Biomedical Informatics: The Science and the Pragmatics

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

- Why is information and knowledge management a central issue in biomedical research and clinical practice?
- What are integrated information management environments, and how might we expect them to affect the practice of medicine, the promotion of health, and biomedical research in coming years?
- 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*?
- 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 way patient care is financed 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

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Dr. Blois coauthored the 1990 (1st edition) version of this chapter shortly before his death in 1988, a year prior to the completion of the full manuscript. Although the chapter has evolved in subsequent editions, we continue to name Dr. Blois as a coauthor because of his seminal contributions to the field as well as to this chapter. Section 1.5 was written by him and, since it is timeless, remains unchanged in each edition of the book. To learn more about this important early leader in the field of informatics, see his classic volume (Blois 1984) and a tribute to him at http://www.amia.org/about-amia/leadership/acmi-fellow/marsden-s-blois-md-facmi (Accessed 3/3/2013).

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on clinical practice. More than six 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" and "big data" fill our newspapers and popular magazines, and today's children show an uncanny ability to make use of computers (including their increasingly mobile versions) as routine tools for study and entertainment. Similarly, clinical workstations have been available on hospital wards and in outpatient offices for years, and are being gradually supplanted by mobile devices with wireless connectivity. Yet many observers cite the health care system as being slow to understand information technology, slow to exploit it for its unique practical and strategic functionalities, slow to incorporate it effectively into the work environment, and slow to understand its strategic importance and its resulting need for investment and commitment. Nonetheless, the enormous technological advances of the last three decades—personal computers and graphical interfaces, new methods for human-computer interaction, innovations in mass storage of data (both locally and in the "cloud"), mobile devices, personal health monitoring devices and tools, the Internet, wireless communications, social media, and more—have all combined to make the routine use of computers by all health workers and biomedical scientists inevitable. A new world is already with us, but its greatest influence is yet to come. This book will teach you both about our present resources and accomplishments and about what you can expect in the years ahead.

When one considers the penetration of computers and communication into our daily lives today, it is remarkable that the first personal computers were introduced as recently as the late 1970s; local area networking has been available only since ~1980; the World Wide Web dates only to the early 1990s; and smart phones, social networking, 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. Yet many observers now believe that the two topics are inextricably related and 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 shall discuss in detail in Chap. 12, no applied clinical computing topic is gaining more attention currently than is the issue of electronic health records (EHRs). Health care organizations have recognized that they do not have systems in place that effectively allow them to answer questions that are crucially important for strategic planning, for their better understanding of how they compare with other provider groups in their local or regional competitive environment, and for reporting to regulatory agencies. In the past, administrative and financial data were the major elements required for such planning, but comprehensive clinical data are now also important for institutional self-analysis and strategic planning. Furthermore, the inefficiencies and frustrations associated with the use of paper-based medical records are now 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: The Future Is Now

Encouraged by **health information technology** (**HIT**) vendors (and by the US government, as is discussed later), most health care institutions are seeking to develop integrated computer-based information-management environments. These are single-entry points into a clinical world in which computational tools assist not only with patient-care matters (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 administrative and financial topics (e.g., tracking of patients within the hospital, managing materials and inventory, supporting personnel functions, and managing the payroll), research (e.g., analyzing the outcomes associated with treatments and procedures, performing quality assurance, supporting clinical trials, and implementing various treatment protocols), scholarly information (e.g., accessing digital libraries, supporting bibliographic search, and providing access to drug information databases), and even 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 Moving Beyond the Paper Record

The traditional paper-based medical record is now recognized as 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 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 has become clear (see Chaps. 12 and 14).

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?"

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 that can be moved around as needed within the institution. For example, on the input side (Fig. 1.1), the EHR requires the integration of processes for data capture and for merging information from diverse sources. The contents of the paper record have traditionally been organized chronologically—often a severe limitation when a clinician seeks to find a specific piece of information that could occur almost anywhere within the chart. To be useful, the record system must 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 is best viewed not as an object, or a product, but rather as a set of processes that an organization must put into place, supported by technology (Fig. 1.3). Implementing electronic records is inherently a systems-integration task; it is not possible to buy a medical record system for a complex organization as an off-the-shelf product. 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 computers, and of EHRs, is most easily achieved when the computing environment offers a critical mass of functionality

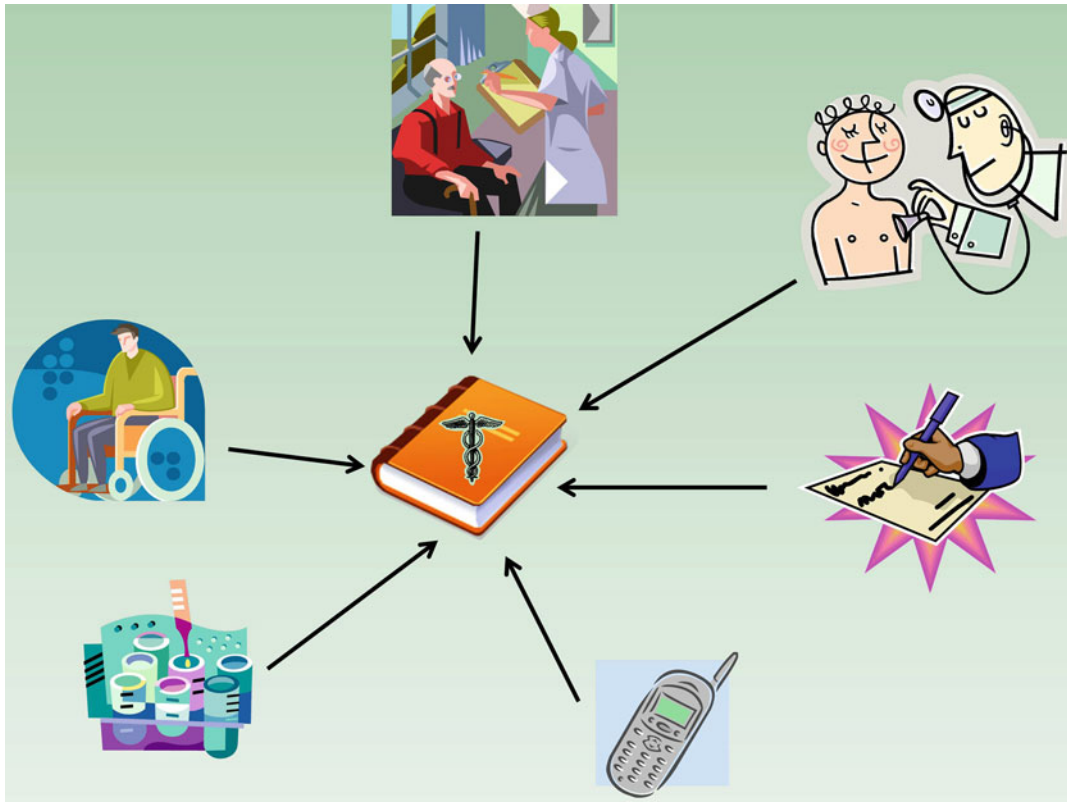

Fig. 1.1 Inputs to the clinical-care record. The traditional paper record is created by a variety of organizational processes that capture varying types of information (notes regarding direct encounters between health professionals and patients, laboratory or radiologic results, reports of telephone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

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 12 and in the now classic Institute of Medicine's report on **computer-based patient records** (**CPRs**) (Dick and Steen 1991 (Revised 1997)). 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 acquiring the data needed for clinical 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. 26). Most obviously, it helps to eliminate the manual task of extracting data from charts or filling out specialized datasheets. 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

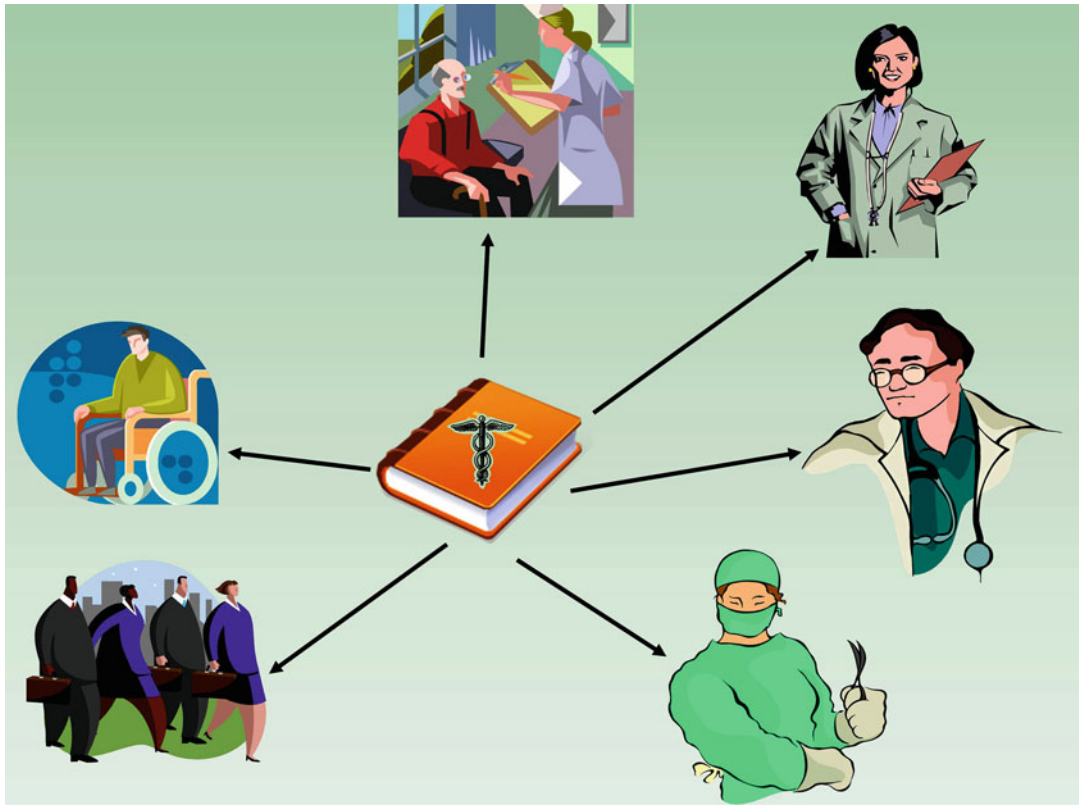

Fig. 1.2 Outputs from the clinical-care record. Once information is collected in the traditional paper chart, it may be provided to a wide variety of potential users of the information that it contains. These users include health professionals and the patients themselves but also a wide variety of "secondary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

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.

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. 22), 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.

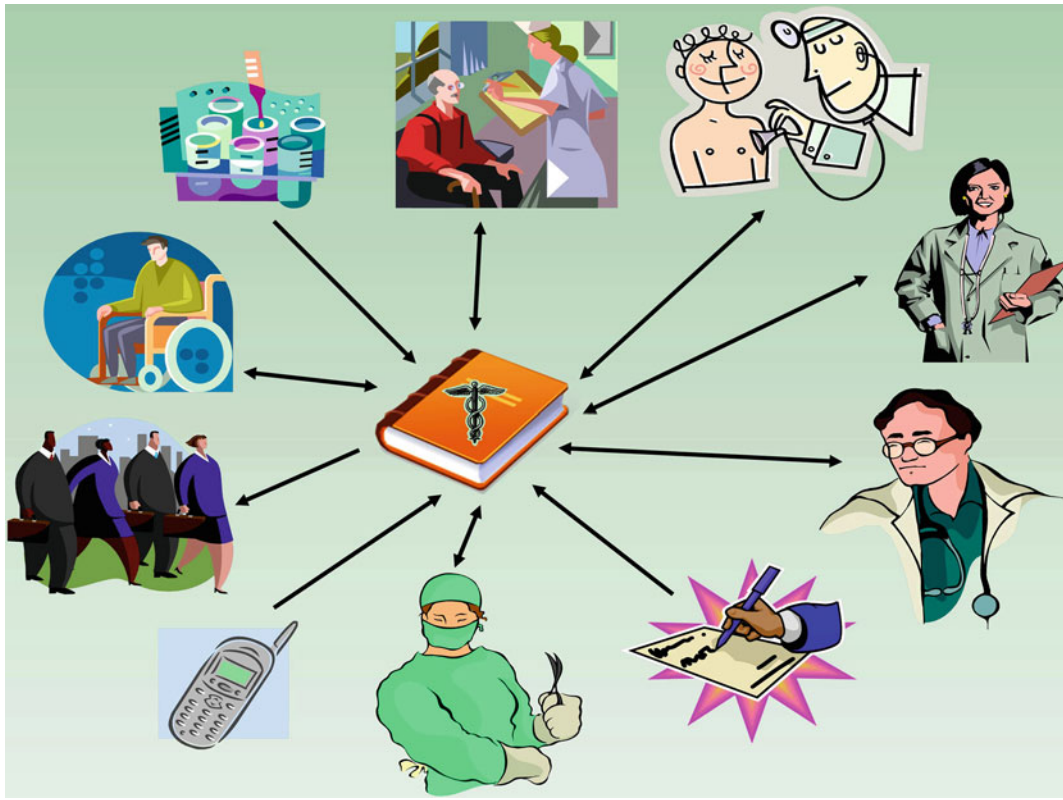

Fig. 1.3 Complex processes demanded of the record. As shown in Figs 1.1 and 1.2, the clinical chart is the incarnation of a complex set of organizational processes, which both gather information to be shared and then distribute that information to those who have valid reasons for accessing it. Paper-based documents are severely limited in meeting the diverse requirements for data collection and information access that are implied by this diagram

Many organizations are accordingly attempting to integrate decision-support tools with their EHR systems, and there are highly visible efforts underway to provide computer-based diagnostic decision support to practitioners.[1]

There are at least four major issues that have consistently constrained our efforts to build effective EHRs: (1) the need for standards in the area of clinical terminology; (2) concerns regarding data privacy, confidentiality, and security; (3) challenges in data entry by physicians; and (4) difficulties associated with the integration of record systems with other information resources in the health care setting. The first of these issues is discussed in detail in Chap. 7, and privacy is one of the central topics in Chap. 10. Issues of direct data entry by clinicians are discussed in Chaps. 2 and 12 and throughout many other chapters as well. Chapter 13 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).

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

[1] http://www.forbes.com/sites/bruceupbin/2013/02/08/ibms-watson-gets-its-first-piece-of-business-in-healthcare/. (Accessed 4/21/13/).

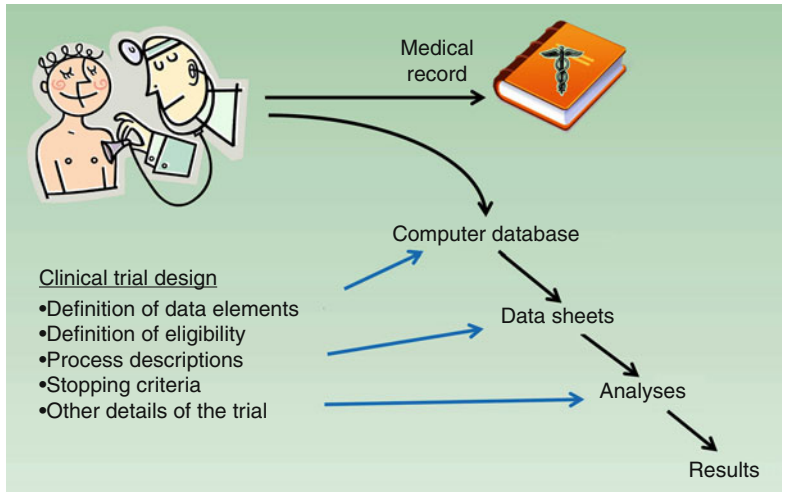

Fig. 1.4 Traditional data collection for clinical trials. Although modern clinical trials routinely use computer systems for data storage and analysis, the gathering of research data is still often a manual task. Physicians who care for patients enrolled in trials, or their research assistants, have traditionally been asked to fill out special datasheets for later transcription into computer databases. Alternatively, data managers have been hired to abstract the relevant data from the chart. The trials are generally designed to define data elements that are required and the methods for analysis, but it is common for the process of collecting those data in a structured format to be left to manual processes at the point of patient care

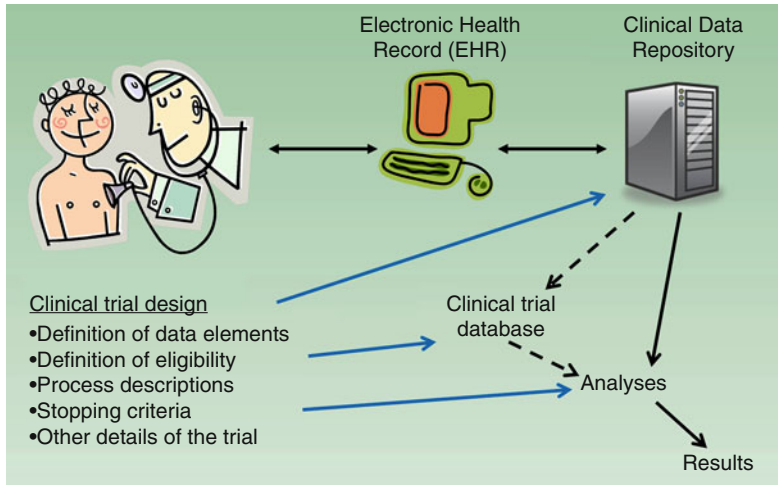

Fig. 1.5 Role of electronic health records (EHRs) in supporting clinical trials. With the introduction of EHR systems, the collection of much of the research data for clinical trials can become a by-product of the routine care of the patients. Research data may be analyzed directly from the clinical 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

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" on the Web, use of color, 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 until recently dominated most of our health care environments. Note 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.

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, accessible through mobile wireless devices, and has provided the invisible but mandatory infrastructure