Biomedical Informatics: The Science and the Pragmatics

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Learning Objectives

After reading this chapter, you should know the answers to these questions:

- Why is information and knowledge management a central issue in biomedical research, clinical practice, and public health?
- What are integrated information management environments, and how are they affecting the practice of medicine, the promotion of health, and biomedical research?
- What do we mean by the terms *biomedical informatics*, *medical computer science*, *medical computing*, *clinical informatics*, *nursing informatics*, *bioinformatics*, *public health informatics*, and *health informatics*?
- What is *translational research*, why is it being heavily promoted and supported, how does it depend on *translational bioinformatics* and *clinical research informatics*, and how do these all relate to *precision medicine*?
- Why should health professionals, life scientists, and students of the health professions learn about biomedical informatics concepts and informatics applications?
- How has the development of modern computing technologies and the Internet changed the nature of biomedical computing?
- How is biomedical informatics related to clinical practice, public health, biomedical engineering, molecular biology, decision science, information science, and computer science?
- How does information in clinical medicine and health differ from information in the basic sciences?
- How can changes in computer technology and the financing of health care influence the integration of biomedical computing into clinical practice?

1.1 The Information Revolution Comes to Medicine

After scientists had developed the first digital computers in the 1940s, society was told that these new machines would soon be serving routinely as memory devices, assisting with calculations and with information retrieval. Within the next decade, physicians and other health professionals had begun to hear about the dramatic effects that such technology would have on clinical practice.

More than seven decades of remarkable progress in computing have followed those early predictions, and many of the original prophesies have come to pass. Stories regarding the "information revolution", "artificial intelligence", and "big data" fill our newspapers and popular magazines, and today's children show an uncanny ability to make use of computers (including their handheld mobile versions) as routine tools for study, communication, and entertainment. Similarly, clinical workstations have been available on hospital wards and in outpatient offices for decades, and in some settings have been supplanted by mobile tablets with wireless connectivity.

Not long ago, the health care system was perceived as being slow to understand information technology and slow to exploit it for its unique practical and strategic functionalities. This is no longer the case. The enormous technological advances of the last four decades—personal computers and graphical interfaces, laptop machines, new methods for human-computer interaction, innovations in mass storage of data (both locally and in the "cloud"), mobile devices, personal health-monitoring devices, the Internet, wireless communications, social media, and more—have all combined to make use of computers by health workers and biomedical scientists part of today's routine. This new world is already upon us, but its greatest influence is yet to come as today's prominent innovations such as

electronic health records and decision-support software are further refined. This book will teach you about our present resources and accomplishments, and about gaps that need to be addressed in the years ahead.

When one considers today's penetration of computers and communication into our daily lives, it is remarkable that the first personal computers were introduced as recently as the late 1970s; local area networking has been available only since the 1980s; the World Wide Web dates only to the early 1990s; and smart phones, social networking, tablet computers, wearable devices, and wireless communication are even more recent. This dizzying rate of change, combined with equally pervasive and revolutionary changes in almost all international health care systems, makes it difficult for public-health planners and health-institutional managers to try to deal with both issues at once.

As new technologies have been introduced and adopted in health settings, unintended consequences have emerged, such as **ransomware** and other security challenges that can compromise the protection and privacy of patient data. Yet many observers now believe that rapid changes in both technology and health systems are inextricably related. We can see that planning for the new health care environments of the coming decades requires a deep understanding of the role that information technology is likely to play in those environments.

What might that future hold for the typical practicing clinician? As we discuss in detail in ▶ Chap. 14, no applied clinical computing topic is gaining more attention currently than is the issue of **electronic health records** (EHRs). Health care organizations have largely replaced their paper-based recording systems, recognizing that they need to have digital systems in place that create opportunities to facilitate patient care that is safe and effective, to answer questions that are crucially important for strategic planning, to support a better understanding of how they and their providers compare with other organizations in their local or regional competitive environment, and to support reporting to regulatory agencies.

In the past, administrative and financial data were the major elements required for planning, but in recent years comprehensive clinical data have also become important for institutional self-analysis and strategic planning. Furthermore, the inefficiencies and frustrations associated with the use of paper-based medical records are well accepted (Dick and Steen 1991 (Revised 1997)), especially when inadequate access to clinical information is one of the principal barriers that clinicians encounter when trying to increase their efficiency in order to meet productivity goals for their practices.

1.1.1 Integrated Access to Clinical Information

Encouraged by **health information technology** (**HIT**) vendors (and by the US government, as is discussed later), most health care institutions have or are developing integrated computer-based information-management environments. These underlie a clinical world in which computational tools assist not only with patient-care matters (e.g., reporting results of tests, allowing direct entry of orders or patient information by clinicians, facilitating access to transcribed reports, and in some cases supporting **telemedicine** applications or decision-support functions) but also with administrative and financial topics (e.g., tracking of patients within the hospital, managing materials and inventory, supporting personnel functions, and managing the payroll), with research (e.g., analyzing the outcomes associated with treatments and procedures, performing quality assurance, supporting clinical trials, and implementing various treatment protocols), with access to

scholarly information (e.g., accessing digital libraries, supporting bibliographic search, and providing access to drug information databases), and even with office automation (e.g., providing access to spreadsheets and document-management software). The key idea, however, is that at the heart of the evolving integrated environments lies an electronic health record that is intended to be accessible, confidential, secure, acceptable to clinicians and patients, and integrated with other types of useful information to assist in planning and problem solving.

1.1.2 Today's Electronic Health Record (EHR) Environment

The traditional paper-based medical record is now recognized as being woefully inadequate for meeting the needs of modern medicine. It arose in the nineteenth century as a highly personalized "lab notebook" that clinicians could use to record their observations and plans so that they could be reminded of pertinent details when they next saw the same patient. There were no regulatory requirements, no assumptions that the record would be used to support communication among varied providers of care, and few data or test results to fill up the record's pages. The record that met the needs of clinicians a century or so ago struggled mightily to adjust over the decades and to accommodate to new requirements as health care and medicine changed. Today the inability of paper charts to serve the best interests of the patient, the clinician, and the health system is no longer questioned (see ▶ Chaps. 14 and 16).

Most organizations have found it challenging (and expensive) to move to a paperless, electronic clinical record. This observation forces us to ask the following questions: "What is a health record in the modern world? Are the available products and systems well matched with the modern notions of a comprehensive health record? Do they meet the needs of individual users as well as the health systems themselves? Are they efficient, easy to use, and smoothly integrated into clinical workflow? How should our concept of the comprehensive health record evolve in the future, as technology creates unprecedented opportunities for innovation?"

The complexity associated with automating clinical-care records is best appreciated if one analyzes the processes associated with the creation and use of such records rather than thinking of the record as a physical object (such as the traditional paper chart) that can be moved around as needed within the institution. For example, on the input side (◘ Fig. 1.1), an electronic version of the paper chart requires the integration of processes for data capture and for merging information from diverse sources.

The contents of the paper record were traditionally organized chronologically—often a severe limitation when a clinician sought to find a specific piece of information that could occur almost anywhere within the chart. To be useful, the electronic record system has to make it easy to access and display needed data, to analyze them, and to share them among colleagues and with secondary users of the record who are not involved in direct patient care (◘ Fig. 1.2). Thus, the EHR, as an adaptation of the paper record, is best viewed not as an object, or a product, but rather as a set of processes that an organization puts into place, supported by technology (◘ Fig. 1.3).

Implementing electronic records is inherently a systems-integration task. It accordingly requires a custom-tailored implementation at each institution, given the differences in existing systems and practices that must be suitably integrated. Joint development and local adaptation are crucial, which implies that the institutions that purchase such systems must have local expertise that can oversee and facilitate an effective implementation process, including elements of process re-engineering and cultural change that are inevitably involved.

Experience has shown that clinicians are "horizontal" users of information technology (Greenes and Shortliffe 1990). Rather than becoming "power users" of a narrowly defined software package, they tend to seek broad functionality across a wide variety of systems and resources. Thus, routine use of comput-

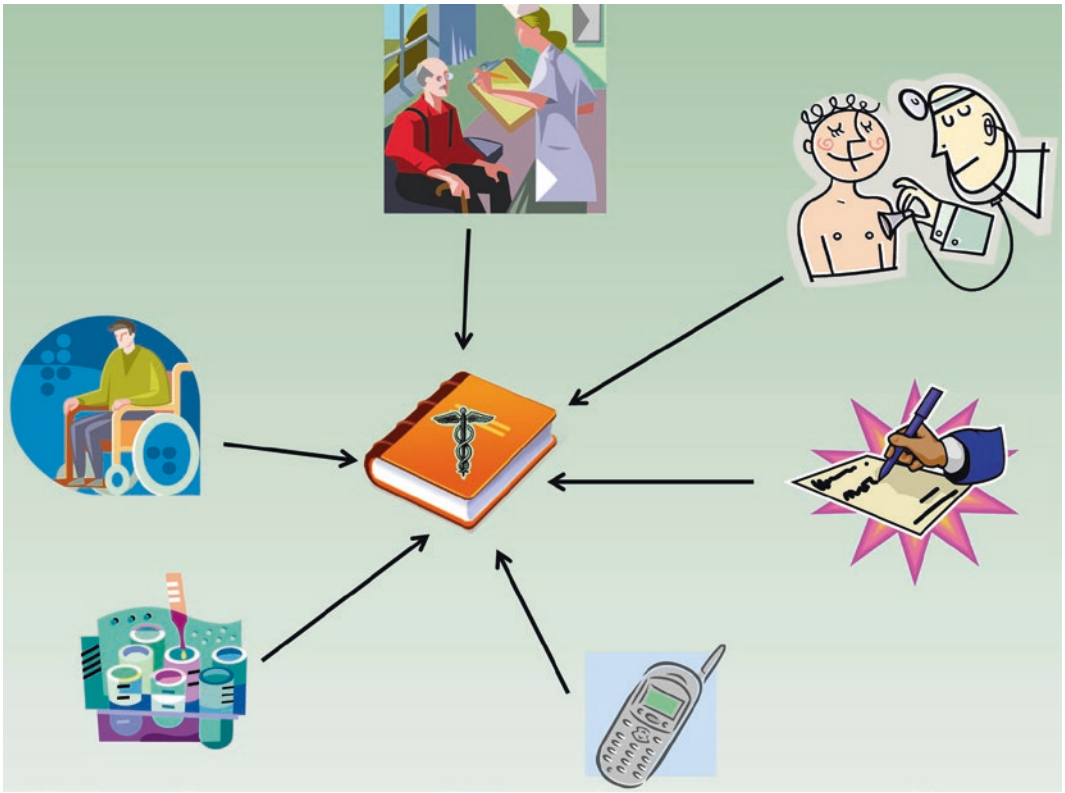


Fig. 1.1 Inputs to the clinical-care record. The traditional paper record was created by a variety of organizational processes that captured varying types of information (notes regarding direct encounters between health professionals and patients, laboratory or radiologic results, reports of telephone calls or prescriptions, and data obtained directly from patients). The paper record thus was a merged collection of such data, generally organized in chronological order

ers, and of EHRs, is most easily achieved when the computing environment offers a critical mass of functionality that makes the system both smoothly integrated with workflow and useful for essentially every patient encounter.

The arguments for automating clinical-care records are summarized in ▶ Chaps. 2 and 14 and in the now classic Institute of Medicine's report on **computer-based patient records** (**CPRs**) (Dick and Steen 1991 (Revised 1997).[1] One argument that warrants emphasis is the importance of the EHR in supporting **clinical trials**—experiments in which data from specific patient interactions are pooled and analyzed in order to learn about the safety and efficacy of new treatments or tests and to gain insight into disease processes that are not otherwise well understood. Medical researchers were constrained in the past by clumsy methods for identifying patients who met inclusion criteria for clinical trials as well as acquiring the data needed for the trials, generally relying on manual capture of information onto datasheets that were later transcribed into computer databases for statistical analysis (Fig. 1.4). The approach was labor-intensive, fraught with opportunities for error, and added to the high costs associated with randomized prospective research protocols.

The use of EHRs has offered many advantages to those carrying out clinical research (see ▶ Chap. 27). Most obviously, it helps to eliminate the manual task of extracting data from charts or filling out specialized data-

1 The Institute of Medicine, part of the National Academy of Sciences, is now known as the National Academy of Medicine.

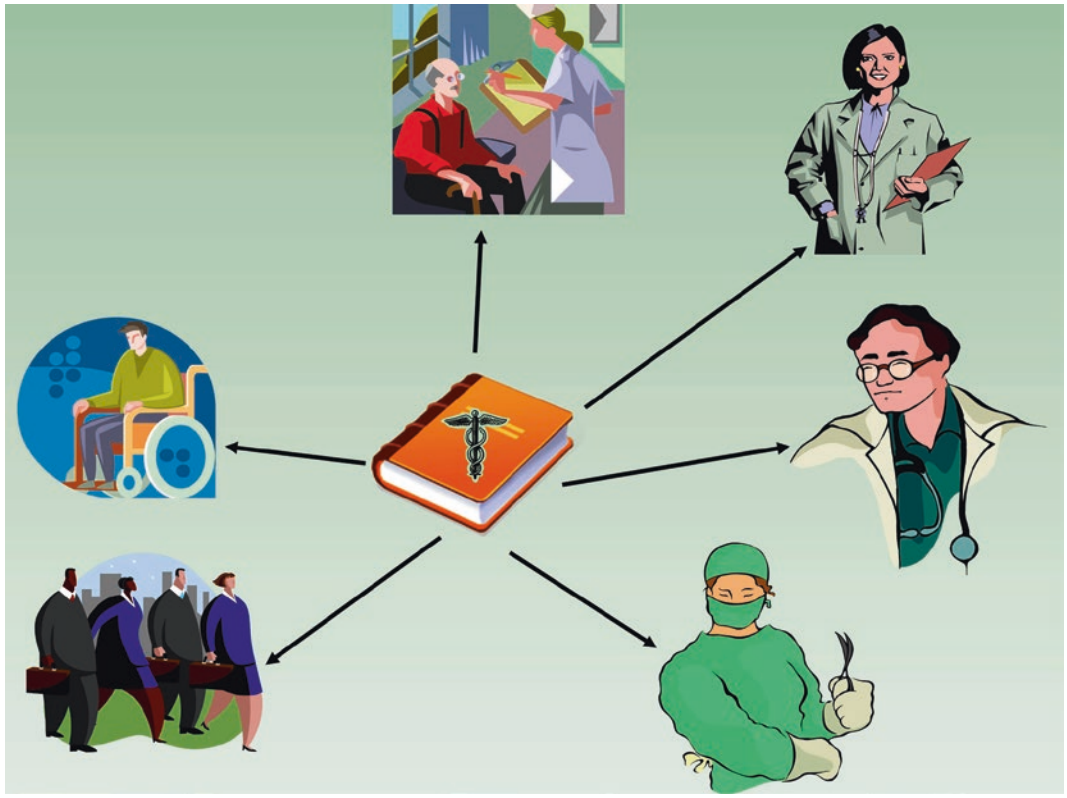


Fig. 1.2 Outputs from the clinical-care record. Once information was collected in the traditional paper chart, it needed to be provided to a wide variety of potential users of the information that it contained. These users included health professionals and the patients themselves, as well as "secondary users" (represented here by the individuals in business suits) who had valid reasons for accessing the record but who were not involved with direct patient care. Numerous providers are typically involved in a patient's care, so the chart also served as a means for communicating among them. The traditional mechanisms for displaying, analyzing, and sharing information from such records resulted from a set of processes that often varied substantially across several patient-care settings and institutions

sheets. The data needed for a study can often be derived directly from the EHR, thus making much of what is required for research data collection simply a by-product of routine clinical record keeping (Fig. 1.5). Other advantages accrue as well. For example, the record environment can help to ensure compliance with a research protocol, pointing out to a clinician when a patient is eligible for a study or when the protocol for a study calls for a specific management plan given the currently available data about that patient. We are also seeing the development of novel authoring environments for clinical trial protocols that can help to ensure that the data elements needed for the trial are compatible with the local EHR's conventions for representing patient descriptors.

Note that Fig. 1.5 represents a study at a single institution and often for a limited subset of the patients who receive care there. Yet much research is carried out with very large numbers of patients, such as within a regional health care system, statewide, or nationally. Accordingly, the size of research datasets can get very large, but analyzing across them introduces challenges related to data exchange and the standardization of the ways in which individual data elements are defined, identified, or stored (see ▶ Chap 8). Retrospective studies on data collected in the past typically cannot assume a prior standardization of the elements that will be needed, thereby requiring analyses that infer relationships among specific descriptors in different institutions represented in different ways. When the number of data elements

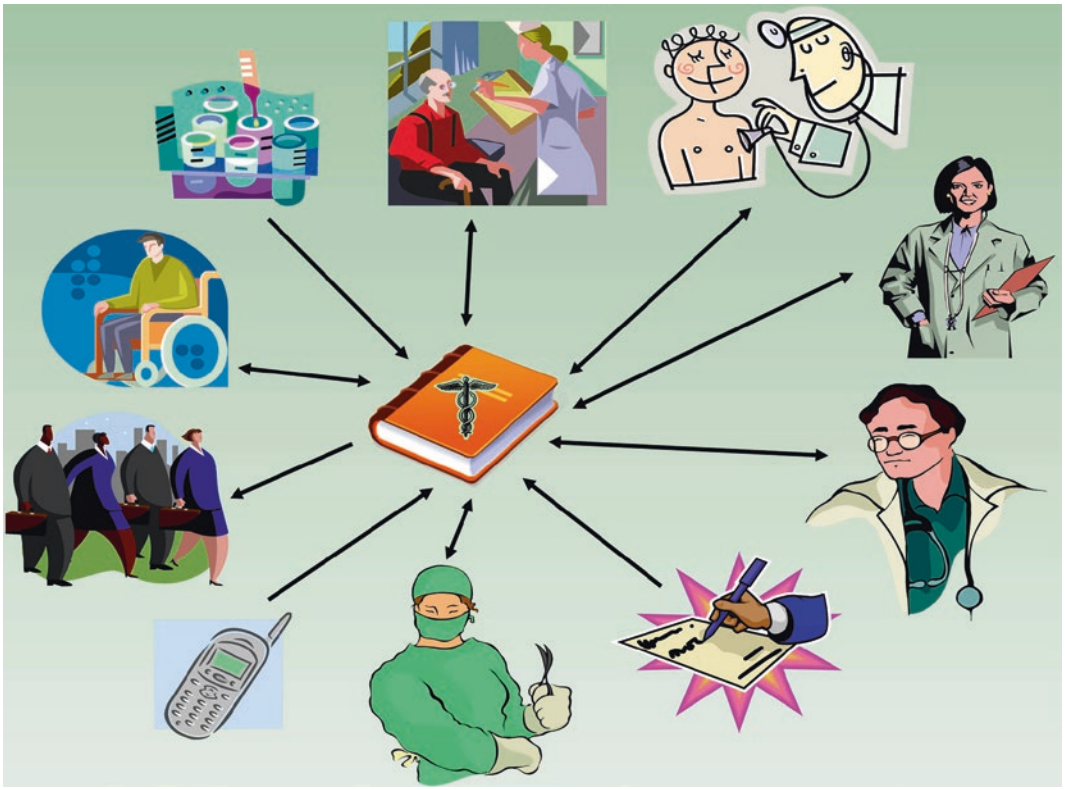


Fig. 1.3 Complex processes demanded of the record. As shown in Figs. 1.1 and 1.2, the paper chart evolved to become the incarnation of a complex set of organizational processes, which both gathered information to be shared and then distributed that information to those who had valid reasons for accessing it. Yet paper-based documents were severely limited in meeting the diverse requirements for data collection and information access that are implied by this diagram. These deficiencies accounted in large part for the effort to create today's electronic health records

is large, and the population being studied is also vast, the challenges are often described as "big data" analytics (James et al. 2013).

Another theme in the changing world of health care is the increasing investment in the creation of **standard order sets**, **clinical guidelines**, and **clinical pathways** (see ▶ Chap. 24), generally in an effort to reduce practice variability and to develop consensus approaches to recurring management problems. Several government and professional organizations, as well as individual provider groups, have invested heavily in guideline development, often putting an emphasis on using clear evidence from the literature, rather than expert opinion alone, as the basis for the advice. Despite the success in creating such **evidence-based guidelines**, there is a growing recognition that we need better methods for delivering the decision logic to the point of care. Guidelines that appear in monographs or journal articles tend to sit on shelves, unavailable when the knowledge they contain would be most valuable to practitioners. Computer-based tools for implementing such guidelines, and integrating them with the EHR, present a means for making high-quality advice available in the routine clinical setting. Many organizations are accordingly integrating decision-support tools with their EHR systems (see ▶ Chaps. 14 and 24), and there are highly visible commercial efforts underway to provide computer-based diagnostic decision support to practitioners.[2]

There are at least five major issues that have consistently constrained our efforts to build effective EHRs: (1) the need for stan-

2 ▶ https://ehrintelligence.com/news/top-clinical-decision-support-system-cdss-companies-by-ambulatory-inpatient; ▶ https://www.ibm.com/watson/health/. (Accessed 5/29/19/).

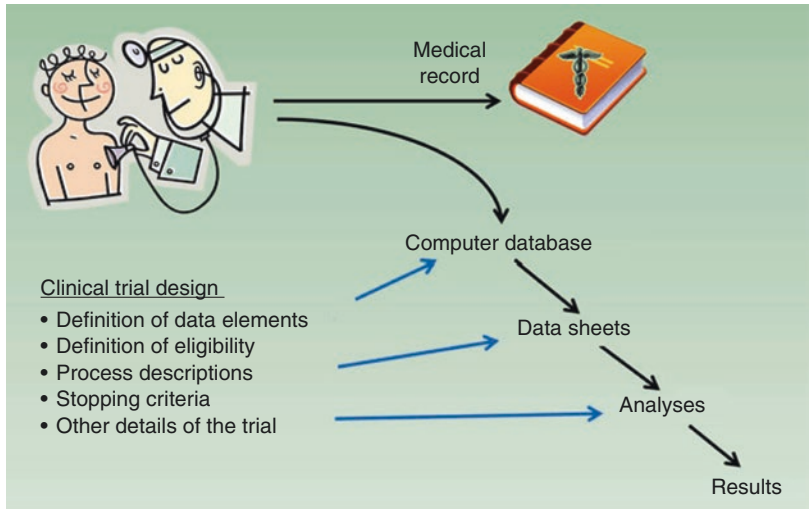


Fig. 1.4 Traditional data collection for clinical trials. Until the introduction of EHRs and similar systems, the gathering of research data for clinical studies was typically a manual task. Physicians who cared for patients enrolled in trials, or their research assistants, would be asked to fill out special datasheets for later transcription into computer databases. Alternatively, data managers were often hired to abstract the relevant data from the paper chart. The trials were generally designed to define data elements that were required and the methods for analysis, but it was common for the process of collecting those data in a structured format to be left to manual processes at the point of patient care

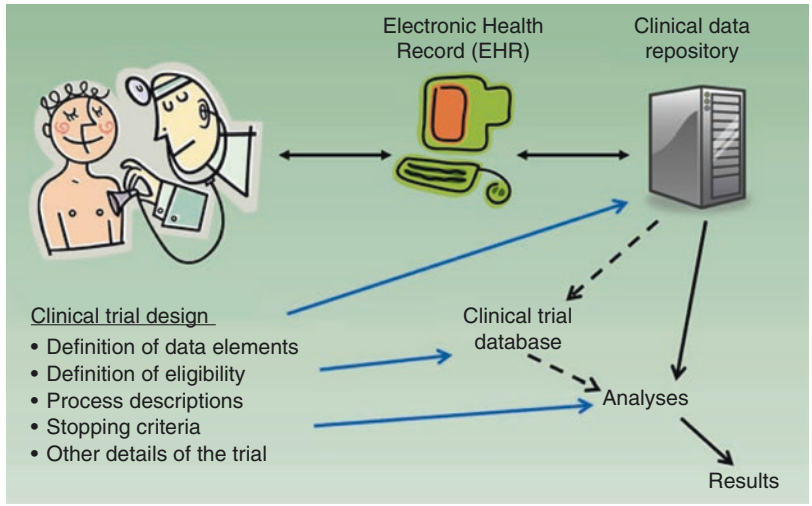


Fig. 1.5 Role of electronic health records (EHRs) in supporting clinical trials. With the introduction of EHR systems, the collection of much of the research data for clinical trials can become a by-product of the routine care of the patients. Research data may be analyzed directly from the clinical data repository, or a secondary research database may be created by downloading information from the online patient records. The manual processes in Fig. 1.4 are thereby largely eliminated. In addition, the interaction of the physician with the EHR permits two-way communication, which can greatly improve the quality and efficiency of the clinical trial. Physicians can be reminded when their patients are eligible for an experimental protocol, and the computer system can also remind the clinicians of the rules that are defined by the research protocol, thereby increasing compliance with the experimental plan

dards in the area of clinical terminology; (2) concerns regarding data privacy, confidentiality, and security; (3) challenges in data entry by physicians; (4) difficulties associated with the integration of record systems with other information resources in the health care setting, and (5) designing and delivering systems that are efficient, acceptable to clinicians, and intuitive to use. The first of these issues is discussed in detail in ▶ Chap. 7, and privacy is one of the central topics in ▶ Chap. 12. Issues of direct data entry by clinicians are discussed in ▶ Chaps. 2 and 14 and throughout many other chapters as well. ▶ Chapter 15 examines the fourth topic, focusing on recent trends in networked data integration, and offers solutions for the ways in which the EHR can be better joined with other relevant information resources and clinical processes, especially within communities where patients may have records with multiple providers and health care systems (Yasnoff et al. 2013). Finally, issues of the interface between computers and clinicians (or other users), with a cognitive emphasis, are the subject of ▶ Chap. 5.

1.1.3 Anticipating the Future of Electronic Health Records

One of the first instincts of software developers is to create an electronic version of an object or process from the physical world. Some familiar notion provides the inspiration for a new software product. Once the software version has been developed, however, human ingenuity and creativity often lead to an evolution that extends the software version far beyond what was initially contemplated. The computer can thus facilitate paradigm shifts in how we think about such familiar concepts.

Consider, for example, the remarkable difference between today's office automation software and the typewriter, which was the original inspiration for the development of "word processors". Although the early word processors were designed largely to allow users to avoid retyping papers each time a minor change was made to a document, the document-management software of today bears little resemblance to a typewriter. Consider all the powerful desktop-publishing facilities, integration of figures, spelling correction, grammar aids, "publishing" online, collaboration on individual documents by multiple users, etc. Similarly, today's spreadsheet programs bear little resemblance to the tables of numbers that we once created on graph paper. To take an example from the financial world, consider automatic teller machines (ATMs) and their facilitation of today's worldwide banking in ways that were never contemplated when the industry depended on human bank tellers.

It is accordingly logical to ask what the health record will become after it has been effectively implemented on computer systems and new opportunities for its enhancement become increasingly clear to us. It is clear that EHRs a decade from now will be remarkably different from the antiquated paper folders that used to dominate our health care environments. We might similarly predict that the state of today's EHR is roughly comparable to the status of commercial aviation in the 1930s. By that time air travel had progressed substantially from the days of the Wright Brothers, and air travel was becoming common. But 1930s air travel seems archaic by modern standards, and it is logical to assume that today's EHRs, albeit much better than both paper records and the early computer-based systems of the 1960s and 1970s, will be greatly improved and further modernized in the decades ahead.

If people had failed to use the early airplanes for travel, the quality and efficiency of airplanes and air travel would not have improved as they have. A similar point can be made about the importance of committing to the use of EHRs today, even though we know that they need to be much better in the future. We must also commit to assuring that those improvements are made, which suggests a dynamic interaction and interdependency among the researchers who address limitations in EHRs and their underlying methods and philosophy, the EHR compa-

nies that currently exist or will arise in the future, and the users who identify requirements and areas for improvement. These companies must look to creative researchers, both within their own companies and in academia, who will forge the changes that will encourage EHR users to embrace and appreciate the technology much more than they often do today.

1.2 Communications Technology and Health Data Integration

An obvious opportunity for changing the role and functionality of clinical-care records in the digital age is the power and ubiquity of the Internet. The Internet began in 1968 as a U.S. research activity funded by the Advanced Research Projects Agency (ARPA) of the Department of Defense. Initially known as the **ARPANET**, the network began as a novel mechanism for allowing a handful of defense-related mainframe computers, located mostly at academic institutions or in the research facilities of military contractors, to share data files with each other and to provide remote access to computing power at other locations. The notion of electronic mail arose soon thereafter, and machine-to-machine electronic mail exchanges quickly became a major component of the network's traffic. As the technology matured, its value for nonmilitary research activities was recognized, and by 1973 the first medically related research computer had been added to the network (Shortliffe 1998a, 2000).

During the 1980s, the technology began to be developed in other parts of the world, and the National Science Foundation took over the task of running the principal high-speed **backbone network** in the United States. Hospitals, mostly academic centers, began to be connected to what had by then become known as the Internet, and in a major policy move it was decided to allow commercial organizations to join the network as well. By April 1995, the Internet in the United States had become a fully commercialized operation, no longer depending on the U.S. government to support even the major backbone connections. Today, the Internet is ubiquitous, worldwide, accessible through mobile wireless devices, and has provided the invisible but mandatory infrastructure for social, political, financial, scientific, corporate, and entertainment ventures. Many people point to the Internet as a superb example of the facilitating role of federal investment in promoting innovative technologies. The Internet is a major societal force that arguably would never have been created if the research and development, plus the coordinating activities, had been left to the private sector.

The explosive growth of the Internet did not occur until the late 1990s, when the **World Wide Web** (which had been conceived initially by the physics community as a way of using the Internet to share preprints with photographs and diagrams among researchers) was introduced and popularized. Navigating the Web is highly intuitive, requires no special training, and provides a mechanism for access to multimedia information that accounts for its remarkable growth as a worldwide phenomenon. It is also accessible by essentially all digital devices—computers, tablets, smart phones, and a plethora of personal monitors and "smart home" tools—which is a tribute to its design and its compatibility with newer networking technologies, such as **Bluetooth** and **Wi-Fi**.

The societal impact of this communications phenomenon cannot be overstated, especially given the international connectivity that has grown phenomenally in the past two decades. Countries that once were isolated from information that was important to citizens, ranging from consumers to scientists to those interested in political issues, are now finding new options for bringing timely information to the desktop machines and mobile devices of individuals with an Internet connection.

There has in turn been a major upheaval in the telecommunications industry, with companies that used to be in different busi-

nesses (e.g., cable television, Internet services, and telephone) now finding that their activities and technologies have merged. In the United States, legislation was passed in 1996 to allow new competition to develop and new industries to emerge. We have subsequently seen the merging of technologies such as cable television, telephone, networking, and satellite communications. High-speed lines into homes and offices are widely available, wireless networking is ubiquitous, and inexpensive mechanisms for connecting to the Internet without using conventional computers (e.g., using cell phones or **set-top boxes**) have also emerged. The impact on everyone has been great and hence it is affecting the way that individuals seek health-related information while also enhancing how patients can gain access to their health care providers and to their clinical data.

The Internet also has exhibited unintended consequences, especially in the world of social media, which has created opportunities for promoting political unrest, social shaming, and dissemination of falsehoods. In the world of health care, the Internet has created opportunities for attacks on personal privacy, even while facilitating socially valuable exchanges of data among institutions and individuals. Many of these practical, legal, and ethical challenges are the subject of ▶ Chap. 12.

Just as individual hospitals and health care systems have come to appreciate the importance of integrating information from multiple clinical and administrative systems within their organizations (see ▶ Chap. 16), health planners and governments now appreciate the need to develop integrated information resources that combine clinical and health data from multiple institutions within regions, and ultimately nationally (see ▶ Chaps. 15 and 18). As you will see, the Internet and the role of digital communications has therefore become a major part of modern medicine and health. Although this topic recurs in essentially every chapter in this book, we introduce it in the following sections because of its importance to modern technical issues and policy directions.

1.2.1 A Model of Integrated Disease Surveillance[3]

To emphasize the role that the nation's networking infrastructure is playing in integrating clinical data and enhancing care delivery, consider one example of how disease surveillance, prevention, and care are increasingly being influenced by information and communications technology. The goal is to create an information-management infrastructure that will allow all clinicians, regardless of practice setting (hospitals, emergency rooms, small offices, community clinics, military bases, multispecialty groups, etc.) to use EHRs in their practices both to assist in patient care and to provide patients with counsel on illness prevention. The full impact of this use of electronic resources will occur when data from all such records are pooled in regional and national **registries** or surveillance databases (◘ Fig. 1.6), mediated through secure connectivity with the Internet. The challenge, of course, is to find a way to integrate data from such diverse practice settings, especially since there are multiple vendors and system developers active in the marketplace, competing to provide value-added capabilities that will excite and attract the practitioners for whom their EHR product is intended.

The practical need to pool and integrate clinical data from such diverse resources and systems emphasizes the practical issues that need to be addressed in achieving such functionality and resources. Interestingly, most of the barriers are logistical, political, and financial rather than technical in nature:

- *Encryption of data*: Concerns regarding privacy and data protection require that Internet transmission of clinical information occur only if those data are encrypted, with an established mechanism for identifying and authenticating individuals before they are allowed to decrypt the information for surveillance or research use.

3 This section is adapted from a discussion that originally appeared in (Shortliffe and Sondik 2004).

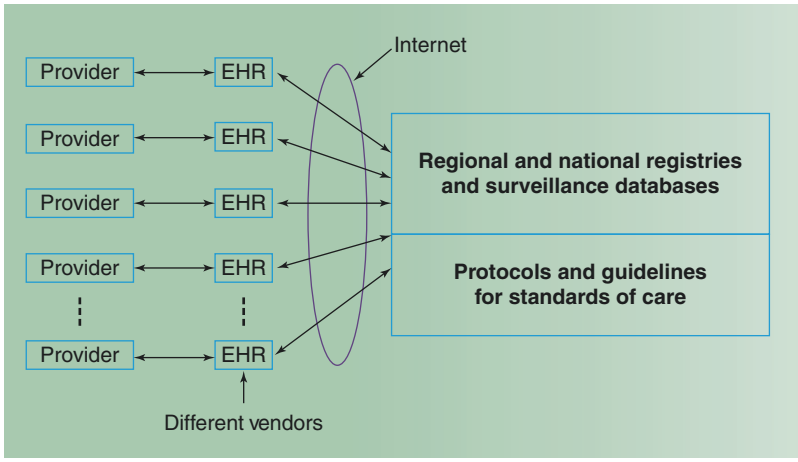


Fig. 1.6 A future vision of surveillance databases, in which clinical data are pooled in regional and national registries or repositories through a process of data submission that occurs over the Internet (with attention to privacy and security concerns as discussed in the text). When information is effectively gathered, pooled, and analyzed, there are significant opportunities for feeding back the results of derived insights to practitioners at the point of care. Thus the arrows indicate a bi-directional process. See also ▶ Chap. 15

- *Protection of stored clinical data*: Even when data are stored within an institution, there are opportunities for attack over the Internet, which can be an affront to patient privacy or, equally seriously, an opportunity for installing **malware** within an institution, resulting in rogue uses of data or even a lockout of valid users from crucially important functions or data. **Cybersecurity** has accordingly become a major topic of concern for health care institutions and other practice settings.[4]
- *HIPAA-compliant policies*: The privacy and security rules that resulted from the 1996 **Health Insurance Portability and Accountability Act (HIPAA)** do not prohibit the pooling and use of such data, but they do lay down policy rules and technical security practices that must be part of the solution in achieving the vision we are discussing here.
- *Standards for data transmission and sharing*: Sharing data over networks requires that all developers of EHRs and clinical databases adopt a single set of standards for communicating and exchanging information. The major enabling standard for such sharing, Health Level 7 (HL7), was introduced decades ago and, after years of work, has been uniformly adopted, implemented, and utilized. However, a uniform "envelope" for digital communication, such as HL7, does not assure that the contents of such messages will be understood or standardized. The pooling and integration of data requires the adoption of standards for clinical terminology and potentially for the schemas used to store clinical information in databases. Thus true interoperability of such systems requires additional standards to be adopted, many of which are discussed in ▶ Chap. 7.
- *Quality control and error checking*: Any system for accumulating, analyzing, and utilizing clinical data from diverse sources must be complemented by a rigorous approach to quality control and error checking. It is crucial that users have faith in the accuracy and comprehensiveness of the data that are collected in such repositories, because policies, guidelines, and a variety of metrics can be derived over time from such information.

4 ▶ https://www.theverge.com/2019/4/4/18293817/cybersecurity-hospitals-health-care-scan-simulation (Accessed 5/29/19).

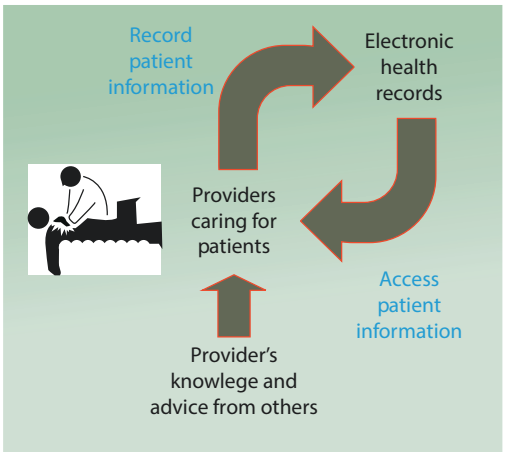
- *Regional and national registries and surveillance databases*: Any adoption of the model in ◘ Fig. 1.6 will require mechanisms for creating, funding, and maintaining the regional and national databases or registries that are involved (see ▶ Chap. 15). The growing amount of data that can be gathered in this way are naturally viewed as part of the "big data" problem that has characterized modern data science. The role of state and federal governments in gathering and curating such databases will need to be clarified, and the political issues addressed (including the concerns of some members of the populace that any government role in managing or analyzing their health data may have societal repercussions that threaten individual liberties, employability, and the like).

With the establishment of registries and surveillance databases, and a robust system of Internet integration with EHRs, summary information can flow back to providers to enhance their decision making at the point of care (◘ Fig. 1.6). This assumes standards that allow such information to be integrated into the vendor-supplied products that the clinicians use in their practice settings. These may be EHRs or their order-entry components that clinicians use to specify the actions that they want to have taken for the treatment or management of their patients (see ▶ Chaps. 14 and 16). Furthermore, as is shown in ◘ Fig. 1.6, the databases can help to support the creation of evidence-based guidelines, or clinical research protocols, which can be delivered to practitioners through the feedback process. Thus one should envision a day when clinicians, at the point of care, will receive integrated, non-dogmatic, supportive information regarding:

- Recommended steps for health promotion and disease prevention
- Detection of syndromes or problems, either in their community or more widely
- Trends and patterns of public health importance, a capability emphasized by the need for rapidly changing data on cases and deaths during the **COVID-19** pandemic in 2020.
- Clinical guidelines, adapted for execution and integration into patient-specific decision support rather than simply provided as text documents
- Opportunities for distributed (community-based) clinical research, whereby patients are enrolled in clinical trials and protocol guidelines are in turn integrated with the clinicians' EHR to support protocol-compliant management of enrolled patients

1.2.2 The Goal: A Learning Health System

We have been stressing the cyclical role of information—its capture, organization, interpretation, and ultimate use. You can easily understand the small cycle that is implied: patient-specific data and plans entered into an EHR and subsequently made available to the same practitioner or others who are involved in that patient's care (◘ Fig. 1.7). Although this view is a powerful contributor to improved data management in the care of patients, it fails to include a larger view of the societal value of the information that is contained in clinical-care records. In fact, such straightforward use of EHRs for direct patient care would not have met some of the



◘ **Fig. 1.7** There is a limited view of the role of EHRs that sees them as intended largely to support the ongoing care of the patient whose clinical data are stored in the record

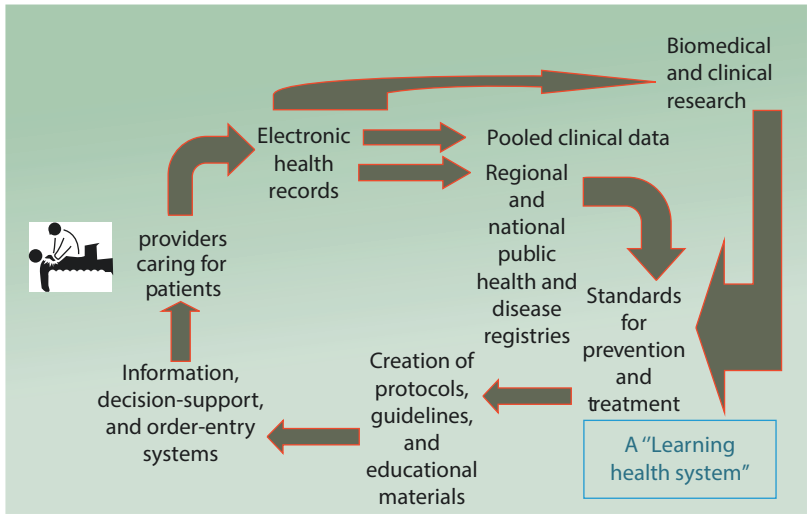


Fig. 1.8 The ultimate goal is to create a cycle of information flow, whereby data from local distributed electronic health records (EHRs) and their associated clinical datasets are routinely and effortlessly submitted to registries and research databases. The resulting new knowledge then can feed back to practitioners at the point of care, using a variety of computer-supported decision-support delivery mechanisms. This cycle of new knowledge, driven by experience, and fed back to clinicians, has been dubbed a "learning health system"

requirements that the US government specified after 2009 when determining eligibility for payment of incentives to clinicians or hospitals who implemented EHRs (see the discussion of the government HITECH program in ▶ Sect. 1.3).

Consider, instead, an expanded view of the health surveillance model introduced in ▶ Sect. 1.2.1 (Fig. 1.8). Beginning at the left of the diagram, clinicians caring for patients use electronic health records, both to record their observations and to gain access to information about the patient. Information from these records is then stored in local patient-care clinical databases and forwarded automatically to regional and national registries as well as to research databases that can support retrospective studies (see ▶ Chap. 15) or formal institutional or community-based clinical trials (see ▶ Chap. 27). The analyzed information from institutional datasets, registries and research studies can in turn be used to develop standards for prevention and treatment, with major guidance from biomedical research. Researchers can draw information either directly from the health records or from the pooled data in registries. The standards for treatment in turn can be translated into protocols, guidelines, and educational materials. This new knowledge and decision-support functionality can then be delivered over the network back to the clinicians so that the information informs patient care, where it is integrated seamlessly with EHRs and order-entry systems.

This notion of a system that allows us to learn from what we do, unlocking the experience that has traditionally been stored in unusable form in paper charts, is gaining wide attention now that we can envision an interconnected community of clinicians and institutions, building digital data resources using EHRs. The concept has been dubbed a **learning health system** and is an ongoing subject of study by the National Academy of Medicine (Daley 2013), which has published a series of reports on the topic.[5] It is also the organizing conceptual framework for a

5 ▶ https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/ (Accessed 05/29/19)

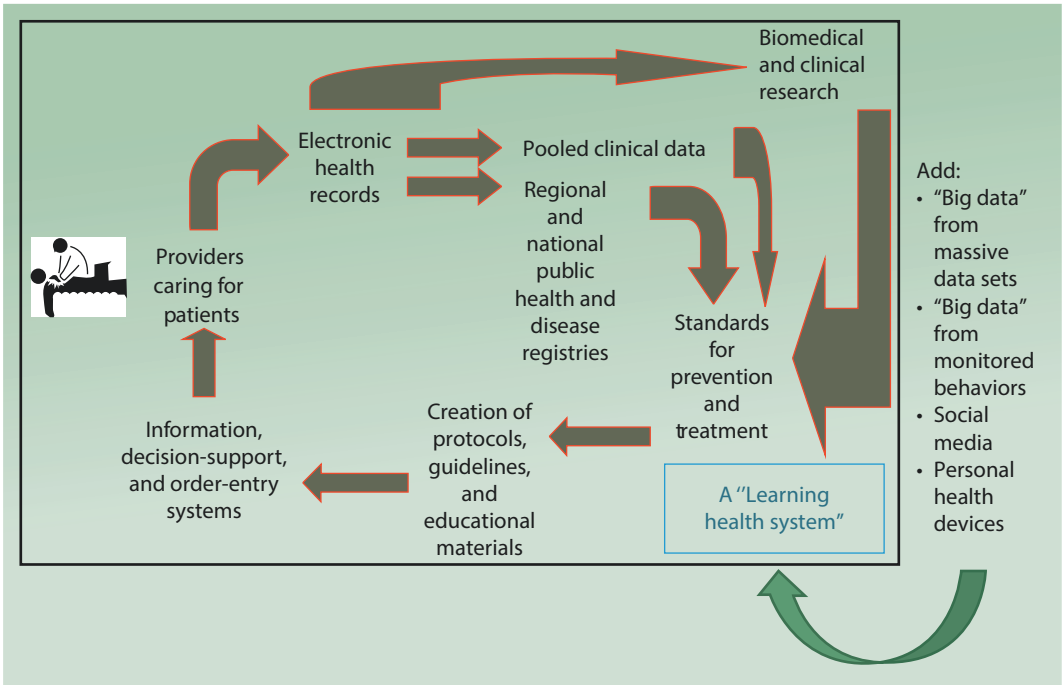


Fig. 1.9 Today the *learning health system* is increasingly embracing new forms of massive health-related data, often from outside the clinical care setting and derived from population activities that reflect individuals' health, activities, and attitudes

recently created department at the University of Michigan Medical School[6] and for a new scientific journal.[7]

Although the learning health system concept of Fig. 1.8 may at first seem expansive and all-inclusive, in recent years we have learned that there are other important inputs to the health care environment and these can have important implications for what we learn by analyzing what both patients and healthy individuals do. Some of these data sources are immense and are in line with the recent interest in "big data" analytics (Fig. 1.9). Consider, for example, the analysis of huge datasets associated with full human genome specifications for individuals and populations. Another approach for gathering massive amounts of relevant health-related data is to monitor the behavior of individuals as they use online information resources, searching for health-related information. Social media exchanges (e.g., Twitter, Facebook) have also been used to extract health-related information, such as complaints that suggest early stages of communicable diseases or expressed attitudes towards diseases and treatment. The explosive adoption of health monitoring devices (e.g., step counters, exercise analyzers, cardiac or sleep monitors) has also offered a useful source of large-scale information that is only beginning to be merged with other data in our learning health system.

1.2.3 Implications of the Internet for Patients

With the penetration of the Internet, patients, as well as healthy individuals, have turned to the Internet for health information. It is a rare North American physician who has not

6 ► https://medicine.umich.edu/dept/learning-health-sciences (Accessed 05/03/2020)

7 ► https://onlinelibrary.wiley.com/journal/23796146 (Accessed 05/03/2020)

encountered a patient who comes to an appointment armed with a question, or a stack of printouts, that arose due to medically related searches on the net. The companies that provide search engines for the Internet report that health-related sites are among the most popular ones being explored by consumers. As a result, physicians and other care providers have learned that they must be prepared to deal with information that patients discover on the net and bring with them when they seek care from clinicians. Some of the information is timely and excellent; in this sense, physicians can often learn about innovations from their patients and need to be open to the kinds of questions that this enhanced access to information will generate from patients in their practices.

On the other hand, much of the health information on the Web lacks peer review or is purely anecdotal. People who lack medical training can be misled by such information, just as they have been poorly served in the past by printed information in books and magazines dealing with fad treatments from anecdotal sources. This also creates challenges for health care providers, who often feel pressured to handle more issues in less time due to economic pressures. In addition, some sites provide personalized advice, sometimes for a fee, with all the attendant concerns about the quality of the suggestions and the ability to give valid advice based on an electronic-mail or Web-based interaction.

In a positive light, communications technologies offer clinicians creative ways to interact with their patients and to provide higher quality care. Years ago, medicine adopted the telephone as a standard vehicle for facilitating patient care, and we now take this kind of interaction with patients for granted. If we extend the audio channel to include our visual sense as well, typically relying on the Internet as our communication mechanism, the notion of **telemedicine** emerges (see ▶ Chap. 20). This notion of "medicine at a distance" arose early in the twentieth century (see ◘ Fig. 1.10), but the technology was too limited for much penetration of the idea beyond telephone conversations until the last 30–40 years. The use of telemedicine has subsequently grown rapidly, and there are settings in which it is already proving to be successful and cost-effective (e.g., rural care, international medicine, **teleradiology**, and video-based care of patients in prisons). Similarly, there are now a large number of **apps** (designed for smart phones, tablets, or desktop machines) that offer specialized medical care or advice or assist with health data management and communication with providers and support groups (see ▶ Chaps. 11 and 20).

1.2.4 Requirements for Achieving the Vision

Efforts that continue to push the state of the art in Internet technology all have significant implications for the future of health care delivery in general and of EHRs and their integration in particular (Shortliffe 1998b, 2000). But in addition to increasing speed, reliability, security, and availability of the Internet, there are many other areas that need attention if the vision of a learning health system is to be achieved.

1.2.4.1 Education and Training

There is a difference between computer literacy (familiarity with computers and their routine uses in our society) and knowledge of the role that computing and communications technology can and should play in our health system. We need to do a better job of training future clinicians in the latter area. Otherwise we will leave them poorly equipped for the challenges and opportunities they will face in the rapidly changing practice environments that surround them (Shortliffe 2010). Not only do they need to feel comfortable with the technology itself, but they need to understand the profound effect that it has had on the practice of medicine—with many more changes to come. Medicine, and other health professions, are being asked to adapt in ways that were not envisioned even a decade or two ago. Not all individuals embrace such change, but younger clinicians, who have grown up with technology in almost all aspects of their lives, have high

Fig. 1.10 "The Radio Doctor": long before television was invented, creative observers were suggesting how doctors and patients could communicate using advanced technologies. This 1924 example is from the cover of a popular magazine and envisions video enhancements to radio. (Source: "Radio News" 1924)

expectations for how digital systems and tools should enhance their professional experience. What is even more challenging, perhaps, is that assumptions that they have made about the field they have entered may no longer be valid in the coming years, as some skills are no longer required and new requirements are viewed as dramatically different from what health professionals have had to know in the past.

Furthermore, in addition to the implications for education of health professionals about computer-related topics, much of the future vision we have proposed here can be achieved only if educational institutions produce a cadre of talented individuals who are highly skilled in computing and communications technology but also have a deep understanding of the biomedical milieu and of the needs of practitioners and other health work-

ers. Computer science training alone is not adequate. Fortunately, there are increasing numbers of formal training programs in what has become known as **biomedical informatics** (see ► Sect. 1.4) that provide custom-tailored educational opportunities. Many of the trainees are life science researchers, physicians, nurses, pharmacists, and other health professionals who see the career opportunities and challenges at the intersections of biomedicine, information science, computer science, decision science, data science, cognitive science, and communications technologies. As has been clear for three decades (Greenes and Shortliffe 1990), however, the demand for such individuals far outstrips the supply, both for academic and industrial career pathways.[8, 9] We need more training programs,[10] expansion of those that already exist, plus support for junior faculty in health science schools who may wish to pursue additional training in this area.

1.2.4.2 Organizational and Management Change

Second, as implied above, there needs to be a greater understanding among health care leaders regarding the role of specialized multidisciplinary expertise in successful clinical systems implementation. The health care system provides some of the most complex organizational structures in society (Begun et al. 2003), and it is simplistic to assume that off-the-shelf products will be smoothly introduced into a new institution without major analysis, redesign, and cooperative joint-development efforts. Underinvestment and a failure to understand the requirements for process reengineering as part of software implementation, as well as problems with technical leadership and planning, account for many of the frustrating experiences that health care organizations report in their efforts to use computers more effectively in support of patient care and provider productivity.

The notion of a learning health system described previously is meant to motivate your enthusiasm for what lies ahead and to suggest the topics that need to be addressed in a book such as this one. Essentially all of the following chapters touch on some aspect of the vision of integrated systems that extend beyond single institutions. Before embarking on these topics, however, we must emphasize two points. First, the cyclical creation of new knowledge in a learning health care system will become reality only if individual hospitals, academic medical centers, and national coordinating bodies work together to provide the standards, infrastructure, and resources that are necessary. No individual system developer, vendor, or administrator can mandate the standards for connectivity, data pooling, and data sharing implied by a learning health care system. A national initiative of cooperative planning and implementation for computing and communications resources within and among institutions and clinics is required before practitioners will have routine access to the information that they need (see ► Chap. 15). A major federal incentive program for EHR implementation was a first step in this direction (see ► Sect. 1.3). The criteria that are required for successful EHR implementation are sensitive to the need for data integration, public-health support, and a learning health system.

Second, although our presentation of the learning health system notion has focused on the clinician's view of integrated information access, other workers in the field have similar needs that can be addressed in similar ways. The academic research community has already developed and made use of much of the technology that needs to be coalesced if the clinical user is to have similar access to data and information. There is also the

8 ► https://www.hcinnovationgroup.com/policy-value-based-care/staffing-professional-development/news/13024360/report-health-informatics-labor-market-lags-behind-demand-for-workers (Accessed 5/30/2019); ► https://www.bestvalueschools.com/faq/job-outlook-health-informatics-graduates/ (Accessed 5/30/2019).

9 ► https://www.burning-glass.com/wp-content/uploads/BG-Health_Informatics_2014.pdf (Accessed 5/30/2019).

10 A directory of some existing training programs is available at ► http://www.amia.org/education/programs-and-courses (Accessed 5/30/19).

patient's view, which must be considered in the notion of patient-centered health care that is now broadly accepted and encouraged (Ozkaynak et al. 2013).

1.3 The US Government Steps In

During the early decades of the evolution of clinical information systems for use in hospitals, patient care, and public health, the major role of government was in supporting the research enterprise as new methods were developed, tested, and formally evaluated. The topic was seldom mentioned by the nation's leaders, however, even during the 1990s when the White House was viewed as being especially tech savvy. It was accordingly remarkable when, in the President's State of the Union address in 2004 (and in each of the following years of his administration), President Bush called for universal implementation of electronic health records within 10 years. The Secretary of Health and Human Services, Tommy Thompson, was similarly supportive and, in May 2004, created an entity intended to support the expansion of the use of EHRs—the **Office of the National Coordinator for Health Information Technology** (initially referred to by the full acronym ONCHIT, but later shortened simply to ONC).

There was initially limited budget for ONC, although the organization served as a convening body for EHR-related planning efforts and the National Health Information Infrastructure (see ▶ Chaps. 14, 15 and 29). The topic of EHRs subsequently became a talking point for both major candidates during the Presidential election in 2008, with strong bipartisan support. Then, in early 2009, Congress enacted the American Recovery and Reinvestment Act (ARRA), also known as the economic "Stimulus Bill". One portion of that legislation was known as the **Health Information Technology for Economic and Clinical Health (HITECH) Act**. It was this portion of the bill that provided significant fiscal incentives for health systems, hospitals, and providers to implement EHRs in their practices and eventual financial penalties for lack of implementation. Such payments were made available, however, only when eligible organizations or individual practitioners implemented EHRs that were "certified" as meeting minimal standards and when they could document that they were making "meaningful use" of those systems. You will see references to such certification and **meaningful use** criteria in other chapters in this volume.

This volume also offers a discussion of HIT policy and the federal government in ▶ Chap. 29. Although the process of EHR implementation is approaching completion in the US, both in health systems and practices, the current status is largely due to this legislative program: because of the federal stimulus package, large numbers of hospitals, systems, and practitioners invested in EHRs and incorporated them into their practices. Furthermore, the demand for workers skilled in health information technology grew much more rapidly than did the general job market, even within health care (◘ Fig. 1.11). It is a remarkable example of how government policy and investment can stimulate major transitions in systems such as health care, where many observers had previously felt that progress had been unacceptably slow (Shortliffe 2005).

1.4 Defining Biomedical Informatics and Related Disciplines

With the previous sections of this chapter as background, let us now consider the scientific discipline that is the subject of this volume and has led to the development of many of the functionalities that need to be brought together in the integrated biomedical-computing environment of the future. The remainder of this chapter deals with biomedical informatics as a field and with biomedical and health information as a subject of study. It provides additional background needed to understand many of the subsequent chapters in this book.

Reference to the use of computers in biomedicine evokes different images depending on the nature of one's involvement in the field. To a hospital administrator, it might suggest

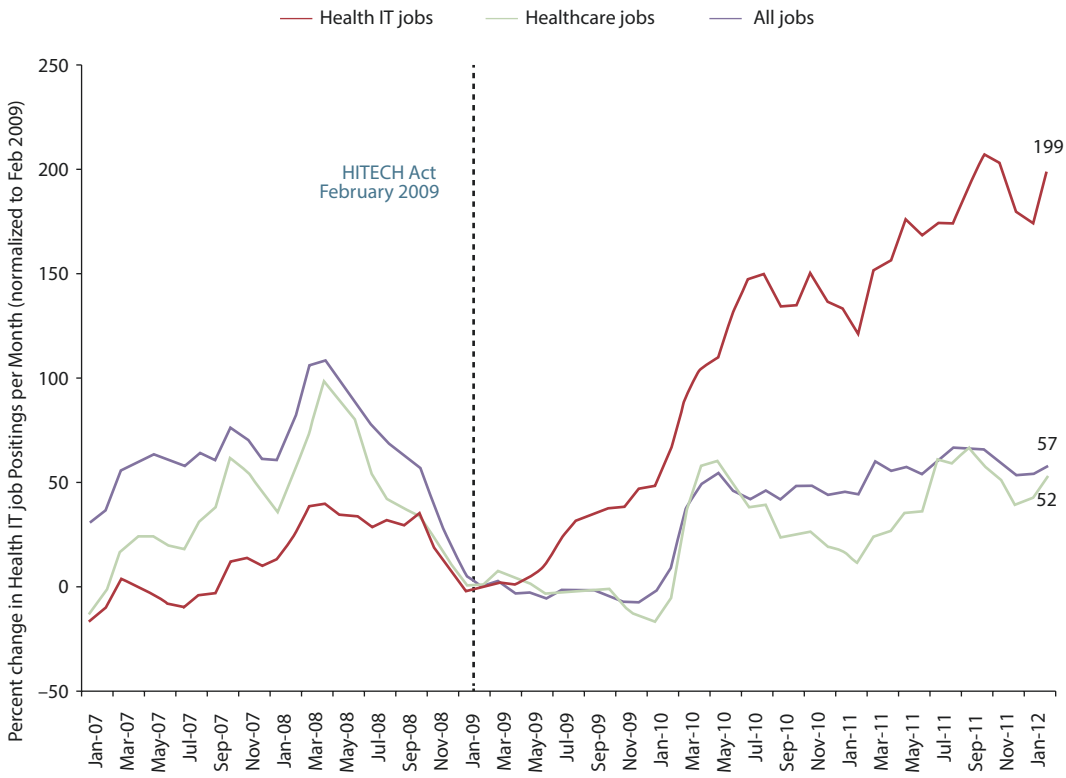


Fig. 1.11 Impact of the HITECH Act on health information technology (IT) employment. Percent change in online health IT job postings per month for first 3 years, relative to health care jobs and all jobs: normalized to February 2009 when ARRA passed. (Source: ONC analysis of data from O'Reilly Job Data Mart, ONC Data Brief, No. 2, May 2012 (▶ https://www.healthit.gov/sites/default/files/pdf/0512_ONCDataBrief2_JobPostings.pdf (Accessed 5/6/2019)))

the maintenance of clinical-care records using computers; to a decision scientist, it might mean the assistance by computers in disease diagnosis; to a basic scientist, it might mean the use of computers for maintaining, retrieving, and analyzing gene-sequencing information. Many physicians immediately think of office-practice tools for tasks such as patient billing or appointment scheduling, and of electronic health record systems for clinical documentation. Nurses often think of computer-based tools for charting the care that they deliver, or decision-support tools that assist in applying the most current patient-care guidelines. The field includes study of all these activities and a great many others too. More importantly, it includes the consideration of various external factors that affect the biomedical setting. Unless you keep in mind these surrounding factors, it may be difficult to understand how biomedical computing can help us to tie together the diverse aspects of health care and its delivery.

To achieve a unified perspective, we might consider four related topics: (1) the concept of biomedical information (why it is important in biological research and clinical practice and why we might want to use computers to process it); (2) the structural features of medicine, including all those subtopics to which computers might be applied; (3) the importance of evidence-based knowledge of biomedical and health topics, including its derivation and proper management and use; and (4) the applications of computers and communication methods in biomedicine and the scientific issues that underlie such efforts. We mention the first two topics briefly in this and the next chapter, and we provide references in the Suggested Readings section for readers who

wish to learn more. The third topic, knowledge to support effective decision making in support of human health, is intrinsic to this book and occurs in various forms in essentially every chapter. The fourth topic, however, is the principal subject of this book.

Computers have captured the imagination (and attention) of our society. Today's younger individuals have grown up in a world in which computers are ubiquitous and useful. Because the computer as a machine is exciting, people may pay a disproportionate amount of attention to it as such—at the expense of considering what the computer can do given the numbers, concepts, ideas, and cognitive underpinnings of fields such as medicine, health, and biomedical research. Computer scientists, philosophers, psychologists, and other scholars increasingly consider such matters as the nature of information and knowledge and how human beings process such concepts. These investigations have been given a sense of timeliness (if not urgency) by the simple existence of the computer. The cognitive activities of clinicians in practice probably have received more attention over the past three or four decades than in all previous history (see ► Chap. 4). Again, the existence of the computer and the possibilities of its extending a clinician's cognitive powers have motivated many of these studies. To develop computer-based tools to assist with decisions, we must understand more clearly such human processes as diagnosis, therapy planning, decision making, and problem solving in medicine. We must also understand how personal and cultural beliefs affect the way in which information is interpreted and decisions are ultimately made.

1.4.1 Terminology

Although, starting in the 1960s, a growing number of individuals conducting serious biomedical research or undertaking clinical practice had access to a computer system, there was initial uncertainty about what name should be used for the biomedical application of computer science concepts. The name computer science was itself new in 1960 and was only vaguely defined. Even today, the term computer science is used more as a matter of convention than as an explanation of the field's scientific content.

In the 1970s we began to use the phrase **medical computer science** to refer to the subdivision of computer science that applies the methods of the larger field to medical topics. As you will see, however, medicine has provided a rich area for computer science research, and several basic computing insights and methodologies have been derived from applied medical-computing research.

The term **information science**, which is occasionally used in conjunction with computer science, originated in the field of library science and is used to refer, somewhat generally, to the broad range of issues related to the management of both paper-based and electronically stored information. Much of what information science originally set out to be is now drawing evolving interest under the name **cognitive science**.

Information theory, in contrast, was first developed by scientists concerned about the physics of communication; it has evolved into what may be viewed as a branch of mathematics. The results scientists have obtained with information theory have illuminated many processes in communications technology, but they have had little effect on our understanding of human information processing.

The terms **biomedical computing** or **biocomputation** have been used for a number of years. They are non-descriptive and neutral, implying only that computers are employed for some purpose in biology or medicine. They are often associated with bioengineering applications of computers, however, in which the devices are viewed more as tools for a bioengineering application than as a primary focus of research.

In the 1970s, inspired by the French term for computer science (*informatique*), the English-speaking community began to use the term **medical informatics**. Those in the field were attracted by the word's emphasis on *information*, which they saw as more central to the field than the computer itself, and it gained momentum as a term for the discipline, espe-

cially in Europe, during the 1980s. The term is broader than **medical computing** (it includes such topics as medical statistics, record keeping, and the study of the nature of medical information itself) and deemphasizes the computer while focusing instead on the nature of the field to which computations are applied. Because the term *informatics* became widely accepted in the United States only in the late 1980s, **medical information science** was also used earlier in North America; this term, however, may be confused with library science, and it does not capture the broader implications of the European term. As a result, the name *medical informatics* appeared by the late 1980s to have become the preferred term, even in the United States. Indeed, this is the name of the field that we used in the first two editions of this textbook (published in 1990 and 2000), and it is still sometimes used in professional, industrial, and academic settings. However, many observers expressed concern that the adjective "medical" is too focused on physicians and disease, failing to appreciate the relevance of this discipline to other health and life-science professionals and to health promotion and disease prevention. Thus, the term **health informatics**, or health care informatics, gained some popularity, even though it has the disadvantage of tending to exclude applications to biomedical research (► Chaps. 9 and 26) and, as we shall argue shortly, it tends to focus the field's name on application domains (clinical care, public health, and prevention) rather than the basic discipline and its broad range of applicability.

Applications of informatics methods in biology and genetics exploded during the 1990s due to the human genome project[11] and the growing recognition that modern life-science research was no longer possible without computational support and analysis (see ► Chaps. 9 and 26). By the late 1990s, the use of informatics methods in such work had become widely known as **bioinformatics** and the director of the National Institutes of Health (NIH) appointed an advisory group called the Working Group on Biomedical Computing. In June 1999, the group provided a report[12] recommending that the NIH undertake an initiative called the **Biomedical Information Science and Technology Initiative (BISTI)**. With the subsequent creation of another NIH organization called the Bioinformatics Working Group, the visibility of informatics applications in biology was greatly enhanced. Today bioinformatics is a major area of activity at the NIH[13] and in many universities and biotechnology companies around the world. The explosive growth of this field, however, has added to the confusion regarding the naming conventions we have been discussing. In addition, the relationship between *medical informatics* and *bioinformatics* became unclear. As a result, in an effort to be more inclusive and to embrace the biological applications with which many medical informatics groups had already been involved, the name *medical informatics* gradually gave way to biomedical informatics (BMI). Several academic groups have changed their names, and a major medical informatics journal (*Computers and Biomedical Research,* first published in 1967) was reborn in 2001 as *The Journal of Biomedical Informatics*.[14]

Despite this convoluted naming history, we believe that the broad range of issues in biomedical information management does require an appropriate name and, beginning with the third edition of this book (2006), we used the term **biomedical informatics** for this purpose. It has become the most widely accepted term for the core discipline and should be viewed as encompassing broadly all areas of application in health, clinical practice, and biomedical research. When we speak specifically about computers and their use within biomedical informatics activities, we use the terms biomedical computer science (for the methodologic issues) or biomedical computing (to describe the activity itself).

11 ► https://www.ornl.gov/sci/techresources/Human_Genome/home.shtml (Accessed 5/31/2019).

12 Available at ► https://acd.od.nih.gov/documents/reports/060399_Biomed_Computing_WG_RPT.htm (Accessed 5/31/2019).

13 See ► http://www.bisti.nih.gov/. (Accessed 5/31/2019).

14 ► http://www.journals.elsevier.com/journal-of-biomedical-informatics (Accessed 5/30/19).

Note, however, that biomedical informatics has many other component sciences in addition to computer science. These include the decision sciences, statistics, cognitive science, data science, information science, and even management sciences. We return to this point shortly when we discuss the basic versus applied nature of the field when it is viewed as a basic research discipline.

Although labels such as these are arbitrary, they are by no means insignificant. In the case of new fields of endeavor or branches of science, they are important both in designating the field and in defining or restricting its contents. The most distinctive feature of the modern computer is the generality of its application. The nearly unlimited range of computer uses complicates the business of naming the field. As a result, the nature of computer science is perhaps better illustrated by examples than by attempts at formal definition. Much of this book presents examples that do just this for biomedical informatics as well.

The American Medical Informatics Association (AMIA), which was founded in the late 1980s under the former name for the discipline, has recognized the confusion regarding the field and its definition.[15] They accordingly appointed a working group to develop a formal definition of the field and to specify the core competencies that need to be acquired by students seeking graduate training in the discipline. The resulting definition, published in AMIA's journal and approved by the full board of the organization, identifies the focus of the field in a simple sentence and then adds four clarifying corollaries that refine the definition and the field's scope and content (► Box 1.1). We adopt this definition, which is very similar to the one we offered in previous editions of this text. It acknowledges that the emergence of biomedical informatics as a new discipline is due in large part to rapid advances in computing and communications technology, to an increasing awareness that the knowledge base of biomedicine is essentially unmanageable by traditional paper-based methods, and to a growing conviction that the process of informed decision making is as important to modern biomedicine as is the collection of facts on which clinical decisions or research plans are made.

Box 1.1: Definition of Biomedical Informatics

Biomedical informatics (*BMI*) *is the interdisciplinary field that studies and pursues the effective uses of biomedical data, information, and knowledge for scientific inquiry, problem solving, and decision making, driven by efforts to improve human health.*

Scope and breadth of discipline: BMI investigates and supports reasoning, modeling, simulation, experimentation, and translation across the spectrum from molecules to individuals and to populations, from biological to social systems, bridging basic and clinical research and practice and the health care enterprise.

Theory and methodology: BMI develops, studies, and applies theories, methods, and processes for the generation, storage, retrieval, use, management, and sharing of biomedical data, information, and knowledge.

Technological approach: BMI builds on and contributes to computer, telecommunication, and information sciences and technologies, emphasizing their application in biomedicine.

Human and social context: BMI, recognizing that people are the ultimate users of biomedical information, draws upon the social and behavioral sciences to inform the design and evaluation of technical solutions, policies, and the evolution of economic, ethical, social, educational, and organizational systems.

15 ► https://www.amia.org/about-amia/science-informatics (Accessed 5//27/19).

1

1.4.2 Historical Perspective

The modern digital computer grew out of developments in the United States and abroad during World War II, and general-purpose computers began to appear in the marketplace by the mid-1950s (Fig. 1.12). Speculation about what might be done with such machines (if they should ever become reliable) had, however, begun much earlier. Scholars, at least as far back as the Middle Ages, often had raised the question of whether human reasoning might be explained in terms of formal or **algorithmic processes**. Gottfried Wilhelm von Leibnitz, a seventeenth-century German philosopher and mathematician, tried to develop a calculus that could be used to simulate human reasoning. The notion of a "logic engine" was subsequently worked out by Charles Babbage in the mid nineteenth century.

The first practical application of automatic computing relevant to medicine was Herman Hollerith's development of a punched-card data-processing system for the 1890 U.S. census (Fig. 1.13). His methods were soon adapted to **epidemiologic** and public health surveys, initiating the era of electromechanical punched-card data-processing technology, which matured and was widely adopted during the 1920s and 1930s. These techniques were the precursors of the stored program and wholly electronic digital computers, which began to appear in the late 1940s (Collen 1995).

One early activity in biomedical computing was the attempt to construct systems that would assist a physician in decision making (see ▶ Chap. 24). Not all biomedical-computing programs pursued this course, however. Many of the early ones instead investigated the notion of a total **hospital information system** (HIS; see ▶ Chap. 16). These projects were perhaps less ambitious in that they were more concerned with practical applications in the short term; the difficulties they encountered, however, were still formidable. The earliest work on HISs in the United States was probably that associated with the MEDINET project at General Electric, followed by work at Bolt, Beranek, Newman in Cambridge, Massachusetts, and then at the Massachusetts General Hospital (MGH) in Boston. A number of hospital application programs were developed at MGH by Barnett and his associates over three decades beginning in the early 1960s. Work on similar systems was undertaken by Warner at Latter Day Saints (LDS) Hospital in Salt Lake City, Utah, by Collen at Kaiser Permanente in Oakland, California, by Wiederhold at

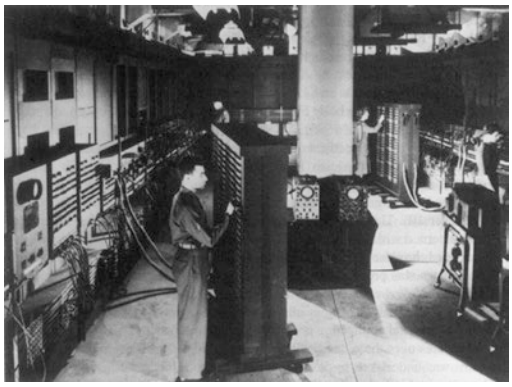


Fig. 1.12 The ENIAC. Early computers, such as the ENIAC, were the precursors of today's personal computers (PCs) and handheld calculators. (US Army photo. See also ▶ http://www.computersciencelab.com/ComputerHistory/HistoryPt4.htm (Accessed 5/31/2019))

Fig. 1.13 Tabulating machines. The Hollerith Tabulating Machine was an early data-processing system that performed automatic computation using punched cards. (Photograph courtesy of the Library of Congress)

Stanford University in Stanford, California, and by scientists at Lockheed in Sunnyvale, California.[16]

The course of HIS applications bifurcated in the 1970s. One approach was based on the concept of an integrated or monolithic design in which a single, large, *time-shared computer* would be used to support an entire collection of applications. An alternative was a distributed design that favored the separate implementation of specific applications on smaller individual computers—minicomputers—thereby permitting the independent evolution of systems in the respective application areas. A common assumption was the existence of a single shared database of patient information. The multimachine model was not practical, however, until network technologies permitted rapid and reliable communication among distributed and (sometimes) heterogeneous types of machines. Such distributed HISs began to appear in the 1980s (Simborg et al. 1983).

Biomedical-computing activity broadened in scope and accelerated with the appearance of the minicomputer in the early 1970s. These machines made it possible for individual departments or small organizational units to acquire their own dedicated computers and to develop their own application systems (Fig. 1.14). In tandem with the introduction of general-purpose software tools that provided standardized facilities to individuals with limited computer training (such as the UNIX operating system and programming environment), the minicomputer put more computing power in the hands of more biomedical investigators than did any other single development until the introduction of the microprocessor, a central processing unit (CPU) contained on one or a few chips (Fig. 1.15).

Everything changed radically in the late 1970s and early 1980s, when the microprocessor and the personal computer (PC) or microcomputer became available. Not only could hospital departments afford minicomputers but now individuals also could afford micro-

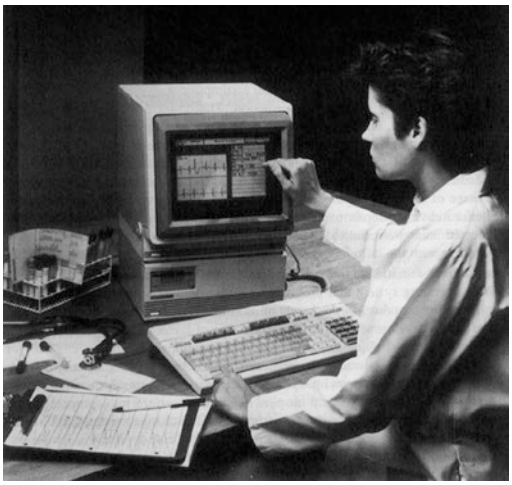


Fig. 1.14 Departmental system. Hospital departments, such as the clinical laboratory, were able to implement their own custom-tailored systems when affordable minicomputers became available. These departments subsequently used microcomputers to support administrative and clinical functions. (Copyright 2013 Hewlett-Packard Development Company, LP. Reproduced from ~1985 original with permission)

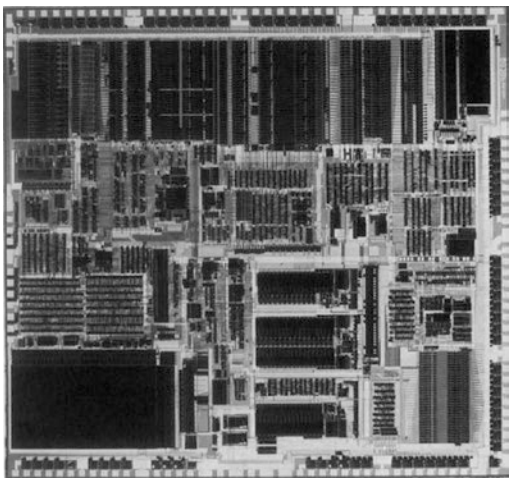


Fig. 1.15 Miniature computer. The microprocessor, or "computer on a chip," revolutionized the computer industry in the 1970s. By installing chips in small boxes and connecting them to a computer terminal, engineers produced the personal computer (PC)—an innovation that made it possible for individual users to purchase their own systems

16 The latter system was later taken over and further developed by the Technicon Corporation (subsequently TDS Healthcare Systems Corporation). Later the system was part of the suite of products available from Eclipsys, Inc. (which in turn was acquired by Allscripts, Inc in 2010).

computers. This change enormously broadened the base of computing in our society and gave rise to a new software industry. The first articles on computers in medicine had appeared in clinical journals in the late 1950s, but it was not until the late 1970s that the first use of computers in advertisements dealing with computers and aimed at physicians began to appear (Fig. 1.16). Within a few years, a wide range of computer-based information-management tools were available as commercial products; their descriptions began to appear in journals alongside the traditional advertisements for drugs and other medical products. Today individual physicians find it practical to employ PCs in a variety of settings, including for applications in patient care or clinical investigation.

Today we enjoy a wide range of hardware of various sizes, types, prices, and capabilities, all of which will continue to evolve in the decades ahead. The trend—reductions in size and cost of computers with simultaneous increases in power (Fig. 1.17)—shows no sign of slowing, although scientists foresee the

Fig. 1.16 Medical advertising. An early advertisement for a portable computer terminal that appeared in general medical journals in the late 1970s. The development of compact, inexpensive peripheral devices and personal computers (PCs) inspired future experiments in marketing directly to clinicians (Reprinted by permission of copyright holder Texas Instruments Incorporated © 1985)

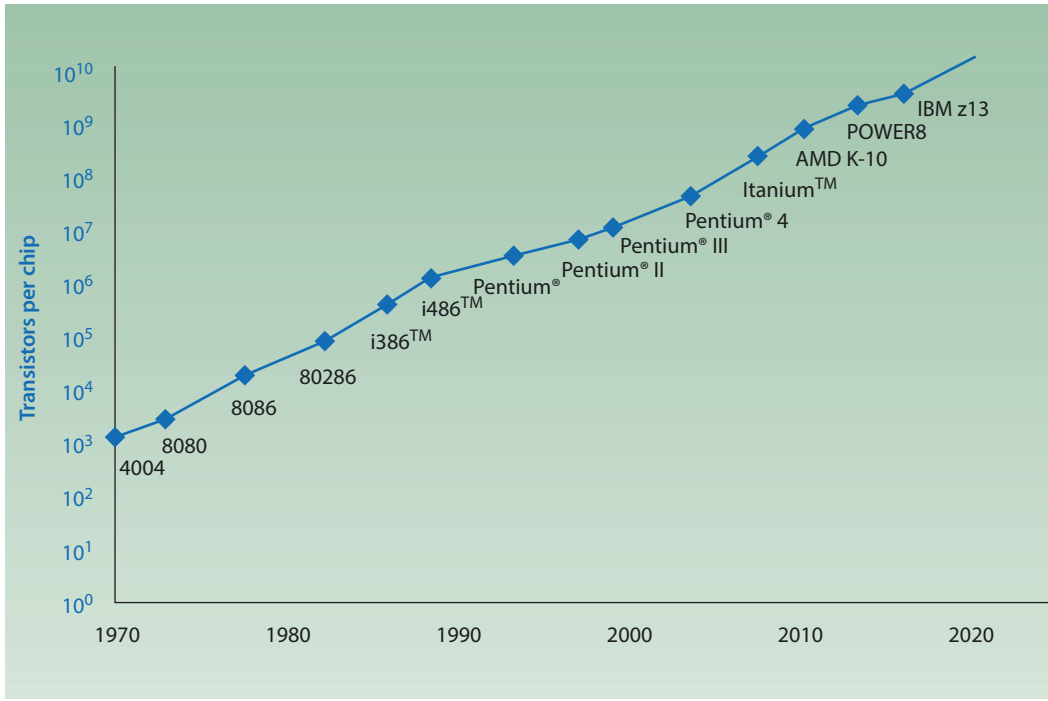


Fig. 1.17 Moore's Law. Former Intel chairman Gordon Moore is credited with popularizing the "law" that the size and cost of microprocessor chips will half every 18 months while they double in computing power. This graph shows the exponential growth in the number of transistors that can be integrated on a single microprocessor chip. The trend continues to this day. (Source: Wikipedia: ▶ https://en.wikipedia.org/wiki/Transistor_count)

Fig. 1.18 The National Library of Medicine (NLM). The NLM, on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland, is the principal biomedical library for the nation (see ▶ Chap. 23). It is also a major source of support for research and training in biomedical informatics, both at NIH and in universities throughout the US. (Photograph courtesy of the National Library of Medicine)

ultimate physical limitations to the miniaturization of computer circuits.[17]

Progress in biomedical-computing research will continue to be tied to the availability of funding from either government or commercial sources. Because most biomedical-computing research is exploratory and is far from ready for commercial application, the federal government has played a key role in funding the work of the last four decades, mainly through the NIH and the Agency for Health Care Research and Quality (AHRQ). The National Library of Medicine (NLM) has assumed a primary role for biomedical informatics, especially with support for basic research in the field (Fig. 1.18). As increasing numbers of applications prove successful in the commercial marketplace, it is likely that more development work will shift to industrial settings and that university programs will focus increasingly on fundamental research problems viewed as too speculative for short-term commercialization – as has occurred in the field of computer science over the past several decades.

17 ▶ https://www.sciencedaily.com/releases/2008/01/080112083626.htm; ▶ https://arstechnica.com/science/2014/08/are-processors-pushing-up-against-the-limits-of-physics/ (Accessed 5/27/19).

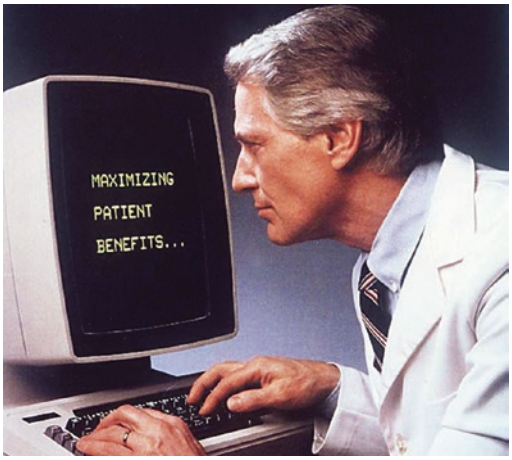


Fig. 1.19 Doctor of the future. By the early 1980s, advertisements in medical journals (such as this one for an antihypertensive agent) began to use computer equipment as props and even portrayed them in a positive light. The suggestion in this photograph seems to be that an up-to-date physician feels comfortable using computer-based tools in his practice. (Photograph courtesy of ICI Pharma, Division of ICI Americas, Inc)

1.4.3 Relationship to Biomedical Science and Clinical Practice

The exciting accomplishments of biomedical informatics, and the implied potential for future benefits to medicine, must be viewed in the context of our society and of the existing health care system. As early as 1970, an eminent clinician suggested that computers might in time have a revolutionary influence on medical care, on medical education, and even on the selection criteria for health-science trainees (Schwartz 1970). The subsequent enormous growth in computing activity has been met with some trepidation by health professionals. They ask where it will all end. Will health workers gradually be replaced by computers? Will nurses and physicians need to be highly trained in computer science or informatics before they can practice their professions effectively? Will both patients and health workers eventually revolt rather than accept a trend toward automation that they believe may threaten the traditional humanistic values in health care delivery (see ▶ Chap. 12) (Shortliffe 1993a)? Will clinicians be viewed as outmoded and backward if they do not turn to computational tools for assistance with information management and decision making (Fig. 1.19)?

1

Biomedical informatics is intrinsically entwined with the substance of biomedical science. It determines and analyzes the structure of biomedical information and knowledge, whereas biomedical science is constrained by that structure. Biomedical informatics melds the study data, information, knowledge, decision making, and supporting technologies with analyses of biomedical information and knowledge, thereby addressing specifically the interface between the science of information and knowledge management and biomedical science. To illustrate what we mean by the "structural" features of biomedical information and knowledge, we can contrast the properties of the information and knowledge typical of such fields as physics or engineering with the properties of those typical of biomedicine (see ► Box 1.2).

Box 1.2: The Nature of Medical Information

This material is adapted from a small portion of a classic book on this topic. It was written by Dr. Scott Blois, who coauthored the introductory chapter to this textbook in its 1st edition, which was published shortly after his death. Dr. Blois was a scholar who directed the informatics program at the University of California San Francisco and served as the first president of the American College of Medical Informatics (ACMI). [Blois, M. S. (1984). *Information and medicine: The nature of medical descriptions*. Berkeley: University of California Press].

From the material in this chapter, you might conclude that biomedical applications do not raise any unique problems or concerns. On the contrary, the biomedical environment raises several issues that, in interesting ways, are quite distinct from those encountered in most other domains of applied computing. Clinical information seems to be systematically different from the information used in physics, engineering, or even clinical chemistry (which more closely resembles chemical applications generally than it does medical ones). Aspects of biomedical information include an essence of uncertainty—we can never know all about a physiological process—and this results in inevitable variability among individuals. These differences raise special problems and some investigators suggest that biomedical computer science differs from conventional computer science in fundamental ways. We shall explore these differences only briefly here; for details, you can consult Blois' book on this subject (see Suggested Readings).

Let us examine an instance of what we will call a low-level (or readily formalized) science. Physics is a natural starting point; in any discussion of the hierarchical relationships among the sciences (from the fourth-century BC Greek philosopher Aristotle to the twentieth-century U.S. librarian Melvil Dewey), physics will be placed near the bottom. Physics characteristically has a certain kind of simplicity, or generality. The concepts and descriptions of the objects and processes of physics, however, are necessarily used in all applied fields, including medicine. The laws of physics and the descriptions of certain kinds of physical processes are essential in representing or explaining functions that we regard as medical in nature. We need to know something about molecular physics, for example, to understand why water is such a good solvent; to explain how nutrient molecules are metabolized, we talk about the role of electron-transfer reactions.

Applying a computer (or any formal computation) to a physical problem in a medical context is no different from doing so in a physics laboratory or for an engineering application. The use of computers in various **low-level processes** (such as those of physics or chemistry) is similar and is independent of the application. If we are talking about the solvent properties of water, it makes no difference whether we happen to be working in geology, engineering, or medicine. Such low-level processes of physics are particularly receptive to

mathematical treatment, so using computers for these applications requires only conventional numerical programming.

In biomedicine, however, there are other **higher-level processes** carried out in more complex objects such as organisms (one type of which is patients). Many of the important informational processes are of this kind. When we discuss, describe, or record the properties or behavior of human beings, we are using the descriptions of very high-level objects, the behavior of whom has no counterpart in physics or in engineering. The person using computers to analyze the descriptions of these high-level objects and processes encounters serious difficulties (Blois 1984).

One might object to this line of argument by remarking that, after all, computers are used routinely in commercial applications in which human beings and situations concerning them are involved and that relevant computations are carried out successfully. The explanation is that, in these commercial applications, the descriptions of human beings and their activities have been so highly abstracted that the events or processes have been reduced to low-level objects. In biomedicine, abstractions carried to this degree would be worthless from either a clinical or research perspective.

For example, one instance of a human being in the banking business is the customer, who may deposit, borrow, withdraw, or invest money. To describe commercial activities such as these, we need only a few properties; the customer can remain an abstract entity. In clinical medicine, however, we could not begin to deal with a patient represented with such skimpy abstractions. We must be prepared to analyze most of the complex behaviors that human beings display and to describe patients as completely as possible. We must deal with the rich descriptions occurring at high levels in the hierarchy, and we may be hard pressed to encode and process this information using the tools of mathematics and computer science that work so well at low levels. In light of these remarks, the general enterprise known as **artificial intelligence** (**AI**) can be aptly described as the application of computer science to high-level, real-world problems.

Biomedical informatics thus includes computer applications that range from processing of very low-level descriptions, which are little different from their counterparts in physics, chemistry, or engineering, to processing of extremely high-level ones, which are completely and systematically different. When we study human beings in their entirety (including such aspects as human cognition, self-consciousness, intentionality, and behavior), we must use these high-level descriptions. We will find that they raise complex issues to which conventional logic and mathematics are less readily applicable. In general, the attributes of low-level objects appear sharp, crisp, and unambiguous (e.g., "length," "mass"), whereas those of high-level ones tend to be soft, fuzzy, and inexact (e.g., "unpleasant scent," "good").

Just as we need to develop different methods to describe high-level objects, the inference methods we use with such objects may differ from those we use with low-level ones. In formal logic, we begin with the assumption that a given proposition must be either true or false. This feature is essential because logic is concerned with the preservation of truth value under various formal transformations. It is difficult or impossible, however, to assume that all propositions have truth values when we deal with the many high-level descriptions in medicine or, indeed, in everyday situations. Such questions as "Was Woodrow Wilson a good president?" cannot be answered with a "yes" or "no" (unless we limit the question to specific criteria for determining the goodness of presidents). Many common questions in biomedicine have the same property.

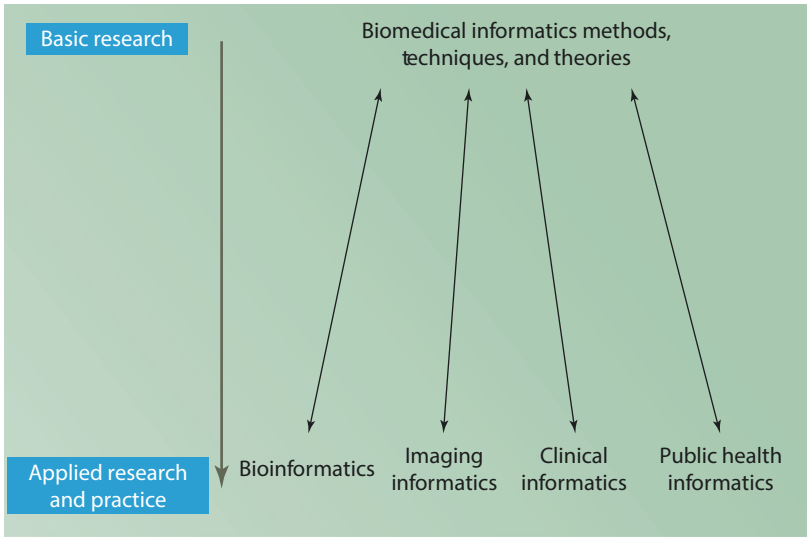


Fig. 1.20 Biomedical informatics as basic science. We view the term biomedical informatics as referring to the basic science discipline in which the development and evaluation of new methods and theories are a primary focus of activity. These core concepts and methods in turn have broad applicability in the health and biomedical sciences. The informatics subfields indicated by the terms across the bottom of this figure are accordingly best viewed as application domains for a common set of concepts and techniques from the field of biomedical informatics. Note that work in biomedical informatics is motivated totally by the application domains that the field is intended to serve (thus the two-headed arrows in the diagram). Therefore the basic research activities in the field generally result from the identification of a problem in the real world of health or biomedicine for which an informatics solution is sought (see text)

Biomedical informatics is perhaps best viewed as a basic biomedical science, with a wide variety of potential areas of application (Fig. 1.20). The analogy with other **basic sciences** is that biomedical informatics uses the results of past experience to understand, structure, and encode objective and subjective biomedical findings and thus to make them suitable for processing. This approach supports the integration of the findings and their analyses. In turn, the selective distribution of newly created knowledge can aid patient care, health planning, and basic biomedical research.

Biomedical informatics is, by its nature, an **experimental science**, characterized by posing questions, designing experiments, performing analyses, and using the information gained to design new experiments. One goal is simply to search for new knowledge, called **basic research**. A second goal is to use this knowledge for practical ends, called **applications (applied) research**. There is a continuity between these two endeavors (see Fig. 1.20). In biomedical informatics, there is an especially tight coupling between the application areas, broad categories of which are indicated at the bottom of Fig. 1.20, and the identification of basic research tasks that characterize the scientific underpinnings of the field. Research, however, has shown that there can be a very long period of time between the development of new concepts and methods in basic research and their eventual application in the biomedical world (Balas and Boren 2000). Furthermore (see Fig. 1.21), many discoveries are discarded along the way, leaving only a small percentage of basic research discoveries that have a practical influence on the health and care of patients.

Work in biomedical informatics (BMI) is inherently motivated by problems encountered in a set of applied domains in biomedicine. The first of these historically has been clinical care (including medicine, nursing, dentistry, and veterinary care), an area of activity that demands patient-oriented informatics applications. We refer to this area as **clinical informatics.**[18] It includes several sub-

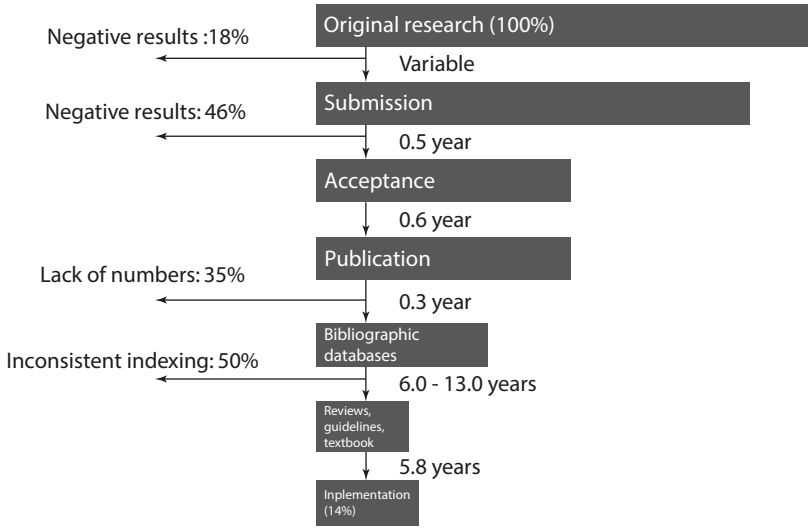


Fig. 1.21 Phases in the transfer of research into clinical practice. A synthesis of studies focusing on various phases of this transfer has indicated that it takes an average of 17 years to make innovation part of routine care (Balas and Boren 2000). Pioneering institutions often apply innovations much sooner, sometimes within a few weeks, but nationwide introduction is usually slow. National utilization rates of specific, well-substantiated procedures also suggest a delay of two decades in reaching the majority of eligible patients. For a well-documented study of such delays and their impact in an important area of clinical medicine, see (Krumholz et al. 1998). (Figure courtesy of Dr. Andrew Balas, used with permission)

topics and areas of specialized expertise, including patient-care foci such as **nursing informatics**, **dental informatics**, and even **veterinary informatics**. Furthermore, the former name of the discipline, **medical informatics**, is now reserved for those applied research and practice topics that focus on disease and the role of physicians. As was previously discussed, the term "medical informatics" is no longer used to refer to the discipline as a whole.

Closely tied to clinical informatics is **public health informatics** (Fig. 1.20), where similar methods are generalized for application to populations of patients rather than to single individuals (see ▶ Chap. 18). Thus clinical informatics and public health informatics share many of the same methods and techniques. The closeness of their relationship was amply demonstrated by the explosion in informatics research and applications that occurred in response to the COVID-19 pandemic.[19] By mid-2020, several articles had appeared to demonstrate the tight relationship between EHRs and public health informatics for management of the outbreak (Reeves et al. 2020).

Two other large areas of application overlap in some ways with clinical informatics and public health informatics. These include **imaging informatics** (and the set of issues developed around both radiology and other image management and image analysis domains such as pathology, dermatology, and molecular visualization—see ▶ Chaps. 10 and 22). Finally, there

18 Clinical informatics was approved in 2013 by the American Board of Medical Specialties as a formal subspecialty of medicine (Finnell and Dixon, 2015), with board certification examinations offered for eligible candidates by the American Board of Preventive Medicine (▶ https://www.theabpm.org/become-certified/subspecialties/clinical-informatics/ (Accessed 6/1/19)). AMIA is formulating a similar certification program, AMIA Health Informatics Certification (AHIC) for non-physicians who are working in the clinical informatics area (▶ https://www.amia.org/ahic, Accessed 1/5/2020).

19 ▶ https://www.amia.org/COVID19 (Accessed 05/03/2020)

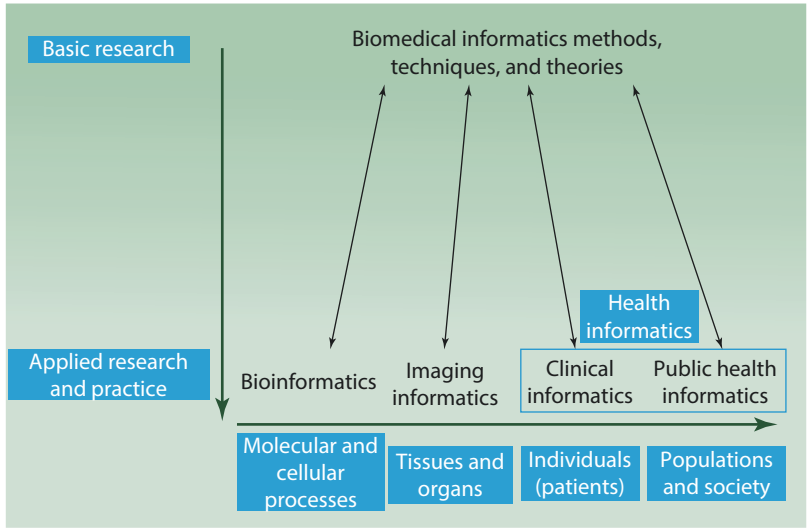


Fig. 1.22 Building on the concepts of Fig. 1.20, this diagram demonstrates the breadth of the biomedical informatics field. The relationship between biomedical informatics as a core scientific discipline and its diverse array of application domains that span biological science, imaging, clinical practice, public health, and others not illustrated (see text). Note that "health informatics" is the term used to refer to applied research and practice in clinical and public health informatics. It is not a synonym for the underlying discipline, which is "biomedical informatics"

is the burgeoning area of **bioinformatics**, which at the molecular and cellular levels is offering challenges that draw on many of the same informatics methods as well (see ▶ Chaps. 9 and 26).

As is shown in Fig. 1.22, there is a spectrum as one moves from left to right across these BMI application domains. In bioinformatics, workers deal with molecular and cellular processes in the application of informatics methods. At the next level, workers focus on tissues and organs, which tend to be the emphasis of imaging informatics work (also called **structural informatics** by some investigators). Progressing to clinical informatics, the focus is on individual patients, and finally to public health, where researchers address problems of populations and of society, including prevention. The core science of biomedical informatics has important contributions to make across that entire spectrum, and many informatics methods are broadly applicable across the full range of domains.

Note from Fig. 1.20 that biomedical informatics and bioinformatics are not synonyms and it is incorrect to refer to the scientific discipline as bioinformatics, which is, rather, an important area of application of BMI methods and concepts. Similarly, the term health informatics, which refers to applied research and practice in clinical and public-health informatics, is also not an appropriate name for the core discipline, since BMI is applicable to basic human biology as well as to health.

We acknowledge that the four major areas of application shown in Fig. 1.19 have "fuzzy" boundaries, and many areas of applied informatics research involve more than one of the categories. For example, **biomolecular imaging** involves both bioinformatics and imaging informatics concepts. Similarly, **personal** or **consumer health informatics** (see ▶ Chap. 11) includes elements of both clinical informatics and public-health informatics. Another important area of BMI research activities is **pharmacogenomics** (see ▶ Chap. 27), which is the effort to infer genetic determinants of human drug response. Such work requires the analysis of linked **genotypic** and **phenotypic** databases, and therefore lies at the intersection of bioinformatics and clinical informatics. Similarly, ▶ Chap. 28 presents the role of informatics in **precision medicine**, which relies heavily on both bioinformatics and clinical informatics concepts and systems.

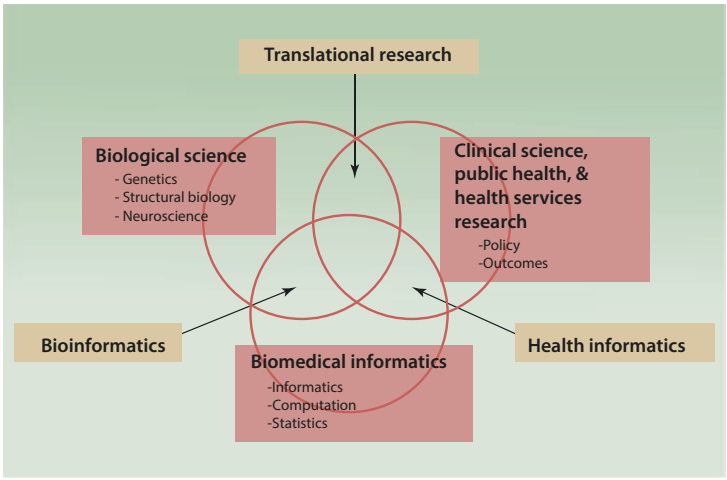


Fig. 1.23 A Venn diagram that depicts the relationships among the three major disciplines: biological research, clinical medicine / public health, and biomedical informatics. *Bioinformatics*, *Health Informatics*, and *Translational Research* lie at the intersections among pairs of these fields as shown. *Precision Medicine,* which relies on *Translational Bioinformatics* and *Clinical Research Informatics*, constitutes the area of common overlap among all three Venn circles. (Adapted with permission from a diagram developed by the Department of Biomedical Informatics at the Vanderbilt Medical Center, Nashville, TN)

Precision medicine is a product of the increasing emphasis on moving both data and concepts from basic science research into clinical science and ultimately into practice. Such efforts are typically characterized as **translational science**—a topic that has attracted major investments by the US National Institutes of Health (NIH) over the past two decades. Informatics scientists are engaged as collaborators in this translational work, which spans all four major categories of application shown in Fig. 1.20, pursuing work in **translational bioinformatics** (► Chap. 26) and **clinical research informatics** (► Chap. 27).[20] Accordingly, informatics was defined as a major component of the **Clinical and Translational Science Awards (CTSA) Program,**[21] support by the National Center for Advancing Translational Sciences (NCATS) at the NIH. AMIA sponsors an annual weeklong conference, known as the Informatics Summit, that presents new research results and applications in these areas.[22] The interactions among bioscience, clinical science, and informatics can be nicely captured by recognizing how informatics fields and translational science relate to one another (Fig. 1.23).

In general, BMI researchers derive their inspiration from one or two, rather than all, of the application areas, identifying fundamental methodologic issues that need to be addressed and testing them in system prototypes or, for more mature methods, in actual systems that are used in clinical or biomedical research settings. One important implication of this viewpoint is that the core discipline is identical, regardless of the area of application that a given individual is motivated to address, although some BMI methods have greater relevance to some domains than to others. This argues for unified BMI educational programs, ones that bring together students with a wide variety of application interests. Elective courses and internships in areas of specific

20 See also the diagram in (Kulikowski et al. 2012), which shows how these two disciplines span all areas of applied biomedical informatics.

21 ► https://ncats.nih.gov/ctsa (Accessed 6/2/2019).

22 ► https://www.amia.org/meetings-and-events (Accessed 6/2/2019)

interest are of course important complements to the core exposures that students should receive (Kulikowski et al. 2012), but, given the need for teamwork and understanding in the field, separating trainees based on the application areas that may interest them would be counterproductive and wasteful.[23]

The scientific contributions of BMI also can be appreciated through their potential for benefiting the education of health professionals (Shortliffe 2010). For example, in the education of medical students, the various cognitive activities of physicians traditionally have tended to be considered separately and in isolation—they have been largely treated as though they are independent and distinct modules of performance. One activity frequently emphasized is formal education regarding medical decision making (see ▶ Chap. 3). The specific content of this area continues to evolve, but the discipline's dependence on formal methods regarding the use of knowledge and information reveal that it is one aspect of biomedical informatics.

A particular topic in the study of medical decision making is **diagnosis**, which is often conceived and taught as though it were a free-standing and independent activity. Medical students may thus be led to view diagnosis as a process that physicians carry out in isolation before choosing therapy for a patient or proceeding to other modular tasks. A number of studies have shown that this model is oversimplified and that such a decomposition of cognitive tasks may be quite misleading (Elstein et al. 1978a; Patel and Groen 1986). Physicians seem to deal with several tasks at the same time. Although a diagnosis may be one of the first things physicians think about when they see a new patient, patient assessment (diagnosis, management, analysis of treatment results, monitoring of disease progression, etc.) is a process that never really terminates. A physician must be flexible and open-minded. It is generally appropriate to alter the original diagnosis if it turns out that treatment based on it is unsuccessful or if new information weakens the evidence supporting the diagnosis or suggests a second and concurrent disorder. ▶ Chapter 4 discusses these issues in greater detail.

When we speak of making a diagnosis, choosing a treatment, managing therapy, making decisions, monitoring a patient, or preventing disease, we are using labels for different aspects of medical care, an entity that has overall unity. The fabric of medical care is a continuum in which these elements are tightly interwoven. Regardless of whether we view computer and information science as a profession, a technology, or a science, there is no doubt about its importance to biomedicine. We can assume computers are here to stay as fundamental tools to be used in clinical practice, biomedical research, and health science education.

1.4.4 Relationship to Computer Science

During its evolution as an academic entity in universities, computer science followed an unsettled course as involved faculty attempted to identify key topics in the field and to find the discipline's organizational place. Many computer science programs were located in departments of electrical engineering, because major concerns of their researchers were computer architecture and design and the development of practical hardware components. At the same time, computer scientists were interested in programming languages and software, undertakings not particularly characteristic of engineering. Furthermore, their work with algorithm design, computability

23 Many current biomedical informatics training programs were designed with this perspective in mind. Students with interests in clinical, imaging, public health, and biologic applications are often trained together and are required to learn something about each of the other application areas, even while specializing in one subarea for their own research. Several such programs were described in a series of articles in the *Journal of Biomedical Informatics* in 2007 (Tarczy-Hornoch et al. 2007) and many more have been added since that time.

theory,[24] and other theoretical topics seemed more related to mathematics.

Biomedical informatics draws from all of these activities—development of hardware, software, and computer science theory. Biomedical computing generally has not had a large enough market to influence the course of major hardware developments; i.e., computers serve general purposes and have not been developed specifically for biomedical applications. Not since the early 1960s (when health-computing experts occasionally talked about and, in a few instances, developed special medical terminals) have people assumed that biomedical applications would use hardware other than that designed for general use.

The question of whether biomedical applications would require specialized programming languages might have been answered affirmatively in the 1970s by anyone examining the MGH Utility Multi-Programming System, known as the MUMPS language (Greenes et al. 1970; Bowie and Barnett 1976), which was specially developed for use in medical applications. For several years, MUMPS was the most widely used language for medical record processing. Under its subsequent name, M, it is still in widespread use and has been used to develop commercial electronic health record systems. New implementations have been developed for each generation of computers. M, however, like any programming language, is not equally useful for all computing tasks. In addition, the software requirements of medicine are better understood and no longer appear to be unique; rather, they are specific to the kind of task. A program for scientific computation looks pretty much the same whether it is designed for chemical engineering or for pharmacokinetic calculations.

How, then, does BMI differ from biomedical computer science? Is the new discipline simply the study of computer science with a "biomedical flavor"? If you return to the definition of biomedical informatics that we provided in ▶ Box 1.1, and then refer to ◘ Fig. 1.20, you will begin to see why biomedical informatics is more than simply the biomedical application of computer science.[25] The issues that it addresses not only have broad relevance to health, medicine, and biology, but the underlying sciences on which BMI professionals draw are inherently interdisciplinary as well (and are not limited to computer science topics). Thus, for example, successful BMI research will often draw on, and contribute to, computer science, but it may also be closely related to the decision sciences (probability theory, decision analysis, or the psychology of human problem solving), cognitive science, information sciences, or the management sciences (◘ Fig. 1.24). Furthermore, a biomedical informatics researcher will be tightly linked to some underlying problem from the real world of health or biomedicine. As ◘ Fig. 1.24 illustrates, for example, a biomedical informatics basic researcher or doctoral student will typically be motivated by one of the application areas, such as those shown at the bottom of ◘ Fig. 1.22, but a dissertation worthy of a PhD in the field will usually be identified by a generalizable scientific result that also contributes to one of the component disciplines (◘ Fig. 1.20) and on which other scientists can build in the future.

24 Many interesting problems cannot be computed in a reasonable time and require heuristics. Computability theory is the foundation for assessing the feasibility and cost of computation to provide the complete and correct results to a formally stated problem.

25 In fact, the multidisciplinary nature of biomedical informatics has led the informatics term to be borrowed in other disciplines, including computer science organizations, even though the English name for the field was first adopted in the biomedical context. Today we even have generic full departments of informatics in the US (e.g., see ▶ https://informatics.njit.edu, Accessed 11/28/2020) and in other parts of the world as well (e.g., ▶ http://www.sussex.ac.uk/informatics/. Accessed 1/5/2020). In the US, there are full schools with informatics in their title (e.g., ▶ https://luddy.indiana.edu/index.html. Accessed 1/5/2020) and even a School of Biomedical Informatics (▶ https://sbmi.uth.edu/. Accessed 1/2/2020).

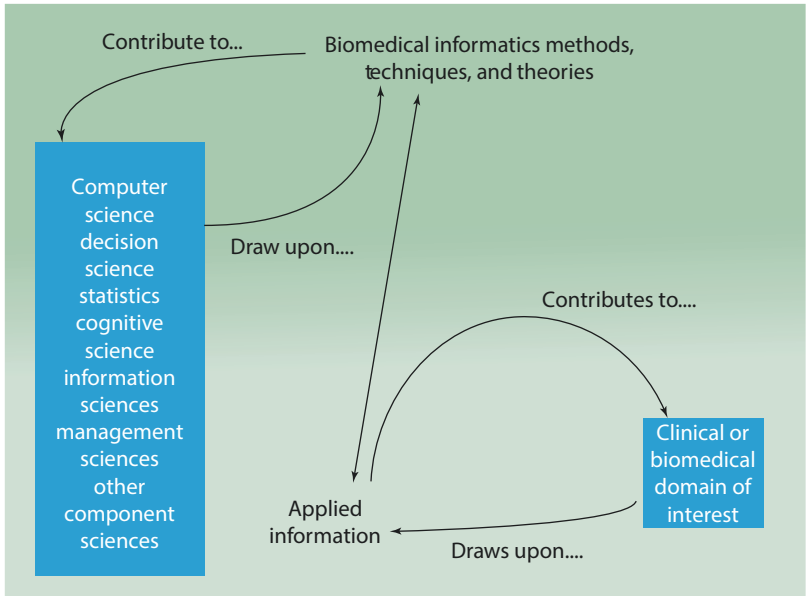


Fig. 1.24 Component sciences in biomedical informatics. An informatics application area is motivated by the needs of its associated biomedical domain, to which it attempts to contribute solutions to problems. Thus any applied informatics work draws upon a biomedical domain for its inspiration, and in turn often leads to the delineation of basic research challenges in biomedical informatics that must be tackled if the applied biomedical domain is ultimately to benefit. At the methodologic level, biomedical informatics draws on, and contributes to, a wide variety of component disciplines, of which computer science is only one. As Figs. 1.20 and 1.22 show explicitly, biomedical informatics is inherently multidisciplinary, both in its areas of application and in the component sciences on which it draws

1.4.5 Relationship to Biomedical Engineering

BMI is a relatively young discipline, whereas biomedical engineering (BME) is older and well-established. Many engineering and medical schools have formal academic programs in BME, often with departmental status and full-time faculty. Only in the last two or three decades has this begun to be true of biomedical informatics academic units. How does biomedical informatics relate to biomedical engineering, especially in an era when engineering and computer science are increasingly intertwined?

Biomedical engineering departments emerged in the late 1960s, when technology began to play an increasingly prominent role in medical practice.[26] The emphasis in such departments has tended to be research on, and development of, instrumentation (e.g., as discussed in ▶ Chaps. 21 and 22, advanced monitoring systems, specialized transducers for clinical or laboratory use, and imaging methods and enhancement techniques for use in radiology), with an orientation toward the

26 By the late 1960s the first BME departments were formed in the US at the University of Virginia, Case Western Reserve University, Johns Hopkins University, and Duke University (see ▶ https://navigate.aimbe.org/why-bioengineering/history/, Accessed 6/2/2019). Duke's undergraduate degree program in BMI was the first to be accredited by the Engineering Council for Professional Development (September 1972).

development of medical devices, **prostheses**, and specialized research tools. There is also a major emphasis on tissue engineering and related wet-bench research efforts. In recent years, computing techniques have been used both in the design and construction of medical devices and in the medical devices themselves. For example, the "smart" devices increasingly found in most medical specialties are all dependent on computational technology. Intensive care monitors that generate blood pressure records while calculating mean values and hourly summaries are examples of such "intelligent" devices.

The overlap between biomedical engineering and BMI suggests that it would be unwise for us to draw compulsively strict boundaries between the two fields. There are ample opportunities for interaction, and there are chapters in this book that clearly overlap with biomedical engineering topics—e.g., ▶ Chap. 21 on patient-monitoring systems and ▶ Chap. 22 on radiology systems. Even where they meet, however, the fields have differences in emphasis that can help you to understand their different evolutionary histories. In biomedical engineering, the emphasis is on medical devices and underlying methods; in BMI, the emphasis is on biomedical information and knowledge and on their management with the use of computers. In both fields, the computer is secondary, although both use computing technology. The emphasis in this book is on the informatics end of the spectrum of biomedical computer science, so we shall not spend much time examining biomedical engineering topics.

1.5 Integrating Biomedical Informatics and Clinical Practice

It should be clear from the material in this chapter that biomedical informatics is a remarkably broad and complex topic. We have argued that information management is intrinsic to both life-science research and clinical practice and that, in biomedical settings over a half century, the use of computers to aid in information management has grown from a futuristic notion to an everyday occurrence. In fact, the EHR and other information technology tools may now be the only kind of equipment that is used by every single health care professional, regardless of specialty or professional title. In this chapter and throughout the book, we emphasize the myriad ways in which computers are used in biomedicine to ease the burdens of information management and the means by which new technology is changing the delivery of health care. The degree to which such changes are positively realized, and their rate of occurrence, are being determined in part by external forces that influence the costs of developing and implementing biomedical applications and the ability of scientists, clinicians, patients, and the health care system to accrue the potential benefits.

We can summarize several global forces that are affecting biomedical computing and that will continue to influence the extent to which computers are assimilated into clinical practice: (1) new developments in communications plus computer hardware and software; (2) a further increase in the number of individuals who have been trained in both medicine, or another health profession, and in BMI; and (3) ongoing changes in health care financing designed to control the rate of growth of health-related expenditures.

We touched on the first of these factors in ▶ Sect. 1.4.2, when we described the historical development of biomedical computing and the trend from mainframe computers, to microcomputers and PCs, and to the mobile devices of today. The future view outlined in ▶ Sect. 1.1 similarly builds on the influence that the Internet has provided throughout society during the last decade. Hardware improvements have made powerful computers inexpensive and thus available to hospitals, to departments within hospitals, and even to individual physicians. The broad selection of computers of all sizes, prices, and capabilities makes computer applications both attractive and accessible. Technological advances in

information storage devices,[27] including the movement of files to the "cloud", are facilitating the inexpensive storage of large amounts of data, thus improving the feasibility of data-intensive applications, such as drawing inferences from human genome datasets (see ▶ Chaps. 9, 26, and 28) and the all-digital radiology department (▶ Chap. 22). Standardization of hardware and advances in network technology are making it easier to share data and to integrate related information-management functions within a hospital or other health care organization, although inadequacies in standards for encoding and sharing data continue to be challenging (▶ Chaps. 7, 14, 15, and 16).

The second factor is the frustratingly slow increase in the number of professionals who are being trained to understand the biomedical issues as well as the technical and engineering ones. Computer scientists who understand biomedicine are better able to design systems responsive to actual needs and sensitive to workflow and the clinical culture. Health professionals who receive formal training in BMI are likely to build systems using well-established techniques while avoiding the past mistakes of other developers. As more professionals are trained in the special aspects of both fields, and as the programs they develop are introduced, health care professionals are more likely to have useful and usable systems available when they turn to the computer for help with information management tasks.

The third factor affecting the integration of computing technologies into health care settings is our evolving health care system and the increasing pressure to control medical spending. The escalating tendency to apply technology to all patient-care tasks is a frequently cited phenomenon in modern medical practice. Mere physical findings no longer are considered adequate for making diagnoses and planning treatments. In fact, medical students who are taught by more experienced physicians to find subtle diagnostic signs by examining various parts of the body nonetheless often choose to bypass or deemphasize physical examinations in favor of ordering one test after another. Sometimes, they do so without paying sufficient attention to the ensuing cost. Some new technologies replace less expensive, but technologically inferior, tests. In such cases, the use of the more expensive approach is generally justified. Occasionally, computer-related technologies have allowed us to perform tasks that previously were not possible. For example, the scans produced with computed tomography or magnetic resonance imaging (see ▶ Chaps. 10 and 22) have allowed physicians to visualize cross-sectional slices of the body, and medical instruments in intensive care units perform continuous monitoring of patients' body functions that previously could be checked only episodically (see ▶ Chap. 21).

The development of expensive new technologies, and the belief that more technology is better, have helped to fuel rapidly escalating health care costs. In the 1970s and 1980s, such rising costs led to the introduction of managed care and **capitation**—changes in financing and delivery that were designed to curb spending. Today we are seeing a trend toward **value-based reimbursement**, which is predicated on the notion that payment for care of patients should be based on the demonstrated value received (as defined by high quality at low cost) rather than simply the existence of an encounter or procedure. Integrated computer systems can provide the means to capture data to help assess such value, while they also support detailed cost accounting, the analysis of the relationship of costs of care to the benefits of that care, evaluation of the quality of care provided, and identification of areas of inefficiency. Systems that improve the quality of care while reducing the cost of providing that care clearly will be favored. The effect of cost containment pressures on technologies that increase the cost of care while improving the quality are less clear. Medical technologies, including computers, will be

27 Technological progress in this area is occurring at a dizzying rate. Consider, for example, the announcement that scientists are advancing the notion of using DNA for data storage and can store as much as 704 terabytes of information in a gram of DNA. ▶ http://www.engadget.com/2012/08/19/harvard-stores-704tb-in-a-gram-of-dna; ▶ https://homes.cs.washington.edu/~bornholt/dnastorage-asplos16/ (Accessed 5/30/19).

embraced only if they improve the delivery of clinical care while either reducing costs or providing benefits that clearly exceed their costs.

Designers of medical systems must address satisfactorily many logistical and engineering questions before innovative solutions are integrated optimally into medical practice. For example, are the machines conveniently located? Should mobile devices further replace tethered workstations? Can users complete their tasks without excessive delays? Is the system reliable enough to avoid loss of data? Can users interact easily and intuitively with the computer? Does it facilitate rather than disrupt workflow? Are patient data secure and appropriately protected from prying eyes? In addition, cost-control pressures produce a growing reluctance to embrace expensive technologies that add to the high cost of health care. The net effect of these opposing trends is in large part determining the degree to which specific systems are embraced and effectively implemented in the health care environment.

In summary, rapid advances in communications, computer hardware, and software, coupled with an increasing computer literacy of health care professionals and researchers, favor the implementation of effective computer applications in clinical practice, public health, and life sciences research. Furthermore, in the increasingly competitive health care industry, providers have a greater need for the information management capabilities supplied by computer systems. The challenge is to demonstrate in persuasive and rigorous ways the financial and clinical advantages of these systems (see ► Chap. 13).

Suggested Readings

Blois, M. S. (1984b). Information and medicine: The nature of medical descriptions. Berkeley: University of California Press. In this classic volume, the author analyzes the structure of medical knowledge in terms of a hierarchical model of information. He explores the ideas of high- and low-level sciences and suggests that the nature of medical descriptions accounts for difficulties in applying computing technology to medicine. A brief summary of key elements in this book is included as Box 1.2 in this chapter.

Coiera, E. (2015). *Guide to health informatics* (3rd ed.). Boca Raton, FL: CRC Press. This introductory text is a readable summary of clinical and public health informatics, aimed at making the domain accessible and understandable to the non-specialist.

Collen, M. F., & Ball, M. J. (Eds.). (2015). *A history of medical informatics in the United States* (2nd ed.). London: Springer. This comprehensive book traces the history of the field of medical informatics, and identifies the origins of the discipline's name (which first appeared in the English-language literature in 1974). The original (1995) edition was being updated by Dr. Collen when he passed away shortly after his 100th birthday. Dr. Ball organized an effort to complete the 2nd edition, enlisting participation by many leaders in the field.

Elstein, A. S., Shulman, L. S., & Sprafka, S. A. (1978b). *Medical problem solving: An analysis of clinical reasoning*. Cambridge, MA: Harvard University Press. This classic collection of papers describes detailed studies that have illuminated several aspects of the ways in which expert and novice physicians solve medical problems. The seminal work described remains highly relevant to today's work on problem solving and clinical decision support systems.

Friedman, C. P., Altman, R. B., Kohane, I. S., McCormick, K. A., Miller, P. L., Ozbolt, J. G., Shortliffe, E. H., Stormo, G. D., Szczepaniak, M. C., Tuck, D., & Williamson, J. (2004). Training the next generation of informaticians: The impact of BISTI and bioinformatics. *Journal of American Medical Informatics Association, 11*, 167–172. This important analysis addresses the changing nature of biomedical informatics due to the revolution in bioinformatics and computational biology. Implications for training, as well as organization of academic groups and curriculum development, are discussed.

Hoyt, R. E., & Hersh. W. R. (2018). *Health informatics: Practical guide* (7th ed). Raleigh: Lulu.com. This introductory volume provides a broad view of informatics and is aimed especially at health professionals in management roles or IT professionals who are entering the clinical world.

Institute of Medicine[25]. (1991 [revised 1997]). *The computer-based patient record: An essential*

technology for health care. Washington, DC: National Academy Press. National Research Council (1997). For The Record: Protecting Electronic Health Information. Washington, DC: National Academy Press. National Research Council (2000). Networking Health: Prescriptions for the Internet. Washington, DC: National Academy Press. This set of three reports from branches of the US National Academies of Science has had a major influence on health information technology education and policy over the last 25 years.

Institute of Medicine25. (2000). To err is human: Building a safer health system. Washington, DC: National Academy Press. Institute of Medicine (2001). Crossing the Quality Chasm: A New Health Systems for the 21st Century. Washington, DC: National Academy Press. Institute of Medicine (2004). Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academy Press. This series of three reports from the Institute of Medicine has outlined the crucial link between heightened use of information technology and the enhancement of quality and reduction in errors in clinical practice. Major programs in patient safety have resulted from these reports, and they have provided motivation for a heightened interest in health care information technology among policy makers, provider organizations, and even patients.

Kalet, I. J. (2013). *Principles of biomedical informatics* (2nd ed.). New York: Academic. This volume provides a technical introduction to the core methods in BMI, dealing with storage, retrieval, display, and use of biomedical data for biological problem solving and medical decision making. Application examples are drawn from bioinformatics, clinical informatics, and public health informatics.

National Academy of Medicine. (2018). *Procuring interoperability: Achieving high-quality, connected, and person-centered care*. Washington, DC: National Academy Press. National Academy of Medicine (2019). Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril. Washington, DC: National Academy Press. This series of two reports from the National Academy of Medicine outlines emerging issues in biomedical informatics: interoperability (which is discussed in greater detail in Chapter 8), and artificial intelligence (which is discussed in in many chapters throughout this volume).

National Academy of Medicine. (2019). *Taking action against clinician burnout: A systems approach to professional well-being*. Washington, DC: National Academy Press. This consensus study from the National Academy of Medicine discusses the problem of clinician burnout in the United States, including areas where health care information technology may contribute or reduce these problems.

Shortliffe, E. (1993b). Doctors, patients, and computers: Will information technology dehumanize health care delivery? *Proceedings of the American Philosophical Society, 137*(3), 390–398 In this paper, the author examines the frequently expressed concern that the introduction of computing technology into health care settings will disrupt the development of rapport between clinicians and patients and thereby dehumanize the therapeutic process. He argues, rather, that computers may eventually have precisely the opposite effect on the relationship between clinicians and their patients.

Questions for Discussion

1. How do you interpret the phrase "logical behavior"? Do computers behave logically? Do people behave logically? Explain your answers.
2. What do you think it means to say that a computer program is "effective"? Make a list of a dozen computer applications with which you are familiar. List the applications in decreasing order of effectiveness, as you have explained this concept. Then, for each application, indicate your estimate of how well human beings perform the same tasks (this will require that you determine what it means for a human being to be effective). Do you discern any pattern? If so, how do you interpret it?
3. Discuss three society-wide factors that will determine the extent to which computers are assimilated into clinical practice.
4. Reread the future vision presented in ▶ Sect. 1.1. Describe the characteristics of an integrated environment for

managing clinical information. Discuss two ways (either positive or negative) in which such a system could change clinical practice.

5. Do you believe that improving the technical quality of health care entails the risk of dehumanization? If so, is it worth the risk? Explain your reasoning.
6. Consider ◘ Fig. 1.20, which shows that bioinformatics, imaging informatics, clinical informatics, and public health informatics are all application domains of the biomedical informatics discipline because they share the same core methods and theories:
   (a) Briefly describe two examples of core biomedical informatics methods or theories that can be applied both to bioinformatics and clinical informatics.
   (b) Imagine that you describe ◘ Fig. 1.20 to a mathematics faculty member, who responds that "in that case, I'd also argue that statistics, computer science, and physics are all application domains of math because they share the same core mathematical methods and theories." In your opinion, is this a legitimate argument? In what ways is this situation similar to, and different from, the case of biomedical informatics?
   (c) Why is biomedical informatics *not* simply computer science applied to biomedicine, or to the practice of medicine, using computers?
   (d) How would you describe the relevance of psychology and cognitive science to the field of biomedical informatics? (Hint: See ◘ Fig. 1.24)
7. In 2000, a major report by the Institute of Medicine[28] entitled "To Err is Human: Building a Safer Health System" (see Suggested Readings) stated that up to 98,000 patient deaths were being caused by preventable medical errors in American hospitals each year.
   (a) It has been suggested that effective electronic health record (EHR) systems should mitigate this problem. What are three specific ways in which they could be reducing the number of adverse events in hospitals?
   (b) Are there ways in which computer-based systems could *increase* the incidence of medical errors? Explain.
   (c) Describe a practical experiment that could be used to examine the impact of an EHR system on patient safety. In other words, propose a study design that would address whether the computer-based system increases or decreases the incidence of preventable adverse events in hospitals – and by how much.
   (d) What are the limitations of the experimental design you proposed in (c)?
8. It has been argued that the ability to capture "nuance" in the description of what a clinician has seen when examining or interviewing a patient may not be as crucial as some people think. The desire to be able to express one's thoughts in an unfettered way (free text) is often used to argue against the use of structured data-entry methods using a controlled vocabulary and picking descriptors from lists when recording information in an EHR.
   (a) What is your own view of this argument? Do you believe that it is important to the quality and/or efficiency of care for clinicians to be able to record their observations, at least part of the time, using free text/natural language?
   (b) Many clinicians have been unwilling to use an EHR system requiring structured data entry

28 The Institute of Medicine (IOM), part of the former National Academy of Sciences (NAS) was reorganized in 2015 to become the National Academy of Medicine (NAM). The NAS is now known as the National Academies of Science, Engineering, and Medicine (NASEM).

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because of the increased time required for documentation at the point of care and constraints on what can be expressed. What are two strategies that could be used to address this problem (other than "designing a better user interface for the system")?

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