery and its regulation is disorganized and fragmented between and within the various sectors. Figure 2.4 illustrates how the sectors are regulated and work together within the delivery system to finance, supply, and serve the health care needs of consumers.

Forces Shaping Health Care Delivery

Over the years, health professionals have recognized the need to improve the quality of the health system while increasing access and reducing costs. However, the complexity of the health system continues to grow and can be "characterized by more to know, more to do, more to manage, more to watch, and more people involved than ever before" [13]. As a result population health and health outcomes in the United States have been largely impacted by poorly organized and uncoordinated health care delivery. In 2001, The Institute of Medicine released a report that stated, "bringing state-of-the-art care to all Americans in every community will require a fundamental, sweeping redesign of the entire health system" [13]. IOM's identifies six aims of quality components necessary for improvement of the health system in the report, which are summarized in Table 2.2.

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

Whereas patient level information is used to drive clinical decision making within health care delivery settings, population level health information is used to drive public health policies which contribute to the environment where health care delivery occurs. However, as data are integrated across the health systems clinical information is becoming increasingly important and will likely play a large role in public health decision making, as described in the vignette.

Clinical Research

Clinical research is the domain of the health system that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for use in individuals and populations. Traditionally research has been conducted using randomized controlled trials (RCTs) or otherwise controlled experiments in which an intervention was compared to "usual care." Evidence that a given intervention is "better" than usual care, or another intervention, should prompt clinical providers to change practice. However, it has been observed that the gap between published research and a change in clinical practice requires, on average, approximately 17 years [19]. Additional details on research methods and the development of evidence-based medicine (EBM) guidelines to influence clinical practice can be found in Chap. 5 of this book.

Clinical informaticians are responsible for ensuring that EHR systems and other health information technologies enable clinicians, allied health professionals, and organizations to provide the best possible care to patients. Currently clinical organizations predominantly use two methods for providing front line staff in a health system with access to the latest evidence from clinical research. First, organizations provide frontline staff with direct access to scholarly journals and scientific publications. Users can access resources from the U.S. National Library of Medicine (NLM), such as MEDLINE or PubMed, which search for available evidence across a wide range of publications. Alternatively, EHR systems can include "infobuttons" that enable frontline staff to directly link to relevant evidence when browsing a patient's chart [20]. For example, a primary care physician might desire more information about a medication prescribed by a specialist because he or she does not typically prescribe it. The infobutton in the EHR would directly link the PCP out to a website that would describe the medication, its indications, and its side effects. A second method for implementing research-derived evidence is through clinical decision support (CDS). With CDS, the EHR system could remind the clinician to perform a task considered a "best practice" in a given context. For example, the PCP might be reminded to order a glycosylated hemoglobin test for a patient with diabetes because the EHR system detected no such test for this person within the past 13 months. Available evidence-based clinical guidelines recommend that people with diabetes should have their glycosylated hemoglobin tested once every 12 months. Additional information on research and evidence-based guidelines as well as their implementation through CDS can be found in Chaps. 5 and 6 of this book.

Personal Health

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

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

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

As the U.S. healthcare delivery system continues to realize its vision of patient-centered primary care, patient activation has become increasingly important. **Patient activation** *refers to a patient's knowledge, skills, ability, and willingness to manage his or her own health and care* [22]. One important factor that influences a patient's ability to manage his or her personal health by working with healthcare providers to personalize care is the patient's ability to collect personal health data and maintain comprehensive personal health records that may be used to inform treatment plans and health strategies. A **personal health record** (PHR) *is an electronic, lifelong resource of health information used by individuals to make decisions related to their personal health*. PHRs contain various types of personal health information (PHI) and are typically a combination of individual records and data collected from healthcare providers. **Personal health information** or protected health information primarily *refers to personal data such as demographic information, medical history, diagnostic results, insurance information or any other data that is collected by a health care professional to identify an individual and determine what type of care that individual should receive* [23].

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

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

Understanding the Flow of Data

In the vignette in Part I, there were obvious examples of how the flow of data through the electronic medical record and within the electronic health system were critical to the care and treatment of the patient during the hospital stay. The vignette also revealed the many other ways that the electronic flow of data is now utilized to maximize multiple aspects of healthcare delivery related to efficiency, quality, and even public health. When the patient's registration information was already on file in the EHR because he had visited another in-network hospital, this saved time for the patient and allowed all of the information from his past visits to be available in his pre-existing EMR. His list of current medications was available, and only needed to confirmed and updated by his current caregivers. Even summaries of his records from out-of-network care were available through the state HIE, giving his current care providers a much broader and more accurate past medical history. Order Sets were utilized to promote the delivery of standardized practices and evidence-based medicine, and archives of his completed hospital stay were stored in a data repository for aggregated patient quality analyses and internal outcomes tracking. Public health needs were addressed through the activation of the NEDSS so that the appropriate agencies could track, assess and minimize the potential threat to public health posed by introduction of the disease into the community. To understand the true depth of the complexity efficiency and impact of electronic data flow in a fully integrated health system today, see Fig. 2.6, which illustrates the flow of data for the patient vignette detailed in Part I. While examining the illustration in Fig. 2.6, keep in mind that this complexity is the domain of the clinical informatician as he/she is generally tasked with sorting out information flows and implementing systems to improve care using redesigned health care delivery workflows.

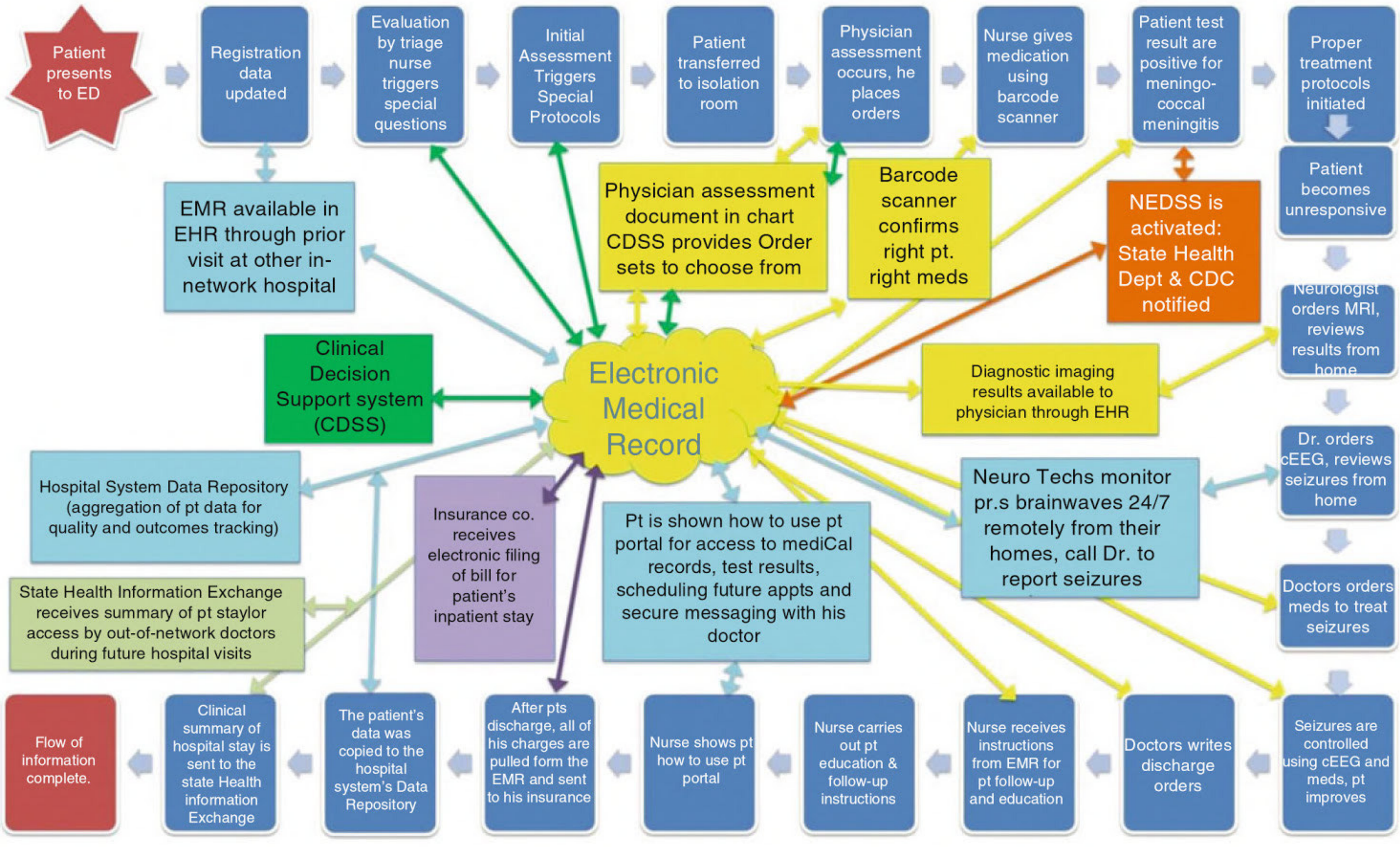

Fig. 2.6 Flow of data and information within the health system. This figure shows the flow of patient data and information within the health system by tracking the data from the beginning of a patient visit. The figure also shows that electronic medical records and clinical informatics is at the center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

Clinical Informatics: Unifying the Health System

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

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

Emerging Trends in Clinical Informatics: An Effort to Improve Quality

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

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Chapter 3
Clinical Informatics Policy and Regulations

Margo Edmunds, Doug Peddicord, and David Westfall Bates

Learning Objectives

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

Core Content

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

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

Case Vignette

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

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

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

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

Introduction

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

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

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

Fundamentals of the Policy Process in the United States

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

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

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

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

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

Organization and Authority of Congress

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

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

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

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

Other Key Federal Agencies for HIT

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

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

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

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

Role of the Private Sector in Policy Development

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

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

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

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

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

The Policy Environment for Clinical Informatics

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

Table 3.1 Timeline of key legislative and regulatory events

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

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

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

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

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

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

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

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

Who Is Covered by the Rule?

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

What Is Covered?

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

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

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

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

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

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

What About Business Associates?

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

Points to Remember

Within the HIPAA Privacy Rule, always think about:

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

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

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

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

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

Changes Made by HITECH Regarding Enforcement and Penalties

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

Under HIPAA and HITECH

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

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

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

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

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

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

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

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

Federal Drug Administration Safety and Innovation Act (FDASIA)

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

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

Emerging Trends

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

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

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

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

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

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

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

Summary

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

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

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

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

Questions for Discussion

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

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Part II
Clinical Decision Making/Care Process Improvement

Chapter 4
Clinical Decision-Making

Stephen M. Downs and Lydia K. Johns

Learning Objectives

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

Core Content

The following core competencies are covered in this chapter:

Clinical Decision Support

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

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