Health Informatics

(formerly Computers in Health Care)

Kathryn J. Hannah Marion J. Ball
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Health Informatics Series

(formerly Computers in Health Care)

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Biomedical Informatics

Computer Applications in Health Care and Biomedicine

Third Edition

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Dedicated to Donald A.B. Lindberg, whose innovative research and visionary leadership of the National Library of Medicine have transformed both the field of biomedical informatics and the institution to which he has dedicated much of his professional life.

Series Preface

This series is directed to healthcare professionals who are leading the transformation of health care by using information and knowledge. Launched in 1988 as Computers in Health Care, the series offers a broad range of titles: some addressed to specific professions such as nursing, medicine, and health administration; others to special areas of practice such as trauma and radiology. Still other books in the series focus on interdisciplinary issues, such as the computer-based patient record, electronic health records, and networked healthcare systems.

Renamed Health Informatics in 1998 to reflect the rapid evolution in the discipline, the series will continue to add titles that contribute to the evolution of the field. In the series, eminent experts, serving as editors or authors, offer their accounts of innovations in health informatics. Increasingly, these accounts go beyond hardware and software to address the role of information in influencing the transformation of healthcare delivery systems around the world. The series also will increasingly focus on "peopleware" and organizational, behavioral, and societal changes that accompany the diffusion of information technology in health services environments.

These changes will shape health services in the new millennium. By making full and creative use of the technology to tame data and to transform information, health informatics will foster the development of the knowledge age in health care. As coeditors, we pledge to support our professional colleagues and the series readers as they share advances in the emerging and exciting field of health informatics.

Kathryn J. Hannah
Marion J. Ball

Preface to the Third Edition

Just as banks cannot practice modern banking without financial software, and airlines cannot manage modern travel planning without shared databanks of flight schedules and reservations, it has become impossible to practice modern medicine, or to conduct modern biological research, without information technologies. Life scientists are generating data at a rate that defies traditional paper-and-pencil methods for information management and data analysis. Health professionals also recognize that a large percentage of their activities relates to information management—for example, obtaining and recording information about patients, consulting colleagues, reading the scientific literature, planning diagnostic procedures, devising strategies for patient care, interpreting results of laboratory and radiologic studies, or conducting case-based and population-based research. It is complexity and uncertainty, plus society's overriding concern for patient well-being, and the resulting need for optimal decision making, that set medicine apart from many other information-intensive fields. Our desire to provide the best possible health and health care for our society gives a special significance to the effective organization and management of the huge bodies of data with which health professionals and biomedical researchers must deal. It also suggests the need for specialized approaches and for skilled scientists who are knowledgeable about biology, clinical medicine, and information technologies.

Information Management in Biomedicine

Although the application of computers to biomedicine is recent, the clinical and research influence of biomedical-computing systems is already remarkably broad. Clinical information systems, which provide communication and information-management functions, are now installed in essentially all healthcare institutions. Physicians can search entire drug indexes in a few seconds, using the information provided by a computer program to anticipate harmful side effects or drug interactions. Electrocardiograms (ECGs) are typically analyzed initially by computer programs, and similar techniques are being applied for interpretation of pulmonary-function tests and a variety of laboratory and radiologic abnormalities. Devices with embedded microprocessors routinely monitor patients and provide warnings in critical-care settings, such as the intensive-care unit (ICU) or the operating room. Both biomedical researchers and clinicians regularly use computer programs to search the medical literature, and modern clinical research would be severely hampered without computer-based data-storage techniques and statistical analysis systems. Advanced decision-support tools also are emerging from research laboratories, are being integrated with patient-care systems, and are beginning to have a profound effect on the way medicine is practiced.

Despite this growing use of computers in healthcare settings and biomedical research, and a resulting expansion of interest in learning more about biomedical computing, many life scientists, health-science students, and professionals have found it difficult to obtain a comprehensive and rigorous, but nontechnical, overview of the field. Both practitioners and basic scientists are recognizing that thorough preparation for their professional futures requires that they gain an understanding of the state of the art in biomedical computing, of the current and future capabilities *and* limitations of the technology, and of the way in which such developments fit within the scientific, social, and financial context of biomedicine. In turn, the future of the biomedical computing field will be largely determined by how well health professionals and biomedical scientists are prepared to guide the discipline's development. This book is intended to meet this growing need for well-equipped professionals. The first edition appeared in 1990 (published by Addison-Wesley) and was used extensively in courses on medical informatics throughout the world. It was updated with a second edition (published by Springer) in 2000, responding to the remarkable changes that occurred during the 1990s, most notably the introduction of the World Wide Web and its impact on adoption and acceptance of the Internet. Like the first two editions, this new version provides a conceptual framework for learning about computer applications in medical care and biology, for critiquing existing systems, and for anticipating future directions that the field may take. In many respects, this new edition is very different from its predecessors, however. Most important, it reflects the remarkable changes in computing and communications that continue to occur, most notably in communications, networking, and health information technology policy and the exploding interest in the role that information technology must play in systems integration and the melding of genomics with innovations in clinical practice and treatment. In fact, the name of the book has been changed from *Medical Informatics* to *Biomedical Informatics,* reflecting (as is discussed in Chapter 1) both the increasing breadth of the basic discipline and the evolving new name for academic units, societies, research programs, and publications in the field. In addition, new chapters have been introduced, while others have been revamped. We have introduced new chapters on cognitive science, natural language processing, imaging informatics, consumer health informatics, and public health informatics. The previous chapters on bioinformatics and imaging systems have also undergone major revisions. All other chapters have been significantly rewritten and updated as well. Those readers who are familiar with the first two editions will find that the organization and philosophy are unchanged, but the content is either new or extensively updated.*

This book differs from other introductions to the field in its broad coverage and in its emphasis on the field's conceptual underpinnings. Our book presumes no health- or computer-science background, but it does assume that readers are interested in a comprehensive summary of the field that stresses the underlying concepts, and it introduces technical details only to the extent that they are necessary to meet the principal goal. It thus differs from an impressive early text in the field (Ledley, 1965) that emphasized

* As with the first two editions, this book has tended to draw both its examples and its contributors from North America. There is excellent work in other parts of the world as well, although variations in healthcare systems, and especially financing, do tend to change the way in which systems evolve from one country to the next. The basic concepts are identical, however, so the book is intended to be useful in educational programs worldwide.

technical details but did not dwell on the broader social and clinical context in which biomedical computing systems are developed and implemented.

Overview and Guide to Use of This Book

This book is written as a text so that it can be used in formal courses, but we have adopted a broad view of the population for whom it is intended. Thus, it may be used not only by students of medicine and of the other health professions, but also as an introductory text by future biomedical computing professionals, as well as for self-study and for reference by practitioners. The book is probably too detailed for use in a 2- or 3-day continuing-education course, although it could be introduced as a reference for further independent study.

Our principal goal in writing this text is to teach *concepts* in biomedical informatics—the study of biomedical information and its use in decision making—and to illustrate them in the context of descriptions of representative systems that are in use today or that taught us lessons in the past. As you will see, biomedical informatics is more than the study of computers in biomedicine, and we have organized the book to emphasize that point. Chapter 1 first sets the stage for the rest of the book by providing a glimpse of the future, defining important terms and concepts, describing the content of the field, explaining the connections between biomedical informatics and related disciplines, and discussing the forces that have influenced research in biomedical informatics and its integration into medical practice and biological research.

Broad issues regarding the nature of data, information, and knowledge pervade all areas of application, as do concepts related to optimal decision making. Chapters 2 and 3 focus on these topics but mention computers only in passing. They serve as the foundation for all that follows. A new Chapter 4 on cognitive science issues enhances the discussions in Chapters 2 and 3, pointing out that decision making and behavior are deeply rooted in the ways in which information is processed by the human mind. Key concepts underlying system design, human–computer interaction, educational technology, and decision making are introduced in this chapter.

Chapters 5 and 6 introduce the central notions of computer hardware and software that are important for understanding the applications described later. Also included is a discussion of computer-system design, with explanations of important issues to consider when reading about specific applications and systems throughout the remainder of the book.

Chapter 7 summarizes the issues of standards development, focusing in particular on data exchange and issues related to sharing of clinical data. This important and rapidly evolving topic warrants inclusion given the evolution of the national health information infrastructure and the increasingly central role of standards in enabling clinical systems to have their desired influence on healthcare practices.

Chapter 8 is a new chapter that addresses a topic of increasing practical relevance in both the clinical and biological worlds: natural language understanding and the processing of biomedical texts. The importance of these methods is clear when one considers the amount of information contained in free-text dictated notes or in the published biomedical literature. Even with efforts to encourage structured data entry in clinical systems, there will likely always be an important role for techniques that allow computer systems to extract meaning from natural language documents.

Chapter 9 is another new chapter, this one developed in response to the growing complexity and size of the radiology systems chapters that had appeared in the first two editions. In this volume, we divide the former material into two chapters, one on Imaging and Structural Informatics (Chapter 9 in the *Methods* section of the book) and the other on Imaging Systems in Radiology (Chapter 18). This division has allowed us to separate the conceptual underpinnings, as represented in methods and imaging techniques, from the applications issues, highlighted in the world of radiological imaging and image management (e.g., in picture archiving and communication systems).

Chapter 10 addresses the key legal and ethical issues that have arisen when health information systems are considered. Then, in Chapter 11, the challenges associated with technology assessment and the evaluation of clinical information systems are introduced.

Chapters 12 through 22 survey many of the key biomedical areas in which computers are being used. Each chapter explains the conceptual and organizational issues in building that type of system, reviews the pertinent history, and examines the barriers to successful implementations.

Chapter 23 provides a historical perspective on changes in the way society pays for health care. It discusses alternative methods for evaluating the costs and the benefits of health care, and suggests ways in which financial considerations affect medical computing. The book concludes in Chapter 24 with a look to the future—a vision of how informatics concepts, computers, and advanced communication devices one day may pervade every aspect of biomedical research and clinical practice.

The Study of Computers in Biomedicine

The actual and potential uses of computers in health care and biomedicine form a remarkably broad and complex topic. However, just as you do not need to understand how a telephone or an ATM machine works to make good use of it and to tell when it is functioning poorly, we believe that technical biomedical-computing skills are not needed by health workers and life scientists who simply wish to become effective computer users. On the other hand, such technical skills are of course necessary for individuals with a career commitment to developing computer systems for biomedical environments. Thus, this book will neither teach you to be a programmer, nor show you how to fix a broken computer (although it might motivate you to learn how to do both). It also will not tell you about every important biomedical-computing system or application; we shall use an extensive bibliography to direct you to a wealth of literature where review articles and individual project reports can be found. We describe specific systems only as examples that can provide you with an understanding of the conceptual and organizational issues to be addressed in building systems for such uses. Examples also help to reveal the remaining barriers to successful implementations. Some of the application systems described in the book are well established, even in the commercial marketplace. Others are just beginning to be used broadly in biomedical settings. Several are still largely confined to the research laboratory.

Because we wish to emphasize the concepts underlying this field, we generally limit the discussion of technical implementation details. The computer-science issues can be learned from other courses and other textbooks. One exception, however, is our emphasis on the details of decision science as they relate to biomedical problem solving (Chapters 3 and 20). These topics generally are not presented in computer-science courses, yet they play a central role in the intelligent use of biomedical data and knowledge. Sections on medical decision making and computer-assisted decision support accordingly include more technical detail than you will find in other chapters.

All chapters include an annotated list of Suggested Readings to which you can turn if you have a particular interest in a topic, and there is a comprehensive listing of References at the end of the book. We use **boldface** print to indicate the key terms of each chapter; the definitions of these terms are included in the Glossary at the end of the book. Because many of the issues in biomedical informatics are conceptual, we have included Questions for Discussion at the end of each chapter. You will quickly discover that most of these questions do not have "right" answers. They are intended to illuminate key issues in the field and to motivate you to examine additional readings and new areas of research.

It is inherently limiting to learn about computer applications solely by reading about them. We accordingly encourage you to complement your studies by seeing real systems in use—ideally by using them yourself. Your understanding of system limitations and of what you would do to improve a biomedical-computing system will be greatly enhanced if you have had personal experience with representative applications. Be aggressive in seeking opportunities to observe and use working systems.

In a field that is changing as rapidly as computer science is, it is difficult ever to feel that you have knowledge that is completely current. However, the conceptual basis for study changes much more slowly than do the detailed technological issues. Thus, the lessons you learn from this volume will provide you with a foundation on which you can continue to build in the years ahead.

The Need for a Course in Biomedical-Computing Applications

A suggestion that new courses are needed in the curricula for students of the health professions is generally not met with enthusiasm. If anything, educators and students have been clamoring for *reduced* lecture time, for more emphasis on small group sessions, and for more free time for problem solving and reflection. A 1984 national survey by the Association of American Medical Colleges found that both medical students and their educators severely criticized the traditional emphasis on lectures and memorization. Yet the analysis of a panel on the General Professional Education of the Physician (GPEP) (Association of American Medical Colleges, 1984) and several subsequent studies and reports have specifically identified biomedical informatics, including computer applications, as an area in which new educational opportunities need to be developed so that physicians and other health professionals will be better prepared for clinical practice. The AAMC has recommended the formation of new academic units in biomedical informatics in our medical schools, and subsequent studies and reports have continued to stress the importance of the field and the need for its inclusion in the educational environments of health processionals.

The reason for this strong recommendation is clear: *The practice of medicine is inextricably entwined with the management of information.* In the past, practitioners handled medical information through resources such as the nearest hospital or medical-school library; personal collections of books, journals, and reprints; files of patient records; consultation with colleagues; manual office bookkeeping; and (all-too-often flawed) memorization. Although all these techniques continue to be valuable, the computer is offering new methods for finding, filing, and sorting information: online bibliographic-retrieval systems, including full-text publication; personal computers or PDAs, with database software to maintain personal information and reprint files; office-practice and clinical information systems to capture, communicate, and preserve key elements of the medical record; consultation systems to provide assistance when colleagues are inaccessible or unavailable; practice-management systems to integrate billing and receivable functions with other aspects of office or clinic organization; and other online information resources that help to reduce the pressure to memorize in a field that defies total mastery of all but its narrowest aspects. With such a pervasive and inevitable role for computers in clinical practice, and with a growing failure of traditional techniques to deal with the rapidly increasing information-management needs of practitioners, it has become obvious to many people that a new and essential topic has emerged for study in schools that train medical and other health professionals.

What is less clear is how the subject should be taught, and to what extent it should be left for postgraduate education. We believe that topics in biomedical computing are best taught and learned in the context of health-science training, which allows concepts from both the health sciences and computer science to be integrated. Biomedical-computing novices are likely to have only limited opportunities for intensive study of the material once their health-professional training has been completed.

The format of biomedical-informatics education is certain to evolve as faculty members are hired to develop it at more health-science schools, and as the emphasis on lectures as the primary teaching method diminishes. Computers will be used increasingly as teaching tools and as devices for communication, problem solving, and data sharing among students and faculty. In the meantime, biomedical informatics will be taught largely in the classroom setting. This book is designed to be used in that kind of traditional course, although the Questions for Discussion also could be used to focus conversation in small seminars and working groups. As resources improve in schools, integration of biomedical-computing topics into clinical experiences also will become more common. The eventual goal should be to provide instruction in biomedical informatics whenever this field is most relevant to the topic the student is studying. This aim requires educational opportunities throughout the years of formal training, supplemented by continuing-education programs after graduation.

The goal of integrating biomedicine and computer science is to provide a mechanism for increasing the sophistication of health professionals, so that they know and understand the available resources. They also should be familiar with biomedical computing's successes and failures and its research frontiers and its limitations, so that they can avoid repeating the mistakes of the past. Study of biomedical computing also should improve their skills in information management and problem solving. With a suitable integration of hands-on computer experience, computer-based learning, courses in clinical problem solving, and study of the material in this volume, health-science students will be well prepared to make effective use of computer-based tools and information management in healthcare delivery.

The Need for Specialists in Biomedical Informatics

As mentioned, this book also is intended to be used as an introductory text in programs of study for people who intend to make their professional careers in biomedical informatics. If we have persuaded you that a course in biomedical informatics is needed, then the requirement for trained faculty to teach the courses will be obvious. Some people might argue, however, that a course on this subject could be taught by a computer scientist who had an interest in biomedical computing or by a physician or biologist who had taken a few computing courses. Indeed, in the past, most teaching—and research—has been undertaken by faculty trained primarily in one of the fields and later drawn to the other. Today, however, schools are beginning to realize the need for professionals trained specifically at the interfaces among biomedicine, computer science, and related disciplines such as statistics, cognitive science, health economics, and medical ethics. This book outlines a first course for students training for careers in the biomedical informatics field. We specifically address the need for an educational experience in which computing and information-science concepts are synthesized with biomedical issues regarding research, training, and clinical practice. It is the *integration* of the related disciplines that traditionally has been lacking in the educational opportunities available to students with career interests in biomedical informatics. If schools are to establish such courses and training programs (and there are growing numbers of examples of each), they clearly need educators who have a broad familiarity with the field and who can develop curricula for students of the health professions as well as of engineering and computer science.

The increasing introduction of computing techniques into biomedical environments will require that well-trained individuals be available not only to teach students, but also to design, develop, select, and manage the biomedical-computing systems of tomorrow. There is a wide range of context-dependent computing issues that people can appreciate only by working on problems defined by the healthcare setting and its constraints. The field's development has been hampered because there are relatively few trained personnel to design research programs, to carry out the experimental and developmental activities, and to provide academic leadership in biomedical computing. A frequently cited problem is the difficulty a health professional (or a biologist) and a technically trained computer scientist experience when they try to communicate with one another. The vocabularies of the two fields are complex and have little overlap, and there is a process of acculturation to biomedicine that is difficult for computer scientists to appreciate through distant observation. Thus, interdisciplinary research and development projects are more likely to be successful when they are led by people who can effectively bridge the biomedical and computing fields. Such professionals often can facilitate sensitive communication among program personnel whose backgrounds and training differ substantially.

It is exciting to be working in a field that is maturing and having a beneficial effect on society. There is ample opportunity remaining for innovation as new technologies evolve and fundamental computing problems succumb to the creativity and hard work of our colleagues. In light of the increasing sophistication and specialization required in computer science in general, it is hardly surprising that a new discipline should arise at that field's interface with biomedicine. This book is dedicated to clarifying the definition and to nurturing the effectiveness of that discipline: biomedical informatics.

Edward H. Shortliffe
New York, N.Y.

James J. Cimino
New York, N.Y.
February 2006

Acknowledgments

In the 1980s, when Larry Fagan, Gio Wiederhold, and I decided to compile the first comprehensive textbook on what was then called medical informatics, none of us predicted the enormity of the task we were about to undertake. Our challenge was to create a multi-authored textbook that captured the collective expertise of leaders in the field yet was cohesive in content and style. The concept for the book first developed in 1982. We had begun to teach a course on computer applications in health care at Stanford University School of Medicine and had quickly determined that there was no comprehensive introductory text on the subject. Despite several collections of research descriptions and subject reviews, none had been developed with the needs of a rigorous introductory course in mind.

The thought of writing a textbook was daunting due to the diversity of topics. None of us felt he was sufficiently expert in the full range of important subjects for us to write the book ourselves. Yet we wanted to avoid putting together a collection of disconnected chapters containing assorted subject reviews. Thus, we decided to solicit contributions from leaders in the respective fields to be represented but to provide organizational guidelines in advance for each chapter. We also urged contributors to avoid writing subject reviews but, instead, to focus on the key conceptual topics in their field and to pick a handful of examples to illustrate their didactic points.

As the draft chapters began to come in, we realized that major editing would be required if we were to achieve our goals of cohesiveness and a uniform orientation across all the chapters. We were thus delighted when, in 1987, Leslie Perreault, a graduate of our training program, assumed responsibility for reworking the individual chapters to make an integral whole and for bringing the project to completion. The final product, published in 1990, was the result of many compromises, heavy editing, detailed rewriting, and numerous iterations. We were gratified by the positive response to the book when it finally appeared, and especially that of students of biomedical informatics who have often come to us at scientific meetings and told us about their appreciation of the book.

As the 1990s progressed, however, we began to realize that, despite our emphasis on basic concepts in the field (rather than a survey of existing systems), the volume was beginning to show its age. A great deal had changed since the initial chapters were written, and it became clear that a new edition would be required. The original editors discussed the project and decided that we should redesign the book, solicit updated chapters, and publish a new edition. Leslie Perreault by this time was a busy Director at First Consulting Group in New York City and would not have as much time to devote to the project as she had when we did the first edition. With trepidation, in light of our knowledge of the work that would be involved, we embarked on the new project.

As before, the chapter authors did a marvelous job, trying their best to meet our deadlines, putting up with editing changes that were designed to bring a uniform style to the book, and contributing excellent chapters that nicely reflected the changes in the field in the preceding decade.

No sooner had the second edition appeared in print than we started to get inquiries about when the next update would appear. We began to realize that the maintenance of a textbook in a field such as biomedical informatics was nearly a constant, ongoing process. By this time I had moved to Columbia University and the initial group of editors had largely disbanded to take on other responsibilities, with Leslie Perreault no longer in New York City. Accordingly, as plans for a third edition began to take shape, my Columbia colleague Jim Cimino joined me as the new associate editor, whereas Drs. Fagan, Wiederhold, and Perreault continued to be involved as chapter authors. Once again the authors did their best to try to meet our deadlines as the third edition took shape. This time we added several chapters, attempting to cover additional key topics that readers and authors had identified as being necessary enhancements to the earlier editions. We are once again extremely appreciative of all the authors' commitment and for the excellence of their work on behalf of the book and the field.

The completed third edition reflects the work and support of many people in addition to the editors and chapter authors. Particular gratitude is owed to Andi Cimino, our developmental editor whose rigorous attention to detail was crucial given the size and the complexity of the undertaking. At Springer we have been delighted to work on this edition with the responsible editors, first with Laura Gillan and, subsequently, with Michelle Schmitt-deBonis. Katharine Cacace has also played a key coordinating role at our interface with Springer and the production processes for the volume.

The unsung hero of the effort has been my assistant, Eloise Wender, who has shouldered the burden for creating the Name Index and for updating the Glossary in the third edition. These are arduous tasks that needed to be undertaken with great care, and I am grateful to Eloise for the attention to detail that she provided in helping with these important elements of the final product.

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New York, N.Y.
February 2006

Contents

UNIT II BIOMEDICAL INFORMATICS APPLICATIONS

UNIT III BIOMEDICAL INFORMATICS IN THE YEARS AHEAD

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Unit I
Recurrent Themes in Biomedical Informatics

1
The Computer Meets Medicine and Biology: Emergence of a Discipline

Edward H. Shortliffe and Marsden S. Blois†

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

- Why is information 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 *medical computer science*, *medical computing*, *biomedical informatics*, *clinical informatics*, *nursing informatics*, *bioinformatics*, 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, 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 medical care is financed influence the integration of medical computing into clinical practice?

1.1 Integrated Information Management: Technology's Promise[1]

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 workers had begun to hear about the dramatic effects that such technology would have on medical practice. More than five decades of remarkable progress in computing have followed those early predictions, and many of the original prophesies have

[1] Portions of this section are adapted from a paper presented at Medinfo98 in Seoul, Korea (Shortliffe, 1998a).
† Deceased

come to pass. Stories regarding the "information revolution" fill our newspapers and popular magazines, and today's children show an uncanny ability to make use of computers as routine tools for study and entertainment. Similarly, clinical workstations are now available on hospital wards and in outpatient offices. Yet many observers cite the health care system as being slow to understand information technology, to exploit it for its unique practical and strategic functionalities, and to incorporate it effectively into the work environment. Nonetheless, the enormous technological advances of the last two decades—personal computers and graphical workstations, new methods for human–computer interactions, innovations in mass storage of data, personal digital assistants, the Internet and the World Wide Web, wireless communications—have all combined to make 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 we can expect in the years ahead.

It is remarkable that the first personal computers did not appear until the late 1970s, and the World Wide Web dates only to the early 1990s. This dizzying rate of change, combined with equally pervasive and revolutionary changes in almost all international health care systems during the past decade, makes it difficult for health care planners and 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 twenty-first century 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 Chapter 12, no clinical computing topic is gaining more attention currently than is the issue of electronic health records (EHRs). Health care organizations are finding that they do not have systems in place that allow them to answer questions that are crucially important for strategic planning and for their better understanding of how they compare with other provider groups in their local or regional competitive environment. 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 have become increasingly clear (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 Electronic Health Records: Anticipating the Future

Many health care institutions are seeking to develop integrated clinical workstations. These are single-entry points into a medical world in which computational tools assist not only clinical matters (reporting results of tests, allowing direct entry of orders 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, word processors). The key idea, however, is that at the heart of the evolving clinical workstation lies the medical record in a new incarnation: electronic, accessible, confidential, secure, acceptable to clinicians and patients, and integrated with other types of nonpatient-specific information.

Inadequacy of the Traditional Paper Record

The paper-based medical record is 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 bureaucratic 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 has struggled mightily to adjust over the decades and to accommodate to new requirements as health care and medicine have changed.

Difficulty in obtaining information, either about a specific patient or about a general issue related to patient management, is a frustrating but common occurrence for practitioners. With increasing pressures to enhance clinical productivity, practitioners have begun to clamor for more reliable systems that provide facile, intuitive access to the information they need at the time they are seeing their patients. The EHR offers the hope for such improved access to patient-specific information and should provide a major benefit both for the quality of care and for the quality of life for clinicians in practice.

Despite the obvious need for a new record-keeping paradigm, most organizations have found it challenging to try to move to a paperless, computer-based clinical record (see Chapters 12 and 13). 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?" Companies offer medical record products, yet the packages are limited in their capabilities and seldom seem to meet the full range of needs defined within our complex health care organizations.

The complexity associated with automating medical 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 an object that can be moved around as needed within the institution. For example, on the input side (Figure 1.1), the medical record 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,

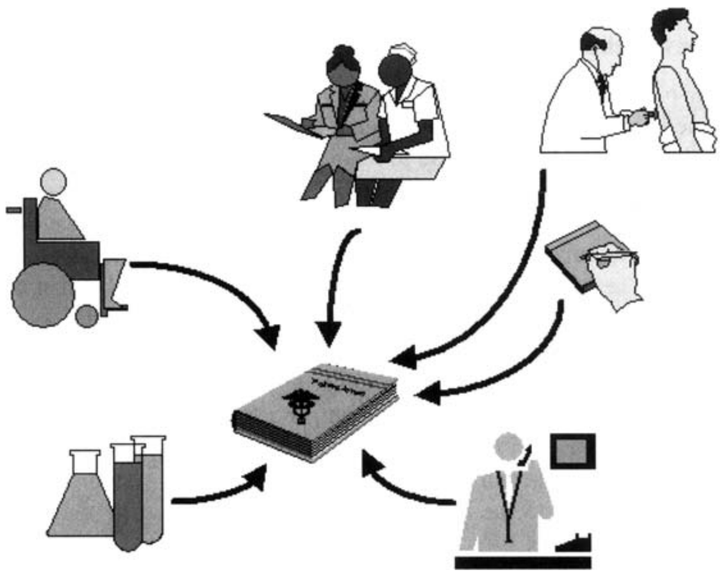

Figure 1.1. Inputs to the medical record. The traditional paper medical record is created by a variety of organizational processes that capture varying types of information (notes regarding direct encounters between health professionals and patients, laboratory or radiologic results, reports of telephone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

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 (Figure 1.2). Thus, the computer-based medical record 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 (Figure 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 is crucial.

The Medical Record and Clinical Trials

The arguments for automating medical records are summarized in Chapters 2 and 12 and in the 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 electronic record 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 are constrained today by clumsy methods for acquiring the data needed for clinical trials, generally relying on manual capture of information onto datasheets that are later transcribed into

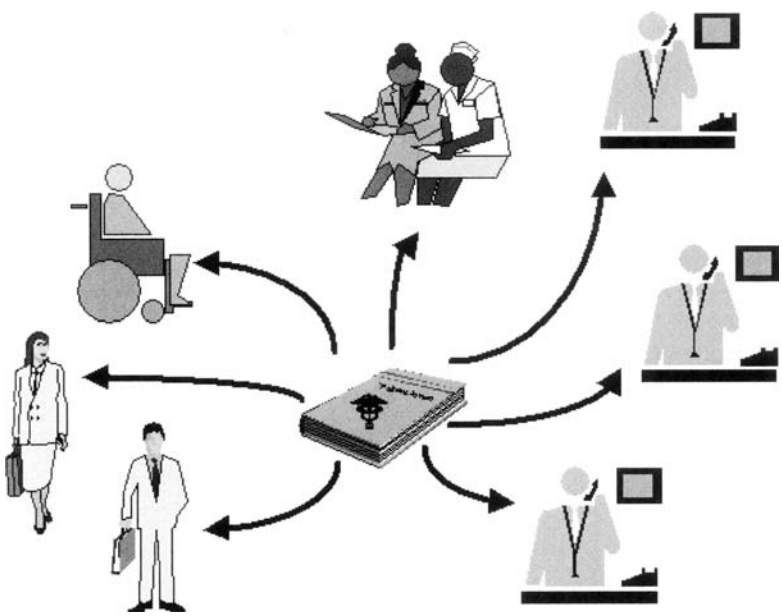

Figure 1.2. Outputs from the medical record. Once information is collected in the traditional paper medical record, it may be provided to a wide variety of potential users of the chart. These users include health professionals and the patients themselves but also a wide variety of "secondary users" (represented 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 vary substantially across several patient care settings and institutions.

computer databases for statistical analysis (Figure 1.4). The approach is labor-intensive, fraught with opportunities for error, and adds to the high costs associated with randomized prospective research protocols.

The use of EHRs offers many advantages to those carrying out clinical research. 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 be derived directly from the EHR, thus making research data collection a by-product of routine clinical record keeping (Figure 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.