

Information Technologies for Transforming Health Care

2

The central event of successful health care is the preservation of health or the healing of an infirmity through employment of medical expertise for the benefit of a patient. This can be deeply satisfying for all parties, but it often occurs within a complicated and frustrating health care delivery system. Working from dimly remembered medical facts and perhaps a few consumer health information brochures or a thin guidebook published by an insurance company, individuals must decide which doctor to select, pay for their care, negotiate reimbursement, evaluate the care they receive, and choose healthy lifestyles. But if patients and consumers have too little information, doctors and other health care practitioners generally have too much. They must keep abreast of a burgeoning medical research literature, gather information from bulging but inadequate paper record systems, diagnose and treat diseases, educate patients, and extend or limit patient access to specialists. Administrators and insurance companies must work within information systems that are often poorly organized to answer complex questions as they compete for customers, comply with shifting regulatory policy, optimize use of resources, provide high-quality health care, and meet investor demands for profitability. And the federal government, in its role as a provider and purchaser of health care, must find ways to minimize the cost of providing health care.

Many of the frustrations encountered by participants in the health care system can be traced to the inability of current information systems to provide adequate, accurate, timely, and appropriate information. Poor information flow has become an impediment to efficient delivery of high-quality health care.



ISLANDS OF AUTOMATION

There is a long history of attempts to solve the problems of inadequate health information systems by using computers. When the first general-purpose laboratory computer was introduced to the market, it was immediately used in a project to compile computer-based medical histories.⁴⁰ Today, many hospitals spend a large portion of their budgets on computers and recordkeeping. An entire academic field called *medical informatics* has developed around the study of administrative, clinical, demographic, research, and educational information generated in the process of delivering health care services. Many health professionals believe that delivery and coordination of care might be greatly improved if all relevant information were collected in a standard digital form and broadly connected in a health data system. This would enable authorized persons to rapidly access and modify data when necessary.

No such system currently exists.

Thirty years of academic, commercial, and government research have produced successful pilot programs and commercial implementations of *parts* of a comprehensive digital health information system. Many hospitals have computerized their administrative or clinical records, many insurance claims and orders for supplies are submitted electronically, many research materials are distributed over computer networks, and electronic distribution of consumer health information has begun. However, *there is still no system that comprehensively facilitates the flow of all types of health information and symmetrically addresses the needs of clinicians, administrators, policymakers, patients, and consumers.* The full potential of digital health information will only be

realized when it begins to flow beyond the confines of single departments, institutions, or communities.

The current situation is often characterized as a series of *islands of automation*. This report provides a tour of that digital archipelago; it surveys the history and terrain of the existing islands of automation and offers potential options for possible federal roles in enlarging and connecting the islands. This chapter begins, as it were, with the ocean: it provides an overview of the organization and flow of information within the broad health care system. It then describes information systems within hospitals and clinics. By focusing on the subset of clinical information that has been stored conventionally as paper-based clinical patient records, the discussion illustrates some of the problems and challenges confronted in the effort to digitize health information. The chapter also describes several key technologies that underlie efforts to build an interconnected health data system. Subsequent chapters describe ways these technologies are being used in administrative systems, clinical decision support and care evaluation systems, and systems for delivering health care to a scattered and diverse population through telemedicine and other techniques.

The story begins with a glimpse of the imagined mainland: the following scenario illustrates some of the many ways that health care might be different should information technology achieve its full potential as a medical tool. The scenario is fictional, but not utopian: it explores how the experiences of consumers, clinical teams, administrators, and policymakers might change in a world where health information flows freely.⁴¹ It implicitly illustrates some of the problematic aspects of

⁴⁰ W.V. Slack et al., "A Computer-Based Medical History System," *New England Journal of Medicine*, vol. 274, 1966, pp. 194-198. Slack used LINC, one of the first general purpose laboratory computers and an ancestor of the desktop computers now spreading throughout the health care delivery system.

⁴¹ In the scenario, information "flows freely" in that structural and technological impediments to exchanging information have been minimized, but *it only flows within prescribed channels*. This qualification will need to be applied to any comprehensive health data system that might develop. There must be adequate security and confidentiality mechanisms in place so that all participants are willing to trust the system and put their information into it. In addition, the legal, regulatory, and technological standards that define the channels must be stable and rational enough for businesses and institutions to depend on them.

the digital revolution in health care, along with the many possible opportunities and advantages. Consider, then, a fictional scenario of health care in a fully digital world.

■ Simplified Administration

Emilia finished her reply to the clinic's e-mail message and launched her web browser. The e-mail had been a reminder confirming her appointment later that day at the maternity clinic at the medical school; with only a month remaining until her due date, she was well acquainted with the routine of arriving at the clinic, having the nurse practitioner check the baby's size and heart-beat, and returning home with a fresh stock of vitamins and increasingly real expectations for the future. Emilia chose the medical school's home page from her browser's list of recently visited sites and typed her name and password into the scheduling inquiry form. In a moment, the response to her query appeared: appointments in the maternity clinic were running about 20 minutes late. She had plenty of time for lunch before the visit.

For the past few years, Emilia had received primary health care through the student health service at her college, but when she became pregnant all that changed. She was referred to the maternity clinic at a teaching hospital associated with the university and had received all her prenatal visits and screening there. From her first visit, it had been apparent that things were done differently at the hospital than at any doctor's office or clinic she had visited. Emilia and her husband John had arrived well before their scheduled appointment, expecting to have to complete a pile of paper forms. Instead, they were directed to one of a set of kiosks in the reception area where they sat down and began interacting with a computer program. The computer asked Emilia to swipe the magnetic-stripe card from the student health service through the reader next to the machine, and then the machine began asking them questions. Most of the questions were the usual ones—"Do you have a history of heart trouble?" for example—but at least she didn't have to fill out all those tedious ad-

resses—her own, her next of kin, and the like. The computer had already read them from the magnetic card. It took only five minutes to complete the program's questions because it didn't ask for the same information in many different ways like paper forms often do. When she clicked on the button indicating that she was an only child, the program didn't ask any further questions about the health history of her siblings. The program had a few sections for John to fill out about his own family history.

The kiosk then provided a curious section about granting the hospital permission to use the information generated during her care. Emilia had seen similar language in small type at the bottom of paper forms and had always initialed the boxes indicating her agreement, but she had never paid much attention to it. This program made the information permission seem almost as important as the health history itself: it requested specific permission to use all her medical information within the hospital, it asked for separate permission to release her record of care anonymously to state or federal authorities for research purposes, it asked for permission to automatically compare her profile with those sought for various clinical trials in the hospital, and on and on. In the end, the program summarized all the permissions she had given and asked her once more to approve the whole set. Emilia realized she didn't fully understand what sorts of clinical trials the questionnaire might be referring to, and so she changed her approval of that item to a request for more information.

After completing the program, she returned to the desk and the receptionist gave her a new plastic card. "It's a smart card," he said, "try not to bend it." Emilia asked why the program had been so annoyingly thorough in asking for permission to use her health information. "If we don't annoy you now, someone else might annoy you later," the receptionist explained. "We keep digital records instead of paper records in this hospital, so we can't control where our information goes just by locking the drawer of a filing cabinet. Of course, we use passwords, encryption, and other security measures to control who can read and al-

ter your records in the hospital, but some of your health information goes elsewhere as well. We bill your insurance company electronically so all you ever have to worry about is the copayment, and we abstract information from your records for reports requested by our management and those required by the government. The permission form you've just completed provides another layer of security that helps ensure that whenever your records are used for purposes other than directly providing care to you, you know about it and have approved it. It's a little like giving us a digital power of attorney—anyone who has your health information and wants to release it to someone else for a different purpose has to check for your permission against the file you've just created. That's the rule, even if everything directly identifying you has been removed from the record. You're not giving us blanket permission to use your health data—that's why the form is broken into so many separate questions covering different aspects of information sharing. And it's fine to decline permission on this form—that just means we'll need to ask your permission on a case-by-case basis later."

Emilia thought for a moment. "So I own my health records?" The receptionist smiled, "No, and you certainly couldn't reassemble all the information once it is released, but you can help determine where that information goes. I see that you've asked for more information about enrollment in clinical trials. The computer has put a reminder on your nurse practitioner's schedule to discuss that with you. She'll tell you about some of our ongoing research and discuss how your care might be affected by your decision to share or withhold information from the system that matches eligible patients with clinical trials."

■ Informed Patients and Consumers

Emilia and John had many more experiences with the kiosk following that initial visit. Each time they came to the clinic, they checked in by inserting the smart card and charging the copayment to their credit card, then used their spare moments before the nurse practitioner was available to learn

more about their baby. The computer referred to information in Emilia's electronic patient record and then presented multimedia modules tied to the gestational age of the baby. When ultrasound scans were taken early in the pregnancy, they could review them on the screen in full motion, and Emilia was able to change the contrast and color schemes so that even John could recognize the baby's face. They still got the little snapshot that most parents take home, but they could also e-mail their parents a minute or so of digitized video as well.

There were modules about the risks and benefits of alpha-fetal protein screening, genetic testing, pain medication during delivery, and the many other decisions they had to make. When John couldn't go with her to the prenatal visits, he would work through the same educational modules at home using a web browser over the Internet. Emilia liked being able to find the answers to some of her questions without having to ask the clinician directly—not only did she avoid having to play telephone tag with the clinic or call in at certain hours of the day, but she could get information on her own so that she was more confident in asking questions face-to-face.

Emilia collected information from several different electronic information sources besides the medical school. She borrowed a health information CD-ROM from a friend and found several more disks and videos at the city library. She subscribed to a free Internet mailing list about pregnancy and childbirth experiences and participated in a chat forum with other women on a commercial online service. And she made a point of regularly exchanging e-mail with some of the other women in her birthing classes at the hospital. That class was definitely not a place for high-tech multimedia programs, but for hand-holding and education from a nurse who had seen many, many births. Nonetheless, the scheduling for the class was set up through the hospital computer system, and the women kept in touch electronically with each other and their teacher between classes.

■ Paperless Medicine

When Emilia arrived at the clinic, she answered a few questions that the kiosk had for her and then went into a room where a nurse recorded her weight and vital signs and measured her belly before the nurse practitioner arrived. The nurse inserted Emilia's smart card into a computer in the examination room and typed the weight and size measurements into a form that appeared on the screen; the blood pressure machine and thermometer were hooked directly into the computer system and their measurements appeared on the same form automatically. Computers in the teaching hospital certainly weren't limited to multimedia kiosks in the reception area. Every doctor, nurse, receptionist, and treatment room had one, and all the computers were interconnected by cables, radio, or infrared links. When the nurse practitioner entered the room, she was invariably holding a small computer in her hand and noting the new datapoint on the graph showing Emilia's weight throughout her pregnancy. A summary of Emilia's previous visits and her responses to the screening questions today were also provided. The nurse practitioner's computer didn't have a keyboard, but that didn't seem to matter because there was little writing or typing involved. If the NP wanted to order a laboratory test, for instance, she selected the proper form from a menu on the screen and most of the information would already be filled in by the computer. She used a stylus to check off boxes indicating what she wanted done and then dispatched the order by tapping out her password on a little keyboard displayed on the screen. During most of the encounter, the NP simply set the computer aside and concentrated on the patient. Today, she had a concerned look on her face.

"Emilia, I'm worried that your baby's size seems to be reaching a plateau rather than sharply increasing in the usual way for the last few weeks of pregnancy." She showed her the screen of her handheld computer, which had a plot of the sequence of Emilia's measurements along with a normative size development chart. "The dashed lines represent the limits for a standard distribution of women. You're still within those bound-

aries, and so your baby may well be developing normally, but I'd like to order a few tests, beginning with another ultrasound. I can see that the ultrasound technician has an opening at 2:20, and I'd like you to get the test done as soon as possible."

Emilia's heart fell. It would be her third ultrasound so far. The first one had been exhilarating, and the second one less so. It had produced the expected pictures, but hadn't really been mentioned by her doctor after it was completed. It seemed that the clinicians were willing to order tests very readily, given that there wasn't any paperwork involved and the results appeared very quickly on their screens. How did they know that ordering so many tests helped ensure healthier deliveries? It certainly wasn't cheap. At this point, though, she wasn't worried that the ultrasound was unnecessary but that it would be a harbinger of bad news. As she refocused her thoughts, she could hear the nurse practitioner saying, "You have an hour. Why don't you spend the time looking at our *Delivery and Birth* CD-ROM just in case you don't have the opportunity to finish those classes?"

■ Empowered Clinical Teams

In the staff conference room, Dr. Conway's pager vibrated and the digital assistant on the table in front of her simultaneously awoke from its electronic slumber. The doctor felt a little sleepy herself, but at least she was getting continuing medical education credits for these lunchtime seminars utilizing the satellite link to Boston. She glanced at the incoming e-mail, which indicated that an obstetrics resident wanted her help with a decision about a potential c-section. The doctor left the seminar quietly and read the case précis that the digital assistant displayed as she walked down the hall.

Emilia's ultrasound technician had used imaging software to measure pockets of amniotic fluid around the baby and had recognized that the volume of the pockets was critically low for this stage of pregnancy. One of the hospital's decision support systems had come to the same conclusion by comparing the numbers in the technician's sum-

mary to the predictions of the OB-GYN expert system. After asking the technician to confirm its finding, the computer issued an alert to the resident on call. The resident's online work history indicated that he hadn't had direct experience with this type of case, so the system prepared a one-page summary of similar cases from the last year and a set of hyperlinks to the abstracts of relevant research literature. The resident skimmed the information as it appeared on his clipboard-shaped computer, talked to Emilia, and came to a quick decision to admit her to the hospital. With the touch of several on-screen buttons, he dispatched software agents that silently scheduled a room for Emilia, requisitioned a suite of monitoring equipment, ordered IV bags and Pitocin from the pharmacy, altered nursing assignments, and summoned Dr. Conway.

Emilia had entered the clinic that morning thinking it would be a normal day, but now she found herself in the labor and delivery room without so much as a suitcase . . . the baby needed to come out, labor would be induced, and the only question was whether a c-section could be avoided. She longed for the sort of uncomplicated birth described in her classes, but it was not to be. As she was calling John on her bedside phone and asking him to drive faster, a nurse wheeled in several monitors and an IV pump and quickly attached them to a bedside computer. The nurse opened a panel on the IV pump and inserted a bar-coded bottle; PITOCIN-FLOW OFF began glowing on the computer screen. Now the monitors hummed all around Emilia, measuring her pulse and blood oxygenation and the baby's as well, and ready to measure the contractions that would come. Emilia was attached to so many wires that she felt her body itself was a part of the information superhighway. She felt disoriented, but at least the nurse had sufficient time to sit with her for a few minutes and explain what was happening.

Dr. Conway walked in with the resident and introduced herself. "We've been watching the fetal monitor data as we discussed your case in the next room—there's no indication that the baby is in distress, so we're going to induce labor as soon as your husband arrives and see how it goes.

Please try to relax—chances are you'll be home with your baby in 24 hours. Do you have any allergies to medications I should know about?" Emilia almost replied that there wasn't anything particularly relaxing about being sent home less than 24 hours after delivery, but she sighed and simply said, "No, no allergies." Dr. Conway already knew that—the pharmacy alert system had cross-checked Emilia's history for potential problems with the pain-management drugs that might be used in the delivery and posted the results along with the drug prices on her digital assistant—but she always asked again, just to be sure. She chose the medications she wanted from the displayed formulary and dispatched a software agent that would arrange for delivery of the drugs to Emilia bedside and update the pharmacy's inventory and reordering system. She performed a quick physical exam and then sat at a console in the corner to dictate her findings into Emilia's patient record. As Dr. Conway spoke into the microphone, the computer recognized her words and inserted them into forms on the screen in front of her much faster than she could have typed them. She filled out the care plan and entered nursing and laboratory orders with a few touches of a stylus on the screen of her digital assistant. Finally, she used a password to attach a digital signature and time stamp to the orders and the findings and then turned in her chair. "Emilia, when your husband arrives, you should start discussing names for the baby. That one decision our computers can't help you make!"

THE LIFE CYCLE OF HEALTH INFORMATION

Emilia's story describes some of the ways that applications of information technologies could change the delivery of health care. The scenario focuses on the experiences of a patient in a specialized clinical setting in an urban hospital. However, similar opportunities, difficulties, and changes will arise as information technologies are incorporated into the jobs of health care workers and into home health care, rural health care, medical education, population-based public health services, and other types of health care delivery. The

first step in this process is the digitization of health information and the creation of an infrastructure that allows health information to flow seamlessly among the various parts of the delivery system.

Although the experiences described in Emilia's story depend on the use of information from many different sources and on communication between networks administered by many different types of institutions, they are sometimes said to be products of an electronic, digital, or computer-based patient record. This report will use the term *computer-based patient record* in a more limited sense: it is a compilation in digital form of all the clinical and administrative information relating to the care of a single individual. Computer-based patient records serve as repositories for clinical information and as records of communications and transactions; their analogs in traditional health information systems are paper-based patient records or charts, usually kept in folders along with films at each site of care. Although computer-based patient records may be localized in a single data file, they might also be widely distributed in computers throughout an institution or among several institutions. In either case, the perceived location of the record is on a computer screen in front of the person using it at any particular moment.

It is possible to design stand-alone computer-based patient record systems and some are in use, but much of the advantage of computerizing health information is lost if other systems and processes within the provider institution are unable to interact with information in the record. Maintaining a stand-alone patient record, for example, could require caregivers or clerical personnel to retype test results that were produced by a computerized lab analyzer in order to get them into the record, or to retype administrative information from the record for use in creating financial statements. To avoid these inefficiencies, computer-based patient records are usually embedded in various other *information systems*.

These systems include not only computer hardware and software and networks, but also the "people, data, rules, procedures, processing and storage devices—and communication and support facilities" involved in managing the record system and distributing data and information throughout the provider organization.⁴² For hospital patients, computer-based patient records are typically linked to *clinical information systems* that track clinician-patient encounters, and they may be linked to administrative, laboratory, nursing, and pharmacy information systems as well. However, most health care encounters occur outside of hospitals. The large amount of health information generated in primary care and home care settings could be captured in computerized patient record systems embedded in information systems appropriate for private and group practice doctors and public health workers.

Ideally, within a single institution, the distinctions between these various information systems should be transparent to users so they become parts of a seamless *enterprise information system*. In practice, however, the components for each type of information system are usually procured separately, and their integration can be plagued by a lack of design coordination and technical standards. New departmental computer systems may be incompatible with each other and with previously installed *legacy systems*. Although the discussion in this chapter primarily encompasses clinical information systems in hospitals, most of the benefits described in the scenario will come from the synergistic interaction between computer-based patient records and broader sources of information assembled from a variety of networked information systems. The next section illustrates how information flows within clinical information systems and discusses the content, utility, strengths, and weaknesses of paper and computer-based patient records.

⁴² Richard S. Dick and Elaine B. Steen (eds.), *The Computer-Based Patient Record: An Essential Technology for Health Care* (Washington, DC: National Academy Press, 1991), p. 12.

■ Clinical Information Systems

Figure 2-1 shows some of the ways that information flows between patient records and the various information systems inside and surrounding a large health care organization.⁴³ The information might be contained in a mixture of paper and computerized records and transferred via computer networks, fax, modem, mail, or courier. The figure indicates general sources and destinations of information, but is not intended to reflect the specific architectures or communication pathways in a particular setting. For instance, the institution's data repositories are shown near the center of the figure, but they may be implemented as a single centralized record system or distributed among various departments in the hospital. The data repositories include administrative and clinical patient records representing information about individual patients. They also include financial and other management-oriented databases that incorporate data gleaned from records of the entire patient population. Information such as schedules, personnel records, internal communications, and regulatory policies that support the operation of the institution are also included. One of the key advantages of shifting to computer-based patient records is the opportunity to strengthen the link between clinical records and management information systems so that resource use and quality of care can be analyzed using clinical data.

Clinical patient records contain encounter information, bedside data and nursing notes generated in the wards, laboratory reports, pharmaceutical receipts, images, and specialized reports from various institutional departments. The administrative departments exchange information with various external health care providers and practitioners and with the patient. They also gen-

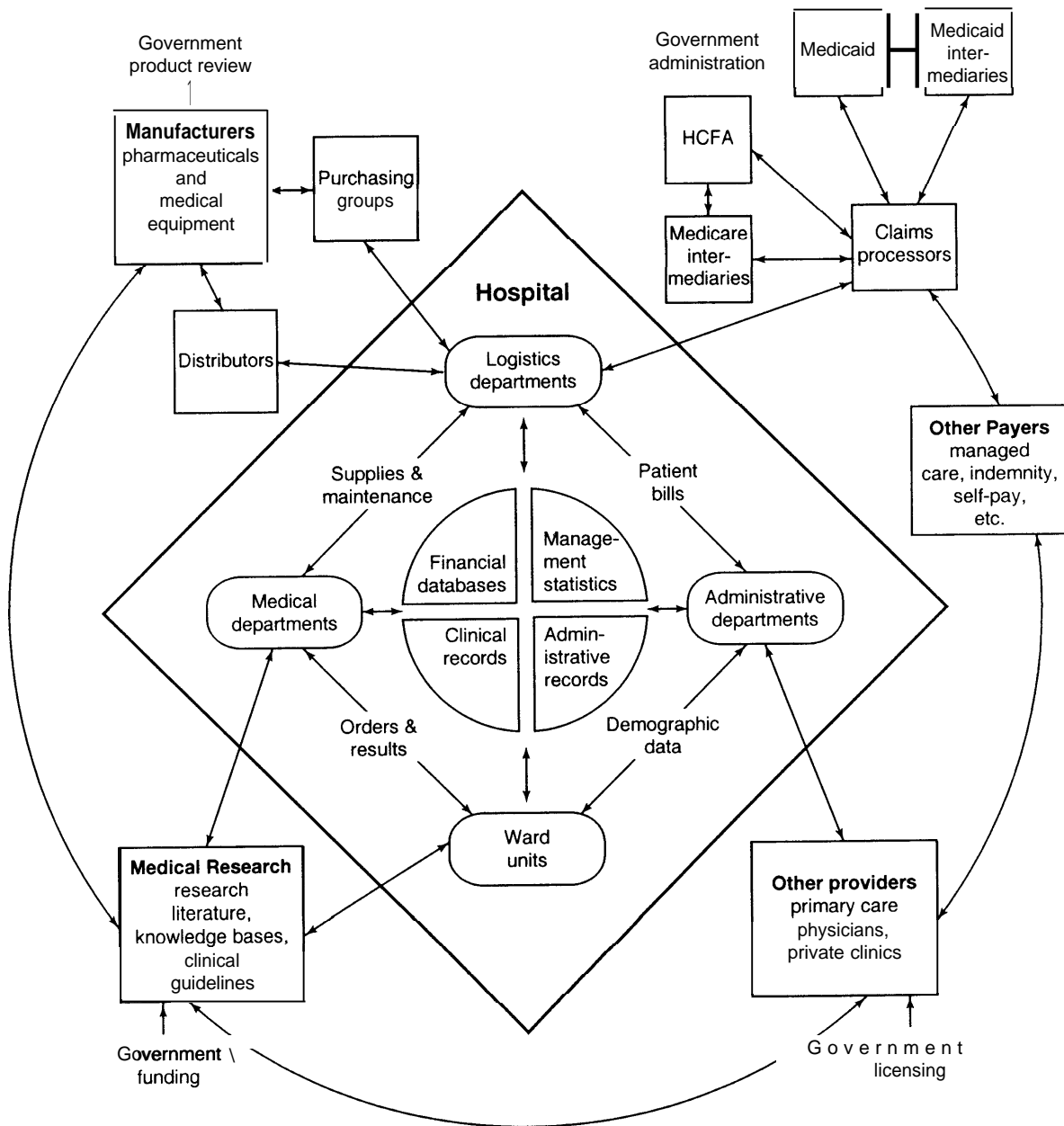
erate information about the patient's demographics and movements within the hospital and compile bills using information from the clinical records. The bills and orders for new supplies are passed to logistics departments, which generate purchase orders for medical supplies and pharmaceuticals. They also send out bills to insurance companies and request (through intermediaries) reimbursement from the Health Care Financing Administration (HCFA) and state agencies for care provided through the Medicare and Medicaid programs. Caregivers may use clinical research literature, public knowledge bases, and other external information resources. Federal and state governments indirectly shape the flow of health care information by funding clinical research and aspects of communication infrastructure development, and through the regulatory activities of the Food and Drug Administration, HCFA, state licensing authorities, and other bodies.

One example of a comprehensive clinical information system is the Regenstrief Medical Record System developed by the Indiana University Medical Center.⁴⁴ This system is used for both hospital and outpatient care in a network of three hospitals and 30 clinics, several health maintenance organization (HMO) offices, and care sites for the homeless and elderly. The system captures data from clinicians through an order-entry system and through links to administrative, laboratory, and pharmacy information systems. In addition, it captures nursing notes and some of the data generated by bedside monitors and electrocardiogram carts. It automatically reviews each patient chart for completeness and uses a set of more than a thousand rules to generate notices about allergies, potential drug-diagnosis interactions, treatment suggestions, preventive care, and

⁴³ The figure gives a central role to the hospital as a reflection of this chapter's emphasis on information systems in hospitals. Of course, most individuals receive very little of their care at hospitals, and while hospitals generate an enormous amount of medical and administrative information, they are only one part of the overall health information complex. Chapters 1, 3, and 5 address this larger context and discuss primary health care, integrated health maintenance organizations, consumer health information, and other generators and users of health information.

⁴⁴ C.J. McDonald et al., "The Regenstrief Medical Record System—Experience with MD Order Entry and Community-Wide Extensions," *Proceedings of the Eighteenth Annual Symposium on Computer Applications in Medical Care*, vol. 18, 1994, p. 1059.

FIGURE 2-1: Health Information Pathways to Hospital Information Systems



SOURCE: Office of Technology Assessment, 1995 Adapted in part from R Van de Velde, *Hospital Information Systems: The Next Generation* (Berlin: Springer-Verlag, 1992), p 107

compliance with institutional guidelines. Ensembles of patient records meeting specific criteria can be assembled by scanning a database describing more than 800,000 patients and 80 million separate clinical observations. Administrators use this capability for quality-control purposes and medical researchers use it to assemble cohorts of eligible patients for clinical trials. The Regenstrief system is a hybrid of paper-based and computer-based information management: some information is captured and disseminated electronically, but the system also prints reports of rounds made by physicians and a set of reminders, alerts, and customized encounter forms on paper prior to each patient's visit. Clerks transcribe and code the handwritten notes on these forms after the encounter.⁴⁵

Some of the institutional capabilities described in this section are also available for individual or group medical practices through software that adds the capability for clinical recordkeeping to administrative practice management systems.

■ Paper-Based Patient Records

Most of the clinical and administrative information that flows throughout the health care system is still recorded on paper. Over 10 billion pages of patient records are produced in the United States each year,⁴⁶ each of them a masterpiece of idiosyncratic functionality. In order to receive accreditation, hospitals must ensure that their records meet certain minimum content standards established by the Joint Commission on Accreditation of Healthcare Organizations, as well as any content requirements mandated by state regulations.⁴⁷ In general, however, health care organizations are free to determine how the information is arranged. Institutions design their own filing and communications systems to meet

internally determined information needs, and individual departments often design forms to reflect information generated in self-contained processes. To some extent, paper records are individualistic even to the level of single sentences because much of the information is handwritten and clinicians may phrase entries using their own terms and conventions.

Box 2-1 lists some of the many types of information that usually appear in a hospital's paper records. Different types of providers might assemble records with different content; for example, ambulatory care records generally have fewer categories of information than hospital records, but they may span a much greater time period because they are historical records documenting many encounters. Patient records also incorporate administrative records such as letters, insurance claims, and bills, although these may be stored separately from clinical records.

Paper records within a single folder have traditionally been kept either in the chronological order of collection or in source-oriented or problem-oriented formats. *Source-oriented records* are organized with forms from nurses, physicians, labs, and other sources in separate sections. *Problem-oriented records* organize the various notes into a brief database of information identifying the patient, a problem list of the aspects of the patient's condition that require treatment, an initial plan for treating the problems, and progress notes detailing actions engendered by the problems and plans.

This nonstandardization of patient records is not necessarily a symptom of poor design; instead, it is a reflection of the main task that patient records once served. They were a highly detailed, patient-centered documentation of the care process and a record of everything that happened

⁴⁵ C.J. McDonald and G.O. Barnett, "Medical Record Systems," *Medical Informatics: Computer Applications in Health Care*, E.H. Shortliffe and L.E. Perreault (eds.), G. Wiederhold and L.M. Fagan (assoc. eds.) (Reading, MA: Addison-Wesley, 1990).

⁴⁶ U.S. Congress, General Accounting Office, *Automated Medical Records: Leadership Needed To Expedite Standards Development* (Washington, DC: General Accounting Office, 1993).

⁴⁷ Some examples of state legal requirements for medical records are discussed in ch. 3.

BOX 2-1: The Content of Patient Records

The *admission/discharge record* provides a synopsis of the overall patient record. It contains basic identifying and financial information about the patient, along with certain clinical information such as the admitting and final diagnoses, a summary of the procedures performed and medical consultations, and a description of the disposition of the patient. This record is typically organized on a sheet attached to the face of the other paper records, which contain two broad categories of information:

Administrative data:

- *Attestation statements* certify that the diagnoses and procedures performed are accurately and completely documented to meet the requirements of Medicare and other payers.
- *Conditions of admission* record the patient's consent to be admitted and receive routine services, diagnostic procedures, and medical treatment.
- *Consents for release of information* allow the hospital to release health information to insurers or others.
- *Special consents* authorize nonroutine diagnostic or therapeutic procedures.

Medical or clinical data:

- *The medical history* includes descriptions of the chief complaint, present illness, past medical history, psychosocial history, family history, review of physiological systems, and physical examination of the patient.
- *Physicians orders* specify tests, medications, and regimens of care.
- *Progress notes* detail the course of the patient illness, response to treatment, and status at discharge.
- *Departmental reports* record the contributions of the pathology, radiology, laboratory, physical therapy, respiratory therapy, and social service departments to the care of the patient.
- *Nursing data* include notes with detailed observations of the patient and descriptions of the nursing care regime, a sheet recording the patient's vital signs and fluid intake and output, and a sheet documenting the time and dosage of each medication the patient receives.
- *Operative reports* include an anesthesia report, description of the surgical event, and a recovery room record.
- = *Discharge summaries* concisely recapitulate the patient's treatment in the hospital and its results

Coronary care, intensive care, psychiatric, and other special care units typically contribute their own special forms to patient records. Obstetrics and gynecology units usually have specific forms that include a patient's antepartum records and medical history, her labor and delivery records, postpartum records, and a newborn record describing the baby's care.

SOURCE: Adapted from Jonathan P. Tomes, *Compliance Guide for Electronic Health Records* (New York, NY: Faulkner & Gray, 1994) pp. 31-32

with respect to a patient during a particular episode of care. In ambulatory care settings, they were also repositories of historical information about an individual's previous care. The records mediated communications and conveyed instructions and responsibilities among members of the medical team. In this context, designing a standard format for documenting patient-clinician encounters made about as much sense as trying to enforce a standard format for phone conversations or diary entries.

The problem is that the functionality required of patient records has grown far beyond the bounds of recordkeeping and communication within a limited team because of changes to both the delivery system and clinical practice. Patient records are now widely used for legal, administrative, and research purposes. They have become sources of information for determining eligibility for insurance payments and for documenting the extent of injuries or the quality of care for use in legal proceedings. They may be used to provide

data for evaluating the quality and appropriateness of care for peer review, accreditation, or other quality assurance programs and for reporting communicable diseases and other required data to civil authorities. With the advent of integrated managed care organizations, clinical records have become information sources for analyzing the resource requirements, outcomes, and profitability of health care practices.

In response to these broader functions, patient records now have at least two phases. In the active phase, clinicians and administrators insert and edit information. As legal documents, patient records are treated like other business records that might be needed in a trial. Recorded entries must be made by people with first-hand knowledge of the events, acting in their ordinary capacity, and the time and date of each entry must be shown. When errors are found and corrected, the record must show clearly both the original entry and the correction, along with the name of the person making the correction. In the passive, permanent phase the patient record serves as an unalterable legal record.⁴⁸ Its contents are occasionally examined, usually by users far removed from the clinical setting. At this point, information may be abstracted from the record for research or management purposes, and all links identifying the information with a particular individual removed.

Even with this adaptation, paper records may not be adequate for the information demands of modern health care delivery systems. A number of weaknesses of paper records have been identified:⁴⁹

- *Paper-based patient records document the caregiving process inadequately.* Medical recordkeeping is a hurried, ancillary activity in the encounter room. Clinicians may not have enough time to completely and accurately fill out the forms comprising the paper records, and

the required health information is sometimes unavailable or of questionable accuracy as the notes are written. Physicians' and nurses' notes may be illegible if handwritten, or inaccurate if dictated and then transcribed. Detailed descriptions of the patient's health problem and the reasoning behind diagnoses and choices of services may be left out or abbreviated because they are hard to summarize and tedious to record. The voluminous data from physiological monitors are difficult to record accurately by hand. Other components, such as laboratory and radiological reports, may be missing because of filing or communication errors.

- *Paper-based patient records hinder information flow.* Once information has been recorded within a set of bulky paper records, it may not be readily accessible later. Efforts to compile a more complete paper record are likely to exacerbate this problem. The data are bound to the paper itself and individual pieces cannot be sorted for relevance, making the record difficult to use when dealing with multiple problems or extended treatments. Collecting and aggregating data from multiple records for purposes of quality monitoring or clinical research involves an expensive and time-consuming manual search. Paper records can be in only one place at a time. Short of laboriously photocopying and then shipping them by courier, records may frequently be unavailable to a caregiver who needs them. When the record is unavailable, new data cannot be entered in a timely manner; entries must often be made from memory or copied from other forms or informal notes. This can lead to the creation of "shadow records" that are difficult to coordinate with the primary record set and which may contain conflicting or anachronistic data. Finally, the data

⁴⁸ J.P. Tomes, *Compliance Guide to Electronic Health Records* (New York, NY: Faulkner and Gray, 1994), pp. 9-11.

⁴⁹ Dick and Steen, op. cit., footnote 3; and M.L. McHugh, "Nurses' Needs for Computer-Based Patient Records," in M.J. Ball and M.F. Collen, *Aspects of the Computer-Based Patient Record* (New York, NY: Springer-Verlag, 1992), pp. 16-29.

are only as secure as the paper itself, and entire records, or individual pages within a record, can easily be misplaced, damaged, lost, or stolen.

- *Paper records impede the integration of health care delivery, research, and administration.* The wide variety of formats, styles, and organizational systems for paper records frustrates the coordination of care between different providers, or even between departments or practitioners in the same institution. The impenetrability of the record means that there are few tools that can use information in the paper records to generate reminders, decision aids, and other supports for work.

■ Computer-Based Patient Records

If all the information in paper-based records were digitized and embedded within information systems that provide rapid, contextualized access to the data and links to other information in the institution, some of the shortcomings of paper record-keeping could be addressed:

- *The health care delivery process could be fully documented.* Information could be gathered as it is generated using a variety of conventional and handheld computers equipped with keyboards, pen-based structured data entry, and voice or handwriting recognition. Illegible or inconsistent entries could be caught and corrected as they are entered. Physiological monitors could collect data and insert them automatically into the record after checking for errors, noise, and inappropriate values. Conflicting data from disparate sources could be reconciled and cross-checked for accuracy. Medical orders, their results, and all other internal transactions could be tracked automatically.
- *Health information could be unfettered.* It could be stored as individually indexed items of information that could be abstracted into reports and compared among patients. Records could be accessed simultaneously by multiple users and easily duplicated when necessary. Information anywhere in the record could be accessed with minimal delay. Data could be

liberated from any one delivery medium and digital devices that access them could be designed with a wide variety of capabilities and capacities.

- *Caregiving, research, and administration could be knit together.* Data from digital records could be extracted and exchanged according to consensus standards. Their content could be enriched through the development of decision support tools. Patient records could be shared within and across institutions, thus avoiding delays.

Not all approaches to collecting health information meet these objectives equally well. Most of the benefits of computerizing the patient record are realized when information is *delivered* to the caregiver or patient, but most of the expense and problems of computerizing the patient record are realized when the information is *collected*. In general, converting raw data into electronic information that can be shared requires that caregivers spend extra time and lose some flexibility in their recordkeeping—at least initially—and it requires institutional investments for training, maintenance of standards, and redesigning work processes. The costs and benefits of electronic patient records are proportional to the effort involved in collecting, organizing, and distilling data into useful information.

For example, a page from a paper patient record could be stored electronically in many different ways. The information could be simply scanned and stored as an image (much like a fax) that is a picture of the paper form, but is not searchable or editable. *Document imaging systems* are widely available that use computers and optical disks to store such images and make them available to clinicians on workstations with graphics terminals. These systems reduce the amount of physical storage space required for patient records, and they allow the records to be shared by clinicians and administrative offices without physically transporting the records. Preparing to implement an image-based system can help institutions streamline their recordkeeping system by forcing them to analyze the paper forms in use and eliminate re-

dundant ones.⁵⁰ Some systems allow clinicians to use electronic signatures to approve document images at the workstations, and others allow information from laboratory instruments or other computerized processes to be captured as text along with the images. While document imaging systems can mitigate some of the problems of the patient record, they are not really a step toward developing a true computer-based patient record or provider information system. They have the distinct disadvantage of being primarily a collection of images rather than a collection of separately addressable facts about each patient, and the information in those images cannot be easily extracted or manipulated for reporting purposes or for integration with decision support systems. Patient records from document imaging systems cannot be easily shared with other departments or institutions using different record systems.

Additional effort can be expended as the data are collected and stored to make the health information in the records more useful. Document images can be converted to textual form either by applying secondary processing techniques such as *optical character recognition* or by manually re-typing the data using word-processing software. Paper documents and document images can be sidestepped entirely by entering the data directly into computers through on-screen forms. Once information is stored as text rather than images of text, it becomes much more mobile because it can be exchanged electronically as files or e-mail with other information systems. Free-text data is still problematic, however, because it is unstructured—there is no set placement or format for the information it contains—and because the terms used in the text may have ambiguous or inconsistent definitions. These problems can be addressed by using *databases* that store data as discrete elements that are separately addressable and editable—rather than as long, unstructured text files—and by the adoption of various standards to consistently define the structure and content of

electronic messages between information systems. Although the existence of various standards may be transparent to the clinician, the use of such standards is often facilitated through the use of *structured data entry*, where the organization of documentation and the choices of terminology are predefined and standardized.

Implementation of an information system with databases, structured data entry, and message standardization requires more sweeping changes in documentation practices than adoption of an image-based system, but the resulting patient records are far more flexible and harness more of the computer's power as an analytical tool. Because each fact about the patient is stored discretely and can be retrieved separately, information can be organized and presented in different ways, depending on the needs of the user. The records can easily incorporate information from laboratory and administrative systems and the information systems of outside providers, and they can be supplemented by decision support systems. On the other hand, collecting such information in usable form from all the different sources can present a plethora of organizational and technical hurdles. Because of the costs involved, in terms of investment in hardware and software, professional effort, and changes in work process, organizations take these hurdles a few at a time. Today, few, if any, provider organizations have a completely electronic patient record. Most providers who are working toward developing computer-stored records find themselves somewhere along an evolutionary continuum, using a hybrid system encompassing both computer and paper records.

KEY TECHNOLOGIES FOR THE EMERGING HEALTH INFORMATION INFRASTRUCTURE

Emilia's scenario at the beginning of this chapter is fictional; it portrays a suite of information tools and resources harmoniously communicating with

⁵⁰ "Case Study: The Toledo Hospital Turns to Document Imaging To Automate Emergency Center Medical Records," *Healthcare Telecomm Report*, Sept. 26, 1994, vol. 2, No. 20, pp. 1, 5-7.

each other and integrated into health care delivery in a way that is not available anywhere today. However, while the synergy between the tools is fictional, the tools themselves are readily available. Information technologies have been used for many years in academic, governmental, and private research, in pilot projects, and in commercial products, and consensus is emerging on which ones will form the basis for an advanced health information infrastructure. This section introduces several important communications and computer technologies, including computerized data capture and distillation, high-capacity digital storage, broadband telecommunications, and advanced human-computer interface techniques.

There are several reasons why the technologies and standards underlying applications must be understood for purposes of setting public policy. First, technological changes are challenging the relevance and enforceability of the existing body of state and federal law. Several states virtually preclude the development of computer-based patient records by specifying in *pen and quill* legislation the required storage media for patient records.⁵¹ These laws were no doubt meant to ensure the singularity and permanence of patient records, but they were probably written without an appreciation of the compactness, duplicability, and durability of optical disks. While it is true that optical disks have only become available relatively recently, their features have been described and expected for at least 20 years. To avoid inflexible and inappropriate laws, it is important to consider technological trends well in advance of their implementation.⁵²

Second, technologies have inherent *affordances*⁵³—they make some activities very easy and others more difficult, and they impose constraints on the behavior of users. For example, Canada has a telecommunications infrastructure that ensures cheap, reliable data transfer using modems, and France has an infrastructure that supports the widespread use of *smart cards*, which can hold several pages of data and be carried in a wallet. One result of the different affordances of these two technologies is that the experience of procuring health care and transferring patient records in Canada is very different from that in France. In Canada, smart cards are being used to transfer data in small, special purpose situations, but the bulk of the flow of health information occurs over integrated data networks.⁵⁴ In France, the extensive smart card infrastructure and the ability of individuals to choose their own doctors, health care establishments, and pharmacies have given rise to over 70 different card systems. Basic health information and the specific details related to a single treatment or prescription are encoded on a card and later accessed by the appropriate health care provider, government services agency, or pharmacy. The cards make patient records more accurate and mobile than paper records, but they do not contain a person's entire health history.⁵⁵ Legislative action that encourages specific technological approaches, such as broadband communications, inevitably affords some conveniences, some problems, and many striking changes in how health care can be delivered. It is important that such consequences be anticipated before legislation is crafted.

⁵¹ The laws, which usually specify paper or microfilm records, are explained more fully in chapter 3.

⁵² This caveat applies to legislation that might endorse any particular storage medium or other specific technology, including optical media. For instance, the equipment to read optical disks is often obsolescent long before the disks themselves.

⁵³ D.A. Norman, *Things That Make Us Smart: Defending Human Attributes in the Age of the Machine* (Reading, MA: Addison-Wesley, 1993), p. 106.

⁵⁴ R. Alvarez, "Canadian Policies and Strategies for Health Cards," unpublished paper presented at *Cartes Santes* conference, Marseilles, France, September 1993.

⁵⁵ Phoenix Planning and Evaluation, Ltd., "Potential Card Applications in the Health Care Industry," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994.

Finally, despite the evanescent nature of high-technology products in an entrepreneurial society, *successful* technologies and standards have enduring influence. Each new generation of information technologies forms a legacy that future generations must support. At the cusp of what may be a major expansion in the purchase of computers and telecommunications equipment for health care purposes, it is important that technological choices embodied in legislative policy and government procurements be consistent with long-range congressional goals for public health, medical research, and personal privacy. The technologies described in the following sections are shown in table 2-1.

■ Capturing Data at the Point of Care

Clinical records document brief encounters between health care professionals and the patient through descriptive text, diagnoses, treatment protocols, and nurses' notes typed or written by hand on charts and forms. Measurements of physiological variables are a second major source of clinical data. Nurses, respiratory therapists, and other practitioners read these measurements from medical monitors periodically and transfer them to the patient record. Although clinicians and other end-users of patient records are most likely to be held legally responsible for their quality, responsibility for entering the data is often either delegated to a transcriptionist or delayed until the end of the shift. Whenever the responsibility for inserting these types of data into the record is delegated or postponed, the possibility of incorporating errors is increased.

Several new technologies may address this problem by capturing clinical data as they are generated at the site of care. This generally improves data quality because that quality is best verified by those who rely on it most frequently.⁵⁶ These data

TABLE 2-1: Key Information Technologies for Health Care

Human-computer interaction

- handheld computers
- handwriting recognition
- personal digital assistants
- speech recognition
- automated data collection
- structured data entry

Storage, processing, and compression

- computer-based patient records
- magnetic stripe cards
- smart cards
- picture archiving and communications systems
- medical imaging
- optical storage
- image compression
- digital signal processors
- object-oriented software design

Connectivity

- clinical information systems
- cabled, optical, and wireless networks
- Internet and electronic mail
- World Wide Web
- Integrated Services Digital Network (ISDN)
- frame relay
- Asynchronous Transfer Mode (ATM)
- client-server computing
- messaging and coding standards
- proprietary and consensus standards
- Medical Information Bus

Security

- passwords
- fault tolerant computers
- redundant disk (RAID) systems
- authenticators
- encryption
- firewalls

Data distillation

- decision support systems
- pattern recognition
- artificial neural networks
- knowledge-based systems
- relational databases
- knowledge discovery
- natural language processing
- encoders and groupers

SOURCE: Office of Technology Assessment, 1995

⁵⁶ S. Henderson et al., "Computerized Clinical Protocols in an Intensive Care Unit: How Well Are They Followed?" *Proceedings of the Fourteenth Annual Symposium on Computer Applications in Medical Care*, vol. 14, 1990, pp. 284-288.

collection technologies include portable computers, digital assistants, speech and handwriting recognition, and the standardization of automated data collection from medical monitors.

Portable computers may be either small versions of desktop computers or they may incorporate entirely new hardware, operating systems, and data organization paradigms. Laptop computers are not widely used in hospital rooms because there is rarely a flat spot on which to rest them. Instead, **tablet computers** that can be operated while being cradled in one arm are used. They usually contain small hard drives, backlit screens, and batteries that last a few hours before recharging. They may contain small **PC cards** (also known as PCMCIA cards) that allow them to communicate via wireless modem or with short-range radio or infrared receivers attached to the computer network in the hospital.⁵⁷ They resemble laptop computers in size and weight, but their keyboards are either missing entirely or folded behind the display screen. The screen itself is a **digitizer** as well as a display, which means that it can detect the presence and position of a nearby stylus. The stylus is used like a mouse on a desktop computer to pull down menus, activate icons, and press “buttons.” Numbers and letters can be entered with the stylus via an image of a conventional keyboard, but medical applications for tablet computers typically avoid ersatz typing as much as possible. Instead, the user chooses from a branching set of possible actions. For instance, to write a prescription, the doctor might use the stylus to pull down a menu to initiate the process and then choose “antibiotic” from a short list of drug types that appears. A list of antibiotics in the hospital’s formulary appears, and when one is chosen a list of appropriate dosages appears, and soon. However, if this process is poorly designed, the clinician is trapped in a single mode of communication—Prescription writing—until entirely finished. It may be diffi-



The Motorola Marco, a personal digital assistant with handwriting and gesture recognition and wireless networking capability. Digital assistants and other handheld computers allow clinical data to be collected at the time and place of care.

cult to navigate through the series of lists and to back up and correct errors.

Personal digital assistants (PDAs) are a different type of portable computer. As shown in the photo, they fit in the pocket of a medical lab coat. They have smaller displays than laptop computers, and their batteries last much longer. PDAs may have wireless communications capabilities, and while they lack hard drives, they typically employ high-performance computer processors. The extra processing power allows them to address some of the shortcomings of mobile computing without keyboards by using human-computer interface designs not found on desktop computers. One approach is to use a *social inter-*

⁵⁷PC cards are not limited to communications devices; they can contain more exotic equipment such as miniature hard drives, encryption chips, or even atomic clocks.

face such as that presented by devices employing General Magic's Magic Cap operating system. Different capabilities of the computer are represented by different physical objects in a room portrayed on the display. To write prescriptions, the clinician might tap on a picture of a notepad; she could also tap on a medical reference book to look up a drug's description even as she works on the prescription.

Other PDAs use handwriting recognition or novel data storage strategies, such as those facilitated by Apple Computer's Newton operating system. A wide variety of clinical applications have been written for Newton PDAs, including charting and patient management software, medical reference texts, applications for accessing drug information and writing prescriptions, and calculators for determining drug dosages, IV drip rates, and other common medical computations. One example is the Constellation Project at Brigham and Women's Hospital and Massachusetts General Hospital in Boston that equipped medical residents with PDAs containing the American College of Physicians' Medical Knowledge Self-Assessment Program, an ICU/CCU Drug Reference Book, the hospitals' Medical Resident Handbooks, a medical calculator, and several other medical reference texts.⁵⁸

Handwriting recognition attempts to recognize words and letters within handwritten script. *Optical character recognition* is a related technology used with desktop computers and optical scanners that attempts to recognize printed or neatly written block letters on paper forms. *Speech recognition* is yet another pattern-matching technology that

facilitates entry of textual notes into a computer without using a keyboard. The technologies underlying handwriting recognition and speech recognition are briefly surveyed in box 2-2. Speech recognition systems capable of recognizing specialized medical vocabularies have been available for several years. They typically cost several thousand dollars per computer workstation. None of the current implementations of speech recognition for clinical use is portable; they are usually deployed to reduce the delay and potential for error involved in transcribing recorded notes, rather than as data collection devices at the point of care. Speech recognition systems are also useful in situations where notes need to be taken, but the clinician's hands are not free.

Another approach to making data collection immediate and accurate involves gathering all the data generated by the suite of medical monitors and therapeutic devices at the bedside without human intervention. *Automated data collection* helps reduce the number of errors introduced and propagated by end-of-shift recordkeeping⁵⁹ and reduces the 40 to 60 percent of nurses' time that is spent taking and organizing notes and charting patient care.⁶⁰ It supports vigilant care by employing computers to constantly monitor critical physiological variables and call attention to dangerous conditions, and by allowing caregivers to check on current patient status and developing trends from afar. By providing accurate and timely depictions of patient status, automated data collection affords greater assurance that computer-based decision support tools will provide correct information on which to base a clinical decision.⁶¹

⁵⁸ S.E. Labkoff et al., "The Constellation Project: Access to Medical Reference Information Using Personal Digital Assistants," *Proceedings of the Eighteenth Annual Symposium on Computer Applications in Medical Care*, vol. 18, 1994, p. 1024.

⁵⁹ R.M. Gardner et al., "Real Time Data Acquisition: Experience with the Medical Information Bus (MIB)," *Proceedings of the Fifteenth Annual Symposium on Computer Applications in Medical Care*, vol. 15, 1991, pp. 813-817.

⁶⁰ B.W. Childs, "Bedside Terminals: One of the Answers to the Nursing Shortage," *Healthcare Informatics*, vol. 7, No. 12, 1990, p. 37.

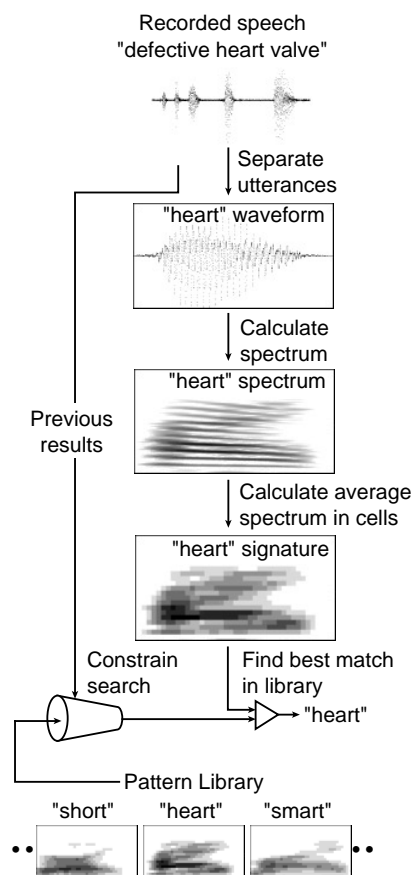
⁶¹ T.P. Clemmer and R.M. Gardner, "Medical Informatics in the Intensive Care Unit: State of the Art 1991," *International Journal of Clinical Monitoring and Computing*, vol. 8, No. 4, 1992, pp. 237-250.

BOX 2-2: Speech and Handwriting Recognition

Doctors may someday consider pocket information tools to be as indispensable as stethoscopes and prescription pads. However, while they may be willing to carry some sort of small computer around, it is unlikely that they will carry a computer keyboard as well. *Speech recognition* and *handwriting recognition* are two technologies that seek to liberate computers from keyboards by transferring directly into the patient record any notes spoken into a tiny pocket computer or written on its face.

The diagram here shows a highly simplified illustration of the speech recognition process. The computer digitizes the electrical signal from the microphone and breaks it into separate *utterances* by identifying short pauses in the speaker's voice. The computer then uses Fourier analysis to determine the frequencies or pitches present in the utterance as a function of time. A lower resolution signature is derived from this spectrum by slicing it into frequency bands and time segments and averaging the spectrum within each cell. Finally, the computer identifies the utterance by selecting the best match for its signature from a library of known speech patterns. Searching for a match within a library containing all possible human utterances would be hopelessly difficult; instead, searches are usually constrained. *Natural language processing* uses the syntax of previously recognized words to limit the range of possible matches for the current utterance signature, and the words in the library typically are further restricted to a certain domain of knowledge, such as radiology. Most of the calculations in current speech-recognition systems are delegated by the computer processor to specialized chips called *digital signal processors (DSPs)*.

Discrete speech recognition systems require speakers to insert short pauses between words. *Continuous speech recognition* systems attempt the much more difficult task of recognizing normal speech, which has pauses for punctuation but no natural silences between words. In this case, dividing the flow of speech into chunks is much more difficult and the utterances correspond more closely to phonemes than to words. Matching the utterance signature to a pattern in the



(continued)

BOX 2-2: Speech and Handwriting Recognition (Cont'd.)

library is more difficult as well because phonemes can be legitimately combined in many more ways than words, and syntax constraints are difficult to apply until the phonemes have been assembled into potential words. The pattern library itself can be built in two ways. *Speaker-dependent recognition* systems require the user to build a database of his or her own voice samples. *Speaker-independent recognition* systems use a preassembled library assembled from averages of the voices of many speakers. *Adaptive* systems customize a speaker-independent library to a user's voice patterns over time.

Currently, discrete speaker-independent voice recognition systems are available for desktop computers, but continuous voice recognition is limited to very brief phrases. Continuous, speaker-independent speech recognition has been demonstrated in research laboratories on computers with 256 DSPs operating in parallel.¹ Most clinical applications employ adaptive or speaker-dependent technology that typically must be trained for a few hours a day over a period of weeks by each clinician. Handwriting recognition is conceptually similar to speech recognition. The input variable is not the loudness of the voice as a function of time, but the position of the pen's tip as a function of time. Commercial handwriting recognition systems have been developed that focus on either block printing or cursive script. Block printing, with well-formed, separated letters, is analogous to discrete speech; smoothly-connected cursive script is analogous to continuous speech. The recognition accuracy of all these technologies is somewhere between 80 percent and 95 percent, which is to say that the text contained in this box would have at least 40 mistakes.

Many experts have questioned the wisdom of using technologies that require either extensive training or the power of hundreds of desktop computers to enter "the patient complains of nausea" in the patient record with 95 percent accuracy. It is likely that successful implementations of these technologies will be a hybrid of recognition technologies with other human-computer interface approaches. One example of this is the PEN-ivory system.² "The computer displays an encounter form with groups of descriptive terms on it. When a term is chosen, PEN-ivory guides the clinician through progressively deeper levels of description by displaying additional terms appropriate for the original choice. For instance, circling "cough" brings up a display with "severity," followed by choices of "mild, moderate, severe" and similar sets of choices for "onset," "frequency," and other criteria. The system must recognize gestures such as circling of terms or crossing them out, but it need not directly recognize handwriting. The program compiles a paragraph of plain English text from content determined by the clinician's choices and transfers it to the patient record. Similar *structured data entry* approaches have been employed in speech recognition systems, and they have an added benefit of helping to standardize medical terminologies and descriptions in the patient record. The success of such an approach depends on the details of its design and the preferences of its users. Some hybrid recognition systems are constraining and inflexible, while others are developing into fast, reliable transcription systems.

In any system that transforms ideas or words into permanent records, there is a tradeoff between two different conveniences: users want perfectly accurate transcriptions of their ideas, but they also want perfect flexibility to structure or amend the ideas as they choose. The competition for speech and handwriting recognition systems is provided by pens, pencils, and paper, which have achieved both of these goals admirably for many years.

SOURCE: Office of Technology Assessment, 1995

¹R.C. Johnson, "Speech Recognition Popping Up All Over," *Electronic Engineering Times*, Feb. 6, 1995, P. 35.

²A.D. Poon and L.M. Fagan, "PEN-Ivory: The Design and Evaluation of Pen-Based Computer System for Structured Data Entry," *Proceedings of the Annual Symposium on Computer Applications in Medical Care*, vol. 18, 1994, pp. 447-451.

Unfortunately, gathering data from medical monitors is not a straightforward task because different devices use different communication protocols and physical connections. Box 2-3 describes the *Medical Information Bus* standard that is a proposed solution to this problem.

■ Data Distillation Tools

Collecting clinical data as they are generated is only the first aspect of the difficult problem of assembling digital patient records. As health care professionals manually enter data in conventional paper records, they perform several crucial but implicit tasks. They make judgments about the validity of the data, often mentally filtering a rapidly changing display or perhaps reconciling readings from one instrument with those of other instruments measuring the same quantity. They certify data as relevant by entering them in the record and reject aberrant observations, such as heart rate measurements made on a patient having a fit of coughing. They convert the data into a standard format, with the physical layout of paper forms serving as an interface that structures the information and highlights its important parts for doctors and other clinicians. Professionals think about what the data they are recording indicate about the patient's condition. Finally, they alert other caregivers if their observations suggest a critical condition.

Data distillation is an informal label for the application of a set of diverse information technologies in the attempt to automate these secondary functions traditionally performed as rapid, skilled human judgments. One expert has observed:

The great mass of useful numbers we generate by computer has got to be tamed and controlled. We have learned how to make the measurements. Now we must learn how to han-

dle the resulting data and present them in understandable terms. Used right, automation can integrate these data, simplify them, scan and evaluate them. Automation is not a cold-blooded monster-machine between us and the patient. It is a tool to expand our medical power, to let us get closer to the patient, and take better care of him.⁶²

Concerns about how to extract meaning from a perceived flood of health data are not new. They were mounting even in the early 1900s when Harvey Cushing began arguing for the necessity of regular monitoring of blood pressure.⁶³ Data distillation technologies can help refine problematic medical data and inform clinical decision-making. In administrative and research contexts, they can also be used to discover patterns and correlations within massive compilations of health information, an undertaking less tractable to manual human effort.

Early computerized attempts to distill clinical data sometimes tried to fully automate the diagnostic process. The programs asked the clinician a set of questions about a patient and then used the answers to navigate among a branching set of mutually exclusive alternative diagnoses. They then delivered the conclusion in oracular fashion; unfortunately, the conclusions were sometimes wrong, and few doctors suffer oracles gladly. These *logical decision-tree systems* overlooked not only the complexity, but the subtlety of medical decisionmaking.

More recent systems attempt to support clinicians' thought processes, rather than supplant them. Three types of data distillation systems in common use are pattern recognition systems, neural networks, and knowledge-based expert systems. *Pattern recognition* is frequently used in medical monitors to recognize emerging trends.

⁶² J.J. Osborne, "Computers in Critical Care Medicine: Promises and Pitfalls," *Critical Care Medicine*, vol. 10, 1982, pp. 808-810.

⁶³ H. Cushing, "On Routine Determination of Arterial Tension in Operating Room and Clinic," *Boston Medical Surgical Journal*, vol. 148, 1903, p. 250, as cited in R.M. Gardner, "Medical Data: Their Acquisition, Storage, and Use," *Medical Informatics: Computer Applications in Health Care*, E.H. Shortliffe and L.E. Perreault (eds.), G. Wiederhold and L.M. Fagan (assoc. eds.) (Reading, MA: Addison-Wesley, 1990), p. 369.

BOX 2-3: Automated Data Collection and the Medical Information Bus

One of the challenges of assembling a fully digital patient record is finding ways to transfer into it the wealth of physiological information generated at the bedside by sophisticated medical monitors. One solution is to let the pulse oximeters, ventilators, IV pumps, and other devices do the job themselves. In fact, most monitors could already do so if they could communicate with the hospital's computers: many bedside monitoring and therapeutic devices have, hidden (and forgotten) on their back panel, tiny communications ports that can transmit in digital form the values displayed as numbers, lights, and bar graphs on the front panel of the instrument. What is missing is agreement among manufacturers about how that port should be designed and how it should exchange data with other machines. Such agreements are difficult because different types of medical devices generate data in widely varying amounts, qualities, and formats, and the communications interface must be implemented inexpensively so that it represents only a small portion of the overall cost of the least expensive instruments.

Vendors of clinical data management systems often design proprietary adapters and software modules to link their computers to individual medical devices. When new monitoring devices are acquired in an intensive care unit, the interface software and hardware must usually be procured from the computer vendor. While this may be an adequate solution for some settings, one director of clinical computing at a major hospital has said, "What happens to us as users is that: 1) we pay a premium price for compatible devices that we are forced to buy from the primary manufacturer, 2) we do not get the monitoring or measuring device at all, and 3) we are not able to integrate the data from multiple devices conveniently." While this grim assessment may not reflect everyone's viewpoint, it is clear that the lack of industry-wide interface standards for medical devices has held back wide-scale connection of bedside devices to the broader hospital information infrastructure.

Consensus messaging standards such as HL7 (see box 2-8) and the *IEEE P1073 Medical Information Bus (MIB)* standard may be one solution to this problem. The MIB committee is a group of doctors, vendors, medical engineers, and information system specialists that is seeking to address the problems inherent in proprietary and custom-device networking approaches by establishing a common standard for the hardware and software used to communicate between medical devices. The MIB standard is conceptually similar to standards that have been developed for communication among electronic devices in airplanes, and it incorporates many existing standards from other areas of communications and computer design. The standard describes three types of "controllers" that comprise a medical device network. Every medical monitoring device is associated with a device *communications controller*

(continued)

Electrocardiogram monitors, for instance, often average the shape of a patient's ECG trace for about 20 heartbeats in order to build a profile of a "normal trace." Subsequent traces are then compared to the normal trace; if they differ significantly, they are classified as aberrations and an alarm can be passed on to a caregiver. Moreover, the aberrant signals can themselves be sorted ac-

cording to their shapes and a library assembled of arrhythmia specific to the patient. Further traces are then compared to the patient's own customized library of heart problems, and the urgency of an alarm matched to the severity of the abnormality.⁶⁴

Another type of pattern recognition can be implemented using arrays of interconnected simple

⁶⁴ Gardner, "Patient-Monitoring Systems," *Medical Informatics: Computer Applications in Health Care*, *ibid.*, p. 382.

BOX 2-3: Automated Data Collection and the Medical Information Bus (Cont'd.)

housed in an external adapter connected to an existing communications port or incorporated Internally, perhaps on a single special-purpose integrated circuit. Every patient is associated with a *bedside communications controller* located in a bedside computer. Caregivers can quickly connect multiple medical devices to the bedside computer in a star topology and then disconnect or Interchange them without turning off the power. Each device identifies itself unambiguously to the bedside controller and automatically establishes communication when it is plugged in. The cables and modular connectors are standardized so that medical devices can be redeployed rapidly much like telephones, modems, and answering machines in the home.

A *master communications controller* connects the various bedside communications controllers with each other and with the rest of the hospital information infrastructure through standard Ethernet or Token Ring networks. Two-way communications among these three controllers provide the means for automatic transfer of data from bedside devices into the patient record and allow device settings to be adjusted remotely. They also facilitate full integration of bedside data with data from other sources in the institution and enable cooperation between devices and systems. Additionally, future devices will likely Incorporate lights on the front panel that indicate whether reliable communication has been established, and textual messages such as the name of the medication in an IV pump.

Software applications running on device, bedside, and master communications controllers will communicate among themselves by sending messages whose syntax is specified by a new object-oriented *Medical Data Device Language (MDDL)* defined by the IEEE PI 073 standard. The MDDL is one of many consensus messaging standards discussed elsewhere in this report that are used to mediate information flows within health care institutions,

KEY: IEEE = Institute of Electrical and Electronics Engineers

SOURCES: M.M. Shabot, "Standardized Acquisition of Bedside Data: The IEEE P1073 Medical Information Bus," *International Journal of Clinical Monitoring and Computing*, vol. 6, No 4, 1989, pp. 197-204, R M Gardner et al , "Real Time Data Acquisition: Experience with the Medical Information Bus (MIB)," *Proceedings of the Fifteenth Annual Symposium on Computer Applications in Medical Care*, vol 15, 1991, pp. 813-817, and J. Wittenber and M.M. Shabot, "The Medical Device Data Language for the PI 073 Medical Information Bus Standard," *International Journal of Clinical Monitoring and Computing*, vol 7, No 2, 1990, pp. 91-98.

¹R.M. Gardner, "Federal Medical Device Regulations What Are the Implications for Respiratory Care?" *Respiratory Care*, vol. 33, No 4, 1988, pp. 258-263

processors⁶⁵ called *artificial neural networks*. Each processor makes a simple calculation based on the values of a small number of input variables that might be physiological measurements for a patient. The output of the calculation for each processor serves as the input for other processors in the network. The network can be trained by using its overall output to adjust the strengths of the connections between various processors. Ideally, a neural network might be exposed to comprehen-

sive sets of physiological data gathered from many patients who died from sudden pulmonary embolisms, and then trained through the feedback process until its output is consistent for all the patients. If that feat could be accomplished, the network would then have "learned" which features in the data set reliably indicate imminent pulmonary embolisms, and it could then be used to monitor other patients. One problem is that comprehensive, comparable data sets covering multiple pa-

⁶⁵The processors are usually simulated in software rather than being discrete electronic chips.

tients are very rare. One of the benefits of digital recordkeeping might be the compilation of data sets that could be used to train artificial neural networks for clinical decision support.

Most of the decision support systems that issue alerts and warnings based on clinical data are *knowledge-based systems*, which attempt to interpret information about a patient using expertise captured in a computerized database known as a knowledge base. In a simple implementation, appropriate actions or diagnoses for a patient could be identified by matching words used by doctors in their written encounter records with terms found in a library of disease descriptions or known patient cases. More typically, expertise is captured as a large set of *heuristics* (rules of thumb) rather than as textual descriptions. *Knowledge engineers* design these *rule-based expert systems* by interviewing medical experts and constructing rule sets based on the experts' practical experiences and insights, institutional policies, and the medical research literature. A typical rule used with a ventilator might read, "If a patient's spontaneous breathing rate changes by more than 10 percent and the change is larger than five breaths per minute and the breathing rate is between 0.5 and 70 breaths per minute and the ventilator mode was changed within the last minute, then bring the change to the attending physician's attention."⁶⁶ An *inference engine* coordinates the process of obtaining information from the patient record or clinician, finding applicable rules, and reconciling the conclusions of multiple rules if the clinical data match more than one. Expert systems work well in narrow application areas such as determining appropriate antibiotic treatments. They are less successful in supporting decisions in broadly

defined application areas because it is difficult to define and maintain a complete, up-to-date set of rules. One implementation of a rule-based expert system in a hospital setting is the HELP system, profiled in box 2-4.

Distillation tools are also important for health administration and research after clinical and administrative data have been abstracted from individual records and stored in large institutional databases. *Relational databases* organize data into sets of two-dimensional tables and allow users to retrieve information from specific rows and columns in the tables using brief requests in a *query language*. While a relational database might be used to store the clinical and administrative data for the patients in an HMO, the data really represent a complex multidimensional data set. It might be very difficult, for instance, to assemble with a query all the data necessary for a cost-of-care analysis of a set of interventions using several different measures of resource consumption over time in different units of the HMO. *Online analytical processing* is a database query technique that is optimized to support decisionmaking using information from complex, multidimensional data sets.⁶⁷ Querying techniques find sets of records within a database that fit a desired pattern. *Knowledge discovery* techniques address the opposite problem: they attempt to identify patterns useful for describing a specified data set. For instance, a typical medical research data set generated in a multiclinic randomized trial designed to study surgical interventions to control lipids contributing to atherosclerosis included 1,400 variables measured on 838 patients for 7 to 14 years.⁶⁸ Knowledge discovery techniques can be used to

⁶⁶ T.D. East, W.H. Young, and R.M. Gardner, "Digital Electronic Communication Between ICU Ventilators and Computers and Printers," *Respiratory Care*, vol. 37, No. 9, 1992, pp. 1113-1123.

⁶⁷ A. Radding, "Blue Cross Climbs Mountain of Data with OLAP," *Infoworld*, Jan. 30, 1995, p. 64.

⁶⁸ H. Buchwals et al., "The Program on the Surgical Control of the Hyperlipidemias," *Surgery*, vol. 92, No. 4, 1982, p. 654.

BOX 2-4: The HELP System

Clinical information systems built around computer-based patient records have the potential to improve the quality of health care. They can help clinicians manage complicated medical situations and make informed decisions involving many variables and complex calculations. Such systems can help Institutions evaluate and standardize the way clinicians deliver care. They also can facilitate the development and evolution of clinical policies and procedures based on the latest research results, on measured links between clinical outcomes and practices, and on considerations, such as local pathogen trends, that may be unique to a particular institution. One example of a clinical information system that achieves some of these benefits is the HELP (Health Evaluation through Logical Processing) system. HELP consists of several logical modules that support data collection and delivery at the point of care and provide a rich system of reminders, alerts, and prompts based on clinical protocols for care of specific disease conditions.

The primary installation of HELP is at LDS Hospital in Salt Lake City, Utah, a private, 520-bed, tertiary-care hospital and teaching center associated with the University of Utah School of Medicine. The HELP system was developed at LDS over a long period of time with direct involvement of clinicians (including nurses and therapists as well as physicians), researchers, and administrators in the design of the system. LDS Hospital is part of the nonprofit Intermountain Health Care, Inc., chain of hospitals and outpatient clinics in Utah, Idaho, and Wyoming. The HELP system is being installed at numerous locations within the Intermountain system and at several other hospitals around the nation. It is distributed commercially by 3M Health Information Systems of St. Paul, Minnesota.

The HELP system at LDS is installed on a centralized group of twelve fault-tolerant processors linked through other computers to over 1,000 terminals at patient bedsides and other sites throughout the hospital. Nurses, physicians, respiratory therapists, and others enter data manually through keyboards as a combination of multiple choice selections, number entry, and some free text entry. In the intensive care unit, many of the medical devices, such as ventilators and pulse oximeters, are linked directly to the HELP system. Patient information is stored in a central patient database connected to the medical records department, radiology and surgical units, and many of the laboratories and other departments. The system processes an enormous amount of information, including over 18,000 data entry items per day for respiratory care alone.

Each data entry is screened by a decisionmaking processor against a series of protocols stored in a separate medical knowledge base. The protocols are derived from the published literature and from consensus opinions of experts at LDS and at other institutions. They are also derived from analysis of the clinical results for selected groups of LDS patients. The protocols may be simply algorithms for calculating derived quantities from measured variables in order to save time and reduce errors. They may also be decision criteria that recognize and alert clinicians to potential drug allergies, drug-drug interactions, drug selection and dosing problems, organ dysfunction, or critical changes in laboratory or physiologic parameters. Costs and charges for clinical care are routinely computed and displayed for all chargeable items and for all nonphysician personnel time.

Managing a complex clinical situation such as ventilator support of respiration can involve consideration of hundreds of potential variables and sources of information. HELP protocols rationalize and systematize that process. They are developed by small working groups, first as flow diagrams on paper and later as software code. Protocol calculations and recommendations are displayed on bedside terminals and incorporated into printed documentation including shift reports, daily rounds reports, weekly reports, daily administrative and management reports, and final reports when patients are discharged. Clinicians may deviate from the recommendations of the protocols, but typically they must justify their

(continued)

BOX 2-4: The HELP System (C

decisions with defensible reasons apart from personal style preferences. The quality and efficacy of the protocols are continuously monitored through daily log reviews, on-call reports, and personal feedback from clinicians to the working group.

One application of HELP protocols has been the empiric design of antibiotic therapies. Antibiotics can be targeted to a patient's specific pathogens once they have been identified through microbiological tests, but it is often impractical to wait for the results of laboratory cultures before beginning antibiotic therapy. Broad-spectrum antibiotics (which are more expensive than single-agent antibiotics) are often prescribed in this situation, and HELP protocols have been developed that recommend one or more antibiotics effective against the most probable pathogens at the lowest possible cost. They use data from the computer-based patient record and infection-specific Information and identify the most likely pathogens on the basis of those identified in patients with similar characteristics during the previous five years and the most recent six months. The recommendations are tailored to the infection site and to the patient's allergies and renal problems. The data are updated every month to provide trend analysis of pathogens and antibiotic resistance patterns within the hospital. Clinical trials have shown that physicians using the protocols prescribe regimens that cost less, utilize fewer antibiotics, and cover a broader range of pathogens than those recommended by physicians in the absence of decision support.

HELP protocols have also been used to contribute to the quality of clinical research through standardization of the care process one example involves randomized clinical trials at LDS comparing two therapies for patients with adult respiratory distress syndrome (ARDS). Mechanical ventilators are used to support the breathing of ARDS patients. Since their lungs are severely dysfunctional, high pressures and volumes of air are sometimes required to maintain sufficient oxygenation levels, but the vigorous ventilation can itself cause further lung injury. One alternative therapy revolves ventilation at lower frequencies and pressures and removal of CO₂ outside the body. Each ventilation technique is complicated and involves numerous adjustments of ventilator parameters throughout a month of care, comparison of the two therapies is extremely problematic unless the criteria for controlling the ventilators are standardized for a suite of patients. HELP protocols were developed that assured equivalent intensity of care for patients in trials of the two therapies. All the patients under protocol-guided care showed higher survival rates than expected from historical patterns, and the uniformity of care afforded by the protocols allowed direct comparison of the two ventilation therapies.

SOURCE: R.S. Evans et al., "Improving Empiric Antibiotic Selection Using Computer Decision Support," *Archives of Internal Medicine*, vol. 154, 1994, pp. 878-884, A.H. Morris, "Protocol Management of Adult Respiratory Distress Syndrome," *New Horizons*, vol. 1, No. 4, 1993, pp. 593-602

find useful correlations or causal connections among the variables in such large databases; the correlations that are found can then serve as a knowledge base for a rule-based expert system.⁶⁹

■ Storage and Compression Technologies

Clinical monitoring and imaging devices spawn copious amounts of data. For example, pulse oximeters report with every heartbeat the con-

⁶⁹J.M. Long et al., "Automating the Discovery of Causal Relationships in a Medical Records Database," in *Knowledge Discovery in Databases*, G. Piatetsky-Shapiro and W.J. Frawley (eds.) (Menlo Park, CA: AAAI Press/The MIT Press, 1991), pp. 465-476.

TABLE 2-2: Storage Requirements for Imaging Techniques

Modality	Image size (pixels)	Dynamic range (bits)	Average number of images per exam	Average storage requirement per exam (MBytes)
Computed tomography	512 X 512	12	30	15.0
Magnetic resonance imaging	256 X 256	12	50	6.5
Digital subtraction angiography	1,000x1,000	8	20	200
Digital fluorography	1,000x1,000	8	15	150
Ultrasound imaging	512 X 512	6	36	9.0
Nuclear medicine	128 X 128	8	26	0.4
Computed radiography	2,000 x 2,000	10	4	32.0
Digitized film	4,000 x 4,000	12	4	128.0

SOURCE: Adapted from K.G. Baxter et al., "Wide Area Networks for Teleradiology," *Journal of Digital Imaging*, vol. 4, No. 1, 1991, pp. 51-59

centration of dissolved gases in the blood. Transferring this oxygenation data directly into the record would generate about 1.5 million bytes of information per day per patient—equivalent to about 400 pages of numbers—and the majority of the data would never be accessed again.⁷⁰ Institutions that develop systems for rapidly collecting and distilling large quantities of health information will need to judiciously moderate their appetites for information and refine their skills for determining which data can be safely discarded. Nonetheless, the demand for permanent storage of patient records is growing rapidly.

Some storage technologies make selected portions of patient records portable. Many institutions issue the ubiquitous *magnetic stripe card* to their patients for identification purposes. These can store about 250 text characters, enough to hold a patient's name, address, identification number, date of birth, copayment information, and a brief password. They are widely used in combination with low-speed modem networks to verify patients' eligibility for insurance benefits. *Smart cards* are the same size as credit cards, but they have embedded computer chips and enough static memory to hold several pages of textual informa-

tion. *Laser optical cards* have an even greater storage capacity, although once information is written onto the cards it typically cannot be altered or supplemented. None of these card technologies can replace computer-based patient records because they are vulnerable to loss and fail to provide continuous access to an individual's health data. They may be widely employed, however, to carry emergency medical information and the demographic information necessary to coordinate a patient access to services at multiple sites. Smart cards have been used in several states to coordinate delivery of multiple social programs, such as Medicaid and the Women, Infants, and Children nutritional program (WIC), and to replace paper vouchers and food stamps.⁷¹ They are widely used in European health care systems. An infrastructure of smart card readers has not developed yet in the United States, largely because the existence of a reliable and relatively cheap telecommunications system has made modem communications and magnetic stripe cards a more attractive way to exchange small amounts of data.⁷²

The storage requirements for textual and numerical data in patient records are dwarfed by the storage space requirements shown in table 2-2 for

⁷⁰ East et al., op. cit., footnote 27.

⁷¹ Phoenix Planning and Evaluation, Ltd., op. cit., footnote 16.

⁷² Card technologies are discussed more fully in chapter 3, box 3-4.

BOX 2-5: Digital Image Compression

Image compression technologies play a crucial role in enabling the efficient storage and inexpensive dissemination of medical images. The digital images shown in this box are representations of dental x-rays (for illustrative purposes, they have been digitized with a far lower resolution than usual radiographic images). The top image occupies approximately 96,000 bytes of storage space on a computer disk. The second image occupies only 21,000 bytes of storage space; it has been compressed using a compression standard known as *JPEG* (Joint Photographic Experts Group). The two images are virtually indistinguishable, but subtracting one image from the other (and enhancing the contrast of the result) reveals the information that was lost in the compression, as shown in the bottom image. This difference image would be a uniform white if the compression were *lossless*. Instead, the image contains delicate grey patterns that represent some of the subtle details present in the original image but missing from the compressed image.

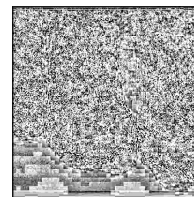
The apparent similarity of the top two images is largely an artifact of the printing technology used in this report: the differences would be more noticeable had the films been reproduced on a high-resolution image setter. Similarly, the appropriateness of compression in hospital settings depends on the display technology used to present the image. To reproduce the enormous dynamic range and spatial resolution of traditional photographic films, radiological images used for interpretive diagnosis are typically sampled 2,000 times per inch and displayed on expensive high-resolution monitors. Compression techniques that result in any loss of detail may be inappropriate for display of such images. Medical images are used in many other less demanding contexts, however. For instance, the referring physician may wish to discuss the image with the radiologist over the telephone while viewing it on a desktop computer monitor that is incapable of displaying the subtleties of the image, even if they were present in the file. JPEG or other compression technologies are often used in situations like this to reduce



Original Image
96kBytes



Compressed Image
21kBytes



Difference
(contrast enhanced)

(continued)

medical images such as x-rays, magnetic resonance images, and computed tomography scans. These new imaging technologies challenge the ability of information systems to store and process data, but they enable the development of new generations of highly localized surgical and radiation therapies that otherwise would not be possible. The computational resources necessary for medical imaging will continue to grow with the increasing use of high-resolution spatial imaging, in which multiple images are assembled into a

three-dimensional model, and with the development of *functional imaging*, where processes such as the rate of oxygen metabolism in a particular body structure are studied by assembling multiple copies of the same image over time.

Conventional films from x-ray and nuclear medicine images are converted to electronic form using laser digitizers, but many other imaging technologies produce digital images from the outset. In some cases, images are compressed using technologies like those described in box 2-5 to re-

BOX 2-5: Digital Image Compression (Cont'd.)

the size of an image file by a factor of 10 or more. Minimizing the size of image files is even more important when they are to be transmitted to a remote site over a telemedicine link or modem because compression can drastically reduce the cost and the elapsed time necessary to transmit the image

Compression technologies work by eliminating redundant information in images. Natural images contain coherent patterns: colors and tones usually change slowly across the width of an image. When an image is relatively free of noise (like the "snow" on a television screen), the intensity of each tiny area (a pixel) in the image is often related to the intensity of its neighboring pixels. For instance, if the numbers 1 to 9 are used to represent the tones from black to white, then a series of pixels in the dental x-rays above that cross the boundary of the tooth might be represented by the string of numbers: 11111111133399999999. A simplistic method for compressing the sequence of greys is *run-length encoding*, in which the string could be replaced by the much shorter string: 91 '33 '89, that is, "nine 1's, followed by three 3's, followed by eight 9's."

Practical schemes for image compression are much more sophisticated. The JPEG compression used for the dental images divides the image into cells containing 64 pixels. Within each cell, the components of the picture that vary quickly across the cell are separated from those that vary slowly. The high-frequency components are suppressed or discarded; they appear as the rapidly varying grey and white pattern in the bottom image above. Remnants of the 64-pixel cells are also visible in the bottom dental image.

Compression technologies are used extensively to store and transmit digital medical images. They have become very fast and inexpensive as a result of the intensive development efforts by computer and communications companies seeking ways to efficiently transmit digitized images and video for publishing and broadcasting.

SOURCE: Office of Technology Assessment, 1995.

duce transmission times and storage space requirements. Medical images are typically stored and manipulated on large hard drives, similar to those in desktop computers, and then transferred to digital tape, magneto-optical disks, recordable CD-ROMs, or COLDS (Computer Output to Laser Disks) for archival storage. The latter three technologies use light beams to store and record information on durable plastic or magnetic disks. Although the disks themselves are likely to last for many decades, it is not clear that the equipment necessary to read the disks will be manufactured throughout the life of the medical information.

Medical imaging is an ideal domain for integration of information technologies. The various imaging machines are expensive and so highly specialized that no single vendor can impose proprietary standards on vendors of different types of

machines. The imaging machines can share the same type of displays and data manipulation computers, however, and this has encouraged the development of broad data exchange standards. Radiology and nuclear medicine are consultative disciplines, but since the images need not be interpreted at the site where they are collected, consultations can be carried out at a distance or even over telemedicine links. Radiologists usually examine images displayed with the highest possible resolution, but primary care physicians who rely on their interpretations may also wish to have access to lower resolution copies of images in order to explain the interpretations to patients. Finally, an economic incentive exists for developing fully digital image storage: medical images are among the most commonly misplaced or unavailable records. Some 40 percent of all x-ray films are unre-

trievable, making it necessary to repeat imaging procedures and extend hospital stays.⁷³

Information systems that manipulate, store, and share digital medical images are called *PACS*, or *picture archiving and communications systems*. PACS typically capture data directly from an imager or a laser film digitizer, and then allow users to share and modify them using a computer, a communications network, a large storage system, and a high-resolution display. The communications between hardware components are governed by a mature standard for PACS developed by a committee of the American College of Radiology and the National Electrical Manufacturers Association.⁷⁴ The *DICOM* (*Digital Imaging and Communications in Medicine*) standard is one example of a communications standard. It defines common formats for data generated by imaging equipment and standard actions that can be performed on the images. It specifies how messages about the data and the processing actions can be exchanged among machines.

The DICOM standard also specifies approaches to compliance reporting and testing. Vendors that sell machines purporting to adhere to the DICOM standard must publish compliance statements indicating which portions of the standard are implemented. Hospitals can then compare compliance statements for all the equipment they purchase and build a functional PACS system using equipment from a variety of vendors. This is one example of how the development of industry-specific voluntary standards can help remove barriers to technology implementation.

The character of radiological practice is changing as PACS develop. PACS make it easier for primary doctors to consult radiologists, but they also

enable doctors to examine radiological images firsthand and make their own interpretations.⁷⁵ The development of PACS may eventually help transform radiology into more of a laboratory service than an independent medical discipline in hospitals.

■ Display and Retrieval of Data

Most hospital information systems use the normal graphical and textual interfaces found on desktop computers, thus exposing their legacy as primarily administrative information systems. It is not clear, however, that interfaces developed for administrative and business applications will be adequate for conveying the huge amount of clinical information that will become available if patient records are fully digitized. The stakes are high because floods of new data make it increasingly likely that people will overlook important parameters and make faulty judgments.

Consider the difficulties in presenting all the types of information in the patient record on a single computer display. One candidate for such a locus of information might be bedside *patient data management systems*, which are dedicated computers connected to various physiological monitors for a patient in an intensive care unit. Currently, they need to display physiological data from up to 10 monitors, either as text or waveforms. If those data are to be entered automatically into electronic records rather than summarized on paper forms, the interface must provide ways for users to attach vocal or textual annotations to the data.⁷⁶ If the bedside computer is to be linked to the broader hospital information systems, the interface must then be able to cluster associated data

⁷³ S.C. Horii et al., "A Comparison of Case Retrieval Times: Film Versus Picture Archiving and Communications Systems," *Journal of Digital Imaging*, vol. 5, No. 3, 1992, pp. 138-143.

⁷⁴ American College of Radiology, National Electrical Manufacturers Association, "Digital Imaging and Communications in Medicine (DICOM): Version 3.0," Draft Standard, ACR-NEMA Committee, Working Group VI, Washington, DC, 1993.

⁷⁵ H.L. Kundel, S.B. Seshadri, and R.L. Arenson, "Clinical Experience with PACS at the University of Pennsylvania," *Computers and Medical Imaging Graphics*, vol. 15, No. 3, 1992, pp. 197-200.

⁷⁶ E.H. Shortliffe and G.O. Barnett, "Medical Data: Their Acquisition, Storage, and Use," *Medical Informatics: Computer Applications in Health Care*, E.H. Shortliffe and L.E. Perreault (eds.), G. Wiederhold and L.M. Fagan (assoc. eds.) (Reading, MA: Addison-Wesley, 1990).

from a broad variety of sources according to patient status: if a patient has an electrolyte imbalance, for instance, all the relevant laboratory results, dietary information, and treatment orders should be displayed alongside blood chemistry data from a bedside analyzer. Because medical decisions are usually made with information from a wide variety of sources, including laboratories and radiology departments, the display must accommodate textual notes and display high-resolution images⁷⁷ and video.

By now, the display is getting a bit cluttered, but there is more. Clinical decision support might be implemented at the bedside so clinicians can be alerted to potentially dangerous situations, such as drug-drug interactions and critical changes in laboratory and physiological parameters. If so, then the screen must not only display the alerts, but provide contextual information so they can be evaluated; it will need to show an appropriate amount of historical data along with the current data. To enable clinicians to act on whatever decisions they make, the display must provide charting and order-entry forms. If administrative functions are integrated as well, the display will need to notify clinicians of the prices of the medications and lab tests they order, and display e-mail, calendars, and scheduling information. It must do all these jobs without the aid of the many tools and customizations that help users cope with desktop computers because bedside computers need a standardized interface to accommodate multiple users.⁷⁸ And on top of all that, the interface should provide for easy editing and annotation of all the types of information mentioned thus

far, as well as robust security and methods for clinicians to disavow data that they do not trust or deem irrelevant.

All of these objectives have to be accomplished on video monitors smaller than a standard piece of paper. In fact, the standard piece of paper remains the main competitor to video displays for most of the information tasks listed above, and many institutions that have implemented the most comprehensive computer-based patient records incorporate high-volume printing as their information distribution medium.⁷⁹ Printed pages can display up to 20 times more information in a given area than standard computer monitors.⁸⁰ Even computer displays with high-resolution graphic monitors often sacrifice much of the available display area to a plethora of semi-permanent “buttons” and other interface elements designed to receive information from users rather than convey information to them.

It is not clear that the display techniques suitable for desktop computers or current-generation patient data management systems are appropriate for high-bandwidth display of clinical information. Interface designers have developed very effective techniques for conveying complicated data to users (in aircraft cockpits, for example) and for receiving complicated data from users (via spreadsheets and word processors), and even for letting users browse within complicated data sets (through hypertext and graphical database front-ends). The medical environment is a curious mix of those three situations. Design approaches that are sufficiently capable may not yet have emerged. Many of the frustrations evinced in pilot

⁷⁷ Current monitors used at the bedside have neither the spatial resolution nor the dynamic range to display diagnostic-quality radiological images.

⁷⁸ This consideration is less critical for long-term users who might design customized presentation configurations to be displayed according to their preferences whenever they use a computer. Nonetheless, the basic functionality of the health information system and the accessibility and interpretability of data it presents must not rely on such customizations because the systems are often used by a rapidly changing ensemble of users with little time for training.

⁷⁹ C.J. McDonald et al., “The Regenstrief Medical Record: 1991 A Campus-Wide System,” *Proceedings of the Fifteenth Annual Symposium on Computer Applications in Medical Care*, vol. 15, 1991, pp. 925-928.

⁸⁰ This is a conservative estimate. For a discussion of high-density information display, see E.R. Tufte, *Envisioning Information* (Cheshire, CT: Graphics Press, 1990), pp. 37-51.

projects are due to inadequate solutions to human-computer interface problems. In the absence of new developments, the displays at the patient's bedside, the nursing station, and the physician's desktop are potentially "choke points" through which most of the benefits of a fully computerized patient record may fit only awkwardly. The advantages of the computer-based patient record may be elusive, if only because they cannot be envisioned.

■ Data Security

People reveal highly sensitive information to health professionals. If clinicians or institutions misuse or misrecord the confidential information, it might be used to restrict or revoke a person's health insurance or revise judgments of their suitability for a job or a loan. When such mistakes are made, it is often difficult for the individual to correct them or hold anyone accountable. Any new health data recordkeeping system must ensure that information is used appropriately or people will avoid using it. In a 1993 Harris-Equifax poll, 27

percent of those responding indicated that their personal health care information had already been improperly disclosed and 71 percent indicated that they felt that use of computers would need to be restricted in order for privacy to be protected.⁸¹

Several issues are involved. First, health information needs to be *confidential*: it should be used only for approved purposes and shared only among authorized people typically associated with the patient by a special relationship, such as the physician-patient relationship. Second, an appropriate level of privacy for the information must be established: some balance must be struck between an individual's right to keep information confidential and the benefits that can accrue to society if the information is shared more broadly. Finally, the records must have adequate *security*: administrative and technical measures must protect them from unwarranted loss, modification, or dissemination. Several technological approaches to securing electronic patient records by restricting access are discussed in box 2-6. Maintaining the privacy, confidentiality, and security of patient records presents organizational and political

BOX 2-6: Security Technologies

Appropriate use of health information can only be ensured if those trusted to use the information merit that trust. However, there are technological approaches to ensuring that the data cannot be inadvertently lost, damaged, or erased, and that they are only available to a defined community of users.

If a computerized patient record system is to operate without a paper backup system, it must function reliably all of the time. To ensure data integrity, computer systems often store critical data on *redundant arrays of independent disks (RAIDs)*. These arrays write data onto two or more hard disks simultaneously. In addition to providing a backup copy of the data, RAIDs also speed up the system, making data accessible from the disk that can retrieve them the quickest. One of the disks is taken offline for a few minutes once each day, and a copy of its contents can be transferred to a backup tape while the other disk continues to function, after the backup is completed, the disks are desynchronized. The data on the tapes are often transferred to magneto-optical or CD-ROM disks for longer term storage. Multiple copies may be made, with one copy remaining offsite. Redundancy is also used for the central processing units and other hardware components of *fault-tolerant computer systems* so that faulty compo-

(continued)

⁸¹ Louis Harris and Associates, A.F. Westin, *The Equifax Report on Consumers in the Information Age* (Atlanta, GA: Equifax, 1990).

BOX 2-6: Security Technologies (Cont'd.)

nents can often be identified and replaced without turning off the computers. Using these techniques, patient record systems have been designed that are available for use 99.5 percent of the time.¹

To restrict access to records to authorized personnel only, clinical personnel must enter their name and a personal password before accessing computer files. This restriction only works if the password cannot be overheard or easily guessed. Some systems either assign complex passwords or require that they be periodically changed, but this raises the possibility that the passwords will be forgotten or mislaid because they are more difficult to remember. More robust techniques require that authorized users possess some physical device in addition to a password. One such device is a handheld *authenticator*, which encrypts a user's password using a short string of text issued as a challenge by the host computer. The challenge text, and hence the expected response, can change with each attempted access to the computer. Alternatively, security systems might require that a device such as a *smart card* be inserted in the computer while files are being accessed. Finally, biometric identifiers such as a retinal scans or fingerprints can identify authorized computer users, although these techniques are rarely employed in health care institutions because they require expensive equipment.

Maintaining a usage log of all documents accessed and changed helps discourage improper use of records by unauthorized (or even authorized) personnel. The log can be scanned manually or automatically to detect attempts to log onto the system or change files, and its presence discourages such attempts. The integrity of a document and responsibility for its contents might be additionally certified by the use of *digital signatures*.

In principle, a hospital might choose to protect its patient records by using encryption techniques as well, making the information uninterpretable. It could encrypt data using *symmetric encryption*, where all users of the data would need to know a particular decoding password, or it might use *asymmetric encryption*, where the documents for a particular user are encoded with a well-known public key and decoded using a private key known only to the intended user. In practice, clinical documents and messages are intended for rapid access by multiple users; they are rarely encrypted because it slows down the processing and because an adequate public key infrastructure has not been established.

Health care institutions often connect their computers to broader networks of computers so their members can communicate via e-mail and have access to remote databases and internet resources. Separate computer networks are sometimes maintained to isolate patient records from these communications needs. Alternatively, *firewalls* may be put in place that stand between computer networks internal and external to the health care institution; firewalls are systems of computers and switches that restrict to approved locations the destination or source of data packets entering or leaving the hospital's network.

SOURCE: Office of Technology Assessment, 1995 Adapted in part from U S Congress, Office of Technology Assessment, *Information Security and Privacy in Network Environment*, OTA-TCT-606 (Washington, DC: U.S. Government Printing Office, September 1994)

¹Institute of Medicine, *The Computer-Based Patient Record: An Essential Technology for Health Care* (Washington, DC: National Academy Press, 1991), p 74

challenges as well as technical challenges; these issues have been discussed in detail in an earlier OTA report.⁸²

When institutional security standards governing the handling of paper-based patient records are inadequate, the records can easily be lost or viewed and copied without leaving any trace of the action. Still, while the confidentiality of paper-based records is easily compromised by authorized people who misuse their access to patient information, the sheer bulk of paper records helps keep them private: information is not easily abstracted from paper records. The fluidity of computer-based patient records, however, makes securing their confidentiality more problematic.

One of the benefits of computer-based records is that information can be used for multiple purposes. The effectiveness of a certain AIDS treatment might be evaluated, for instance, by comparing the outcomes of various treatments for a panel of individuals enrolled in a controlled study. Unfortunately, even if patients' names are removed from copies of the relevant information extracted from their records, their identities can often be determined by correlating the data with information in other publicly available electronic databases. One challenge is to develop identifiers for patients and providers that will allow medical data to be exchanged among various information systems without compromising the patients' privacy.

In addition to developing unique identifiers, a set of privacy principles need to be established that govern who can access health information and how they may use it. Many private and public sector groups have developed strategies and policies for protecting the privacy of health information. For example, the Privacy Working Group of the Information Policy Committee, Information Infrastructure Task Force has published a set of draft

principles for providing and using personal information in all contexts, including health care applications.⁸³ Among other provisions, these principles direct those who plan to collect personal information to assess the impact of those plans on individual privacy and to limit the amount of information collected to that necessary for their immediate use. In addition, they should inform individuals why their information is being collected, how it will be protected, and how it will be used, and they should take reasonable steps to prevent the disclosure or improper alteration of personal information. The principles also charge individuals with the responsibility to understand the consequences of releasing personal information and to discern how and why their information is being collected. The working group's principles encourage both education about the uses of personal information and the establishment of rights of redress for privacy abuse. Legislative action may eventually be appropriate to guarantee the privacy of health information as consensus develops on appropriate policies.

■ High-Bandwidth Communications

Without telecommunications and networking technologies, information is confined to the computer in which it is created. In addition to the traditional uses of telecommunications for phone conversations and paging, there is an increasing need for remote communications to transfer digital health information. Physicians might wish to use computers at home to track the status of patients or receive notification of important lab results. Group practices might submit batches of insurance claims to data-processing intermediaries electronically and remind patients of upcoming appointments using automated phone systems. The term "house call" might reenter the

⁸² U.S. Congress, Office of Technology Assessment, *Protecting Privacy in Computerized Medical Information*, OTA-TCT-576 (Washington, DC: U.S. Government Printing Office, September 1993).

⁸³ Office of Management and Budget, "National Information Infrastructure: Draft Principles for Providing and Using Personal Information and Commentary," *Federal Register*, vol. 60, No. 13, Jan. 20, 1994, pp. 4362-4370.

medical lexicon with the advent of in-home medical monitoring devices for elderly or chronically ill patients, devices that can deliver basic physiological information to doctors via modem. Hospitals might link their information systems to remote medical databases or support videoconferencing and telemedicine applications to broaden their base of patients in the community. Integrated health delivery institutions might link computers at various sites into a single wide area network. *Community health information networks (CHINS)* might link various clinical institutions, components of the public health system, private medical practices, payers, data repositories, and academic institutions so that health information can be shared on a regional basis. The telecommunications and networking technologies underlying these new health information applications are surveyed in box 2-7.

Individuals are also beginning to use telecommunications and networking technologies to gain access to medical information. One of the most prominent applications of broadband commu-

nications is the delivery of educational materials via the international network of computers known as the *Internet*. Individuals can learn about health issues and correspond with others who share common interests by joining *electronic mailing lists* dedicated to discussions of specific medical conditions. Many health care providers now provide educational materials for patients, consumers, and doctors through *World Wide Web pages*, which are collections of pictures, text, sound, and video along with links to related information on other computers. The OncoLink Multimedia Cancer Resource web page at the University of Pennsylvania is shown in figure 2-2. From this page, computer users can navigate to many other pages that give them information about cancer terminology, ongoing clinical trials, how to prepare for a hospital visit, and many other topics.⁸⁴ There is no incremental charge to access this or any of the hundreds of other web sites offering medical and health information on the Internet. However, a home computer and modem are required, as well as access to the network through an account pur-

BOX 2-7: A Voice and Data Communications Primer

How can computers in different parts of the country be connected to each other so they can share health information? One way to answer this question is to start with an understanding of how ordinary telephone calls work. When a caller speaks into a phone mouthpiece, a microphone converts the sounds into smoothly varying analog voltages, which then propagate along wires to the earpiece in the distant phone where they are reconverted to sound. The wires from the two phones are connected by a series of switches. If the two phones are within a hospital, the call will probably pass through just one switch, within the *private branch exchange (PBX)* owned by the hospital. If the call's destination is outside the hospital, the PBX will pass it on to an external switch owned by a *local exchange carrier (LEC)*, which is typically a regional Bell operating company. If the receiving phone is connected to the same switch, the call goes through. Otherwise, it is passed to other switches owned by the same LEC within a *LATA (Local Access Transport Area) region*. The United States is divided into 137 LATAs of various sizes; to go beyond the boundaries of a single LATA, the call must be passed to an *interexchange carrier*, such as AT&T, MCI, Sprint, WilTel, or others. At the far end, the call must again pass through the series of switches owned by a different LEC until it arrives at its destination.

(continued)

⁸⁴“OncoLink,” University of Pennsylvania, April 1995. <URL:<http://oncolink.upenn.edu>>

BOX 2-7: A Voice and Data Communications Primer (Cont'd.)

LECs and interexchange carriers would have to maintain millions of sets of wires if all phone calls were passed along as analog signals. Instead, the signal is usually digitized shortly after it leaves the originating phone, often before it reaches the first switch. Many digitized signals can be easily mixed together or *multiplexed*, carried on a single set of wires, and then separated at the destination. Moreover, the signals needn't travel along wires: they can also be carried as pulses of light along fiberoptic cables or as microwave signals between land stations or satellites. Digital communication links are more robust than analog ones—they are more immune to noise and require less frequent reamplification of the signals. If a hospital has a digital PBX or it wants to connect computers at different sites, its administrators might choose to bring a digital line right into the facility. The capacity or *bandwidth* of such a connection is typically measured by the number of normal voice connections it can carry: a DS-0 connection (64 thousand bits per second) can carry a single voice connection; a DS-1 or T1 connection (1.544 million bits per second) can carry 24 phone conversations; a DS-3 or T3 connection (45 million bits per second) can carry 672 voice conversations, and so on. Various fractional levels between these capacities can be ordered as well. A typical x-ray image could be transferred over a DS-0 connection in about eight minutes, over a DS-1 connection in about 20 seconds, over a DS-3 connection in about 0.7 seconds, and over the high-capacity cross-continent "backbones" in a few milliseconds. The bottleneck in telecommunications is the slowest connection.

A caller initiates a connection by lifting the telephone handset from its cradle. The phone sends an "off-the-hook" message to the nearest switch, which responds with a dial tone. The caller then presses a sequence of touch-tone buttons, and the switch listens to the tones and figures out how to route the call. This is called *in-band switching* because the caller can hear the dial tone, dialing, and pauses on the same connection that will later carry the voice conversation. Some types of digital connections have *out-of-band switching*, where separate connections carry the switching information. For instance, a basic rate *integrated services digital network (ISDN)* line contains two DS-0 channels for the messages and an additional lower capacity channel for the switching signals. When the handset is lifted, the connection to the receiving party is established almost immediately. The familiar whistle and rasp of modems may become rare as basic rate ISDN lines become more common in homes and businesses. Currently, ISDN modems can transfer digital data onto the wider telecommunications system about six times as fast as a typical modem. ISDN services cost only a little more than normal phone lines on a monthly basis, but they are less convenient to set up and require more expensive equipment. ISDN lines with capacities up to DS-1 are also available, again with separate switching and data (or voice) channels.

All the connections discussed so far link remote phones or computers through a series of switches. Often a facility doesn't need that switching capability, however. It may have a pair of computers or PBXs at two sites that it wants to connect without allowing any other outside connections. In that case, it may choose to have a *dedicated* or *leased line* installed between the two sites.

Normal telephone calls carrying voices typically occupy an entire channel for the duration of the conversation—other users wanting to contact the recipient get a busy signal. Voice calls are usually *connection-oriented* because momentary disconnections or imperfections in a conversation are annoying. However, it is not easy to annoy a computer; communications between computers are often intermittent or even connectionless, which means that no constant link between a particular set of originating and receiving computers is maintained. Digital data exchanges often consist of bursts of intense activity surrounded by periods of silence. *Packet-based communications* exploit this pattern by inter-

(continued)

BOX 2-7: A Voice and Data Communications Primer (Cont'd.)

leaving the communications of whole sets of computers at once. Data streams are broken up into *packets*, and each packet contains a destination address indicating where it should go. Packet-based communications are commonly used within *local area networks (LAN)*, which connect a limited number of computers within an institution in a loop or branching structure. Digital signals on LANs may pass along copper wires resembling phone wires or cable-TV cables, or through the air as radio or infrared signals on *wireless LAN* connections. Often several LANs within an institution are connected into an enterprise network by a high-speed *backbone* that sometimes utilizes fiberoptic cables.

Packet-based communications can be used for telecommunications as well as for computer networking, especially when data rather than voices are being conveyed. A long message might be broken up into a huge number of packets. Each packet wends its way through the telecommunications network, guided by *routers* along the way. Computers prepare the packets according to networking protocols published by network vendors or by standards committees. Depending on the protocol, packets can be guided along predefined routes, or they may take different routes to the destination and experience different delays along the way, but be reassembled by the receiving computer into the correct order.

Different computer networks utilize different packet formats and protocols; the packets on different networks might be different sizes or have different addressing schemes. It is inconvenient for a computer launching a packet to have to know what sort of packet is expected by the receiving computer, which might be thousands of miles away. Sometimes this problem is solved by having all parties on the network agree on a common standard such as the *TCP/IP protocol* (Transmission Control Protocol/Internet Protocol) used for communication among computers in the worldwide *Internet*. Still, it is often necessary to transfer packets from one network to a different network with a different protocol. One way to do this is to employ a sort of diplomatic pouch called *frame relay*: packets traveling on the high-capacity telecommunications network are wrapped in standard envelopes or frames and then unwrapped at the receiving end into whatever packet format is required. The frames may have various lengths depending on the size of the packet inside. Frame relay communications work well for transferring data files such as x-ray images, but they are less effective for transferring video streams because unpredictable delays experienced by different-sized frames can lead to pauses and jumps in the video playback. A different and faster approach is to reformat all packets into minimalist cells that are a kind of least common denominator. That is the approach behind *asynchronous transfer mode* communications (*ATM*). Because all ATM cells are exactly alike, the routing equipment that shuttles them around the world can be designed to be extremely fast, and the transmission delays for a series of cells will be relatively constant. Video streams can be reassembled from ATM cells with few noticeable delays. High-speed frame relay and ATM communications will be necessary for any large-scale networking that involves sharing large amounts of health information.

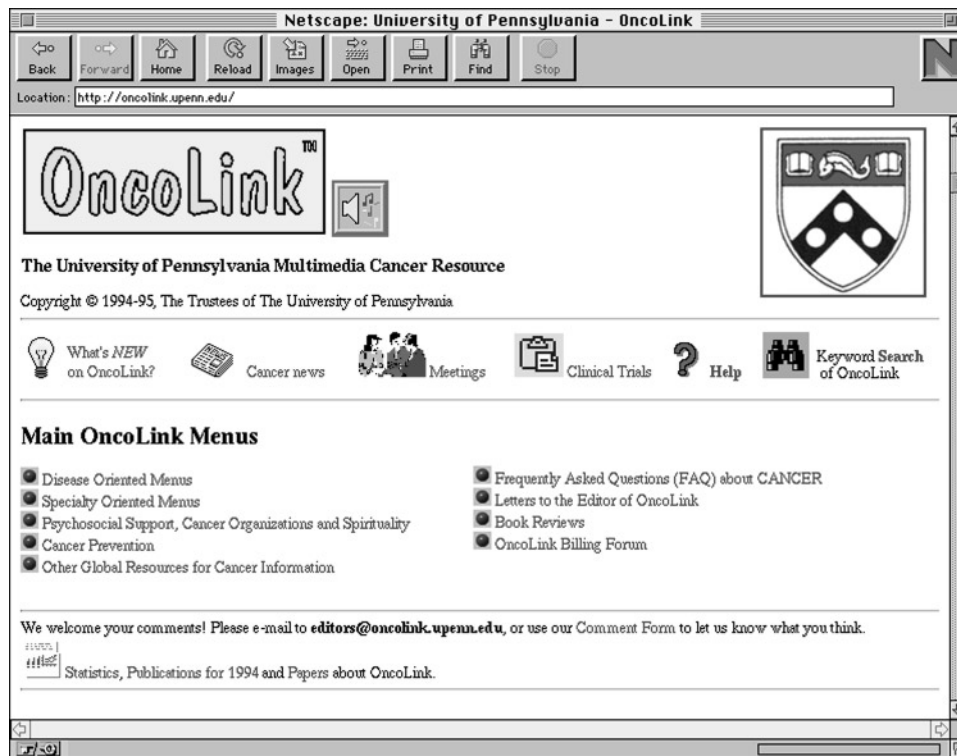
SOURCE: Office of Technology Assessment, 1995, and "The Telecommunications Glossary," Wiltel Communications Corp., April 1995. <URL:<http://www.wiltel.com/glossary/glossary.html>>

chased from an Internet service provider or a commercial online service.

High-bandwidth communications may have a profound effect on the structure and process of health care services analogous to the changes that automated teller machines brought to the banking

industry. Already, *demand management systems* are in place within some integrated HMOs; nurses in centralized locations use telephones to give advice for managing particular health problems to patients located throughout the HMO's service area. Consultative practices such as radiology and

Figure 2-2: Health Information on the Internet



SOURCE: Oncolink, University of Pennsylvania, April 1995. URL: <http://Oncolink.upenn.edu/>

dermatology are slowly beginning to use high-bandwidth communications over dedicated phone lines to practice telemedicine. As switched high-bandwidth connections become widely available, a dramatic change could occur in which the hub-and-spoke topology of most telemedicine networks (with an academic hospital at the hub of most consultations) may dissolve into a more dynamic network, and a competitive market for health advice may emerge. Individuals may eventually be able to get expert information about their health in more convenient ways than from their doctors.

■ Distributed Computing and Object-Oriented Software

Health care information systems, like most other large computer applications, were de-

signed for many years around the capabilities of powerful mainframe computers. Users gained access to information stored in the large databases of a central computer using relatively slow, text-based terminals. Although the central computer might be very fast, it had to perform many duties. Its performance in responding to a user's request for a patient's admission records, for instance, might be slow if it were occupied with another calculation-intensive task, such as preparing a monthly payroll.

As the speed and capabilities of desktop computers and networks have increased, the centralized, hierarchical structure associated with mainframe computers is being replaced in many instances with distributed computing using a *client-server architecture*. The many tasks performed by a monolithic central computer are

decoupled, and the workload dispersed among a series of programs running on a set of smaller computers, or *servers*. Each server handles a specific task, according to requests made by other programs, or *clients*, on the network.

Typically, users interact with client programs running on desktop computers with relatively sophisticated graphics capabilities. A client program for scheduling patient surgery, for instance, might issue requests for information to servers throughout the institution. A request might be for a discrete piece of information, such as the patient's admission date, which could be retrieved from the admissions database. The request could also be more complicated: it could spawn a sophisticated scheduling calculation on an administrative server that itself required information evoked from other servers. The client program melds the information from the various sources and displays it to the user. The data and the computational resources of the information system are distributed throughout the institution rather than being localized in a centralized computer. The failure of any one computer is unlikely to compromise the entire system. In addition, if the admissions server were heavily used, the department might maintain a number of different servers, with the load being passed to the server that is least burdened at a given moment. Thus, capacity can be added incrementally to a client-server network.

Client-server computing replaces large, central computers with interacting networks of servers, each accomplishing specific tasks and communicating with standardized messages. A similar trend known as *object-oriented design* is affecting the internal structure of computer software. Increasingly, developers are decoupling large, multipurpose software applications into sets of interacting *objects*. For instance, a common task for a software designer might be to change the type of information in a record—perhaps making room for nine-digit zip codes instead of five-digit

zip codes. With traditional software design, this type of change might require changing all of the routines that ever manipulate zip codes, including printing routines, file storage routines, sorting routines, and so on. These routines could be scattered throughout the code, and finding and altering them is a difficult and time-consuming project. Moreover, changing any of the routines could have unintended consequences elsewhere in the program for other data that use the same routines. Object-oriented design bundles all of these routines along with the zip code itself into an encapsulated object. Thus, all the zip code routines can be easily changed and tested, without affecting any of the rest of the software in the project.

Ideally, object-oriented design can lead to software code that is modular and reusable. Complicated software applications can be built rapidly from standardized libraries of classes of objects. This new software paradigm may pose significant challenges for regulatory structures governing distribution of medical software. Currently, medical software is regulated by the Food and Drug Administration (FDA) under the same system used for medical devices. Before marketing their products, vendors must register their medical software with the FDA and obtain official approval of its safety and effectiveness. Vendors must document their design process and demonstrate that potential safety hazards associated with software components have been identified and addressed.

Several categories of software are exempt from this process, including general-purpose software such as word processors, software designed for use in teaching, nonclinical research, or private practice, and knowledge-based systems that require human intervention before any impact on human health could occur.⁸⁵ This policy may be adequate for medical software embedded in physical devices or distributed through conventional channels, but it may prove cumbersome as more research institutes become linked by the Internet.

⁸⁵ Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(K) Review" (Washington, DC: 1991).

Software developed for academic research purposes is commonly distributed at no charge to other researchers using a procedure known as *ftp*, or file transfer protocol. In the absence of a clear FDA policy regarding electronic distribution of medical software, concerns that the FDA may treat distributors of free software as medical vendors have delayed the *ftp* distribution of at least one product intended for calculation of radiotherapy treatment doses.⁸⁶

In addition, the policies deal inadequately with software developed using object-oriented design and perhaps assembled from components written by a variety of sources and only assembled by the final vendor. The exemption from regulation for general-purpose software raises the possibility that vendors could avoid FDA oversight of their products by selling a general-purpose “shell” program that could then link together modules with medical functionality that had been distributed via *ftp* at no charge.

Finally, the distinction between *source code* and *object code* for a computer program is becoming a key issue—source code is written in a computer language such as C++ or FORTRAN and can be altered by any competent programmer, whereas object code is a translation of the source code into a form executable by a particular machine. To ensure uniformity of approved software, the FDA has typically allowed vendors to distribute only the object code for their computer programs because it cannot be easily altered by the end-user. A similar restriction on electronically distributed software is problematic, however. Distribution of source code may be protected by the first amendment, and such a restriction would have a burdensome effect on academic research and prevent cross-verification of the soundness of code design by independent groups. The FDA is

currently reviewing and revising its policies on regulation of medical software.

SHARING THE COMMON POOL OF DATA

■ Standards

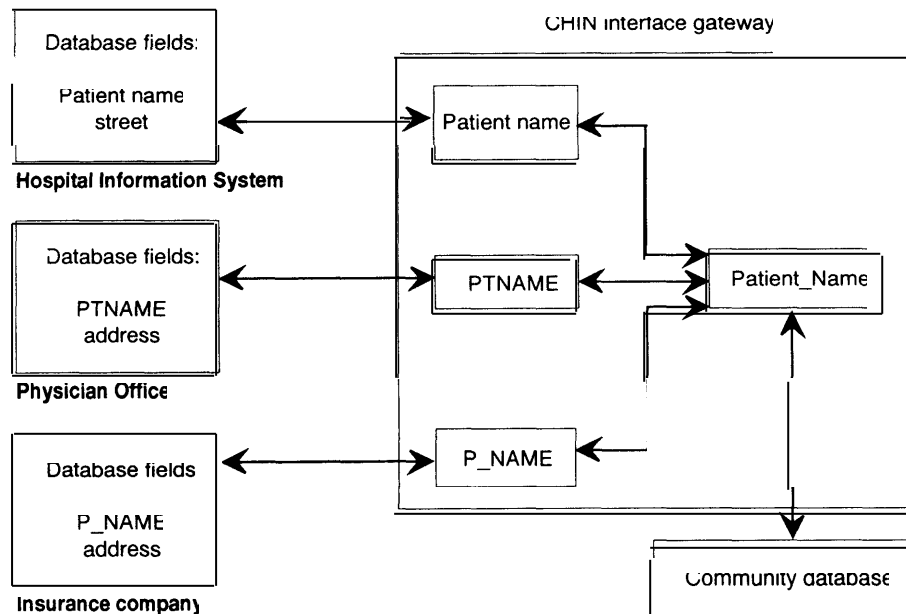
Standards are agreements on how to implement technologies. They allow buyers to choose compatible medical equipment and software from a variety of vendors, and thus encourage both innovation and price competition. Sometimes *de facto proprietary standards* emerge when a single vendor controls a large share of the market for a particular item. *Consensus standards* are developed by committees with representatives from many different stakeholders. The committees can include representatives of vendors, the medical community, the government, unions, and any other interested individuals who choose to participate in the laborious process of writing and agreeing on standards. Standards committees are accredited by organizations such as the American Society for Testing and Materials (ASTM), the American National Standards Institute (ANSI), or by other national or international organizations.⁸⁷ They meet over a period of years and develop drafts that members of the committee vote on after extended revisions and public review. Standards bodies occasionally have problems reaching decisions as rapidly as new technologies are developed.

Understanding consensus standards is complicated in that the name of an individual standard is usually an acronym that reflects the identity of the standards committee, rather than the function of the standard. Figure 2-3 shows the alphabet soup of interrelated *messaging standards* for exchanging data among various parts of a hospital: standards written by ASTM Subcommittee E31.15 specify the format for messages traveling to and

⁸⁶ “Council on Competitiveness Identifies Telemedicine Barriers in Report Summarizing Fall Conference,” *Healthcare Telecom Report*, vol. 3, No. 1, Jan. 2, 1995; and Edward L. Chaney, Professor, North Carolina Clinical Cancer Center, University of North Carolina, personal communication, May 1, 1995.

⁸⁷ A complete description of the standards-setting process can be found in, U.S. Congress, Office of Technology Assessment, *Global Standards: Building Blocks for the Future*, OTA-TCT-512 (Washington, DC: U.S. Government Printing Office, March 1992).

FIGURE 3-5: Federated Database Approach for a Community Health Information System (CHIN)



Note: Systems on the CHIN with their own repositories will require an intelligent gateway to match field names with data
 SOURCE: M. R. Gorsage and J.W. Hoben, "Technological Implications of CHINS," in R.T. Wakerly (ed.), *Community Health Information Networks: Creating the Health Care Data Highway* (Chicago, IL: American Hospital Publishing, Inc., 1994), pp. 115-140.

master or owner of specific data elements is diplomatic and political rather than technological.³⁵

Through use of a common data model, the repository can be mapped onto the various systems of record. Data for different entities can be tied together by using unique identifiers for patients, payers, sites, providers, and other entities.

In time, a central repository containing both clinical and administrative information could become too large to manage efficiently, especially if it includes diagnostic images. An alternative approach to managing community-wide information is to maintain an intelligent central repository that manages a federation of independent databases. All databases would share a common glob-

al model, and the central repository would contain not copies of the transactions, but information on where to find the information. This metatransaction (transactions about transactions) repository would then contact the individual databases to collect information needed by an authorized user, and would have the knowledge needed for resolving any differences between the databases. This concept is illustrated in figure 3-5.

■ Community Networks and Enterprise Networks

There is uncertainty about the role of CHINs as managed care organizations and integrated delivery systems (IDSs) begin to dominate health care

³⁵ Ibid.

from knowledge bases, ANSI X12 standards govern communication of financial data to insurers and others outside the health care institution, the NCPDP standard developed by the National Council of Prescription Drug Pharmacies specifies the format for messages containing pharmaceutical information, and so on. Purchasers of health care equipment and software can more easily build extensible systems by buying items that store and exchange information according to one or more of these consensus standards rather than proprietary standards.

A model of communications published by the International Standards Organization describes seven different levels of computer communications, beginning with physical interconnections and ending with the standards that specify how messages are passed between software applications (the seventh level). One of the most widely used messaging standards is the *HL7 (Health Level Seven) standard* for electronic interchange of health data.

HL7 is explained in more detail in box 2-8. Most of the standards in figure 2-3 are conceptually similar to HL7 and closely related to it. For instance, standards written by ASTM Subcommittee E31.16 specify the format for messages containing neurophysiological data. These messages use the same syntax, and most of the same segments, as HL7 messages, but they include data structures for continuous waveforms such as electroencephalogram traces.⁸⁸ HL7 was originally a standard for communicating laboratory data and other clinical observation data between software applications, but it now includes structures for communicating clinical orders, billing information, and patient admission, discharge, transfer,

and registration information within single institutions.

This suite of standards has brought a modicum of order to the varied approaches to sending messages within and among health care institutions. Each standard defines the structure of messages within a certain jurisdiction. But what happens when a measurement generated by a laboratory instrument and formatted according to the ASTM E1394 standard needs to be passed to a bedside monitor that normally formats information according to the P1073 standard? Individual standard-to-standard translation schemes could be designed, but they would necessarily be in constant flux as the various standards evolve. To address these types of problems, ANSI created a Health Informatics Standards Planning Panel (*HISPP*) in 1993 to coordinate standards development efforts. A number of working groups have formed under the aegis of HISPP, each made up of representatives from organizations involved in developing health messaging standards. One working group, for instance, is developing a framework for a common data model that will serve as an evolving guide and resource for all the various messaging standards. The framework will incorporate the innovations of the various standards committees and harmonize their efforts over the long term using an iterative process.⁸⁹

The messaging standards in figure 2-3 define how messages are communicated, but the content of the messages is set by an entirely different set of standards. Some of these were developed in industrial or scientific settings, such as the “metric system” or *Systemé Internationale* that defines units of measurement. Others are specific to medical contexts. Standards are necessary for coding and

⁸⁸ Moreover, the chair of the group working on automated data within the HL7 committee has agreed to include these same message constructs for transmitting wave forms in HL7 messages, and the same is true for other standards committees. Despite the diversity and multiplicity of committees and working groups, the emerging standards are generally complementary.

⁸⁹ T.E. Rutt, “Work of the IEEE P1157 Medical Data Interchange Committee,” *International Journal of Clinical Monitoring and Computing*, vol. 6, 1989, pp. 45-57, and *Trial-Use Standard for Health Care Data Interchange-Information Model Methods, Data Model Framework, P1157.1 Draft 1* (Piscataway, NJ: IEEE Standards Department, 1994).

BOX 2-8: HL7 and ICD-9-CM

Standards for interchanging health data and assigning codes to medical concepts underlie all efforts to make patient records electronically accessible. This box presents one of the major messaging standards (*HL7—Health Level 7*) and one of the major coding standards (*ICD-9-CM—International Classification of Diseases, 9th Revision, Clinical Modification*). These are representative examples, but HL7 is only one of the many messaging standards used to convey health data, and ICD-9-CM is one of the two major coding systems used in the United States.

Messaging standards specify the *syntax* of an electronic message and coding standards specify its *semantics*. A similar distinction exists for more familiar messages, such as postcards. The syntax of a postcard corresponds to the arrangement of its elements: the addressee's name appears in a standard position, the city in another, the message is placed in a box on the left half and the stamp in the upper right, and so on. The arrangement is set by international postal conventions. The meaning of the letters appearing within a given element (its semantics) is determined by an entirely different set of conventions, namely the language employed by the correspondent. Similarly, HL7 and other messaging standards specify the order of the many discrete elements that make up a message and indicate which elements are required and which are optional. ICD-9-CM and other coding systems assign meaning to the characters in the message.

Electronic Messages

HL7 messages are streams of text that are relatively simple to interpret. As an example, the portion of the message that carries the patient's address might be represented as "...1432 Hosteler Street 'Apt 232' Chicago IL 60603 USA... ". In addition to demographic information identifying the patient, an HL7 message delivering the results of a laboratory test might include hundreds of other data elements containing numerical values for the measured parameters, the measurement units, and portions of the message that bore the initial request so that the request and response can be matched and reconciled. The data elements contain internal indications of the coding standards to be used. For instance, one small portion of the standard message defined by HL7 contains the patient's diagnosis. This slot might be filled with the characters "410.119C. ". The software application receiving this message knows from the position of the characters within the message that this is a diagnosis, and it simply has to assign meaning to the character by looking up diagnosis number 410.1 in the set of codes published by the ICD-9-CM Committee. The table would indicate that the diagnosis is "(anterior myocardial infarction. ". Alternatively, the same diagnosis could be conveyed in a different coding scheme employing an entirely different code set, but still using the same HL7-defined structure. This allows the software application sending a message to choose whatever coding scheme is most appropriate for the data it processes. Libraries of disease and procedure descriptions can evolve without necessitating any changes in the software governing how messages are sent.

(continued)

A model of communications published by the International Standards Organization describes seven different levels of computer communications, beginning with physical interconnections and ending with the standards that specify how messages are passed between software applications (the seventh level). One of the most widely used messaging standards is the *HL7 (Health Level*

Seven) standard for electronic interchange of health data.

HL7 is explained in more detail in box 2-8. Most of the standards in figure 2-3 are conceptually similar to HL7 and closely related to it. For instance, standards written by ASTM Subcommittee E31. 16 specify the format for messages containing neurophysiological data. These mes-

BOX 2-8: HL7 and ICD-9-CM (Cont'd.)

Clinical Coding Systems

Codes are an attempt to standardize the description of clinical practice so that diagnoses or procedures relevant to different patients can be compared side-by-side. They are used for both research purposes and reimbursement of claims. ICD-9-CM codes are widely used to describe inpatient treatments in hospitals, and *CPT-4* codes (Physicians' Current Procedural Terminology, 4th Edition) are used by physicians and other health care professionals for billing purposes. The ICD-9-CM codes are a combination of the ICD-9 diagnostic code set maintained by the World Health Organization for describing diseases and a set of codes for medical procedures maintained by the Health Care Financing Administration (HCFA). HCFA requires that ICD-9-CM diagnostic codes be used for itemized Medicare inpatient and ambulatory care claims, and it determines payment levels based on the grouping of treatments, according to the procedure codes, into *Diagnosis Related Groups (DRGs)*.

Medical coders are employed in hospitals to assign codes to the procedures described in patient records following guidelines published by the American Hospital Association. It is a very complex and sophisticated task. Although there are some aspirations to automate the coding process by assigning codes through computer analysis of clinical orders, it is likely that information technologies will be more commonly used to assist medical coders rather than to replace them. Decision-support systems known as *encoders* are commercially available starting from an initial suggested code, they prompt the coder to investigate related codes and check to make sure that the group of codes ultimately assigned is internally consistent. *Groupers* are software applications that deduce from the final set of assigned codes a DRG, which is the basis for Medicare or other Insurance reimbursement. Finally, many coders use online libraries of coding reference manuals.

Current coding systems have been criticized as too imprecise to describe some aspects of clinical practice. Another common criticism is that the terminology used in various codes is inconsistent. Currently, Medicare reimbursements depend only on the primary DRG without regard for the significant extra expense involved in caring for a patient with a complicated secondary diagnosis. Future revisions of ICD-9-CM may address these problems to some extent. The 10th revision will attempt to incorporate standard clinical definitions used throughout its specifications, and DRGs will be *severity refined* so that reimbursements can more accurately reflect the cost of treating the patient. In recognition of the increasing importance of ambulatory care as managed care institutions seek to minimize the number of hospital admissions, HCFA is also developing a new set of codes for use in outpatient care.

SOURCES: C.J. McDonald, D K Martin, and J.M. Overhage, "Standards for the Electronic Transfer of Clinical Data Progress and Promises," *Topics in Health Records Management*, vol. 11, No. 4, 1991, pp. 1-16, B. Siwicki, "Coding Changes on the Horizon" *Health Data Management*, vol 3, No. 1, 1994, pp. 42-43

sages use the same syntax, and most of the same segments, as HL7 messages, but they include data structures for continuous waveforms such as electroencephalogram traces.⁸⁸ HL7 was originally a

standard for communicating laboratory data and other clinical observation data between software applications, but it now includes structures for communicating clinical orders, billing informa-

⁸⁸ Moreover, the chair of the group working on automated data within the HL7 committee has agreed to include these same message constructs for transmitting wave forms in HL7 messages, and the same is true for other standards committees. Despite the diversity and multiplicity of committees and working groups, the emerging standards are generally complementary.

der way to facilitate that expansion. One example is the nonprofit Healthcare Open Systems and Trials (HOST) consortium.⁹⁰ HOST is establishing test sites for deployment of new information technologies at medical institutions and an Open Systems Laboratory where the compatibility of various technologies can be demonstrated. The HOST consortium has recently received a grant through the Advanced Technology Program (ATP) at the National Institute of Standards and Technology, which is also funding several other projects that develop or implement novel information technologies for use in the health care system.⁹¹

Integration of the various technologies and standards into working systems is also one focus of the High-Performance Computing and Communications (HPCC) program. This multiagency federal effort was initiated by the President's Office of Science and Technology Policy during the Bush Administration and expanded by legislation introduced by then-Senator Albert Gore. The National Science Foundation (NSF), National Aeronautics and Space Administration (NASA), National Institutes of Health (NIH), and other agencies participating in the HPCC program support the development of the underlying technologies essential for telemedicine and other health care applications of the National Information Infrastructure, including the National Research and Education Network (NREN), pilot implementations of advanced information technologies in health care settings, and supercomputer centers.⁹² Recent HPCC grants through NLM have funded research leading to implementation of computer-based patient records in the Indianapolis metro-

politan area,⁹³ creation of a statewide digital network to support telemedicine and rural health care providers in Iowa,⁹⁴ development of advanced computer simulations of human anatomic structure to support surgical planning and medical education, and numerous other projects.

Population-based public health services may also benefit from the development of standards and technologies that will enable health information to flow freely. Advanced techniques for knowledge discovery in databases may be applied to help automate the identification of public health threats, such as the recent Hantavirus outbreak that was identified through a medical examiner surveillance database maintained by the Centers for Disease Control and Prevention (CDC). A small number of grants supporting the development of public health applications have been awarded by the National Telecommunications and Information Administration, and other integrative work is proceeding with support from CDC, AHCPR, the U.S. Public Health Service, and other agencies.

POLICY ISSUES AND OPTIONS

The technologies for collecting, distilling, storing, securing, and communicating data are widely used throughout American industry. They are used in health care organizations as well, but their application has been limited to scattered islands of automation. Despite the incorporation of high technology into almost every other aspect of clinical practice, information technologies have not been fully embraced.

The health care delivery system has several unique characteristics that discourage the spread

⁹⁰ The HOST consortium has over 30 corporate and academic partners. It was co-developed in 1994 by the Microelectronics and Computer Technology Corporation (MCC) and the Computer-based Patient Records Institute.

⁹¹ B. Deming, "Launching a High-Profile Automation Mission," *Health Data Management*, vol. 3, No. 5, May 1995, pp. 15-19.

⁹² D.A.B. Lindberg and B.L. Humphreys, "The High-Performance Computing and Communications Program, the National Information Infrastructure, and Health Care," *Journal of the American Medical Informatics Association*, vol. 2, No. 3, 1995, pp. 156-159.

⁹³ J.M. Overhage, W.M. Tierney, and C.J. McDonald, "Design and Implementation of the Indianapolis Network for Patient Care and Research," *Bulletin of the Medical Library Association*, vol. 83, No. 1, 1995, pp. 48-56.

⁹⁴ M. Kienzie et al., "Iowa's National Laboratory for the Study of Rural Telemedicine: A Description of Work in Progress," *Bulletin of the Medical Library Association*, vol. 83, No. 1, 1995, pp. 37-41.

of information technologies. Clinical practice is extremely complex, and despite the efforts of standards committees, *no unified conceptual model exists that is powerful enough to guide the creation of computer databases that adequately represent medicine as it is practiced*. No consensus has emerged on what information should be kept in electronic patient records, how detailed it should be, or how it should be described and indexed.

It is not a lack of appropriate hardware that limits or impedes productive computing in health care services. Rather, it is a failure to understand the intricacies of health care delivery as related to capture and use of medical data, and the ways in which they must be manipulated. Hence, what is put into software, and thus the software itself, does not adequately reflect the real needs of health care providers or the ways in which they conduct their activities.⁹⁵

Experience gained in solving problems in one area of medical practice may not be applicable to other areas. A clear example of this occurs with decision support systems. Self-contained, rule-based systems are widely used in well-defined areas such as infection diagnosis and in some medical equipment, but attempts to extend the scale of decision support to broader areas of medical expertise have been frustrated. This resembles the general pattern of medical research: narrow problems are solved on a local basis. The result is an idiosyncratic vocabulary and nonuniform clinical practice. Perhaps medical informatics works best at solving a large number of microproblems. If so, efforts should turn toward smoothly integrating all the microsolutions.

In addition to the complexity of clinical knowledge, *the structure of the health care industry discourages implementation of information technologies*. Providers of health care services are often isolated in separate corporate entities from

the insurance companies that pay them for their services. Providers and payers are further isolated from the medical research community, government health care agencies, and public health organizations. A network of private sector intermediaries has formed to facilitate the complicated relationships between the various organizations. None of these entities is likely to be willing to collect or organize data that saves money or effort for some other organization, but delivers it no immediately useful benefit; systemic savings may be irrelevant in a vertically fractured industry. In addition, many communities have only a few hospitals or major insurers. The cooperation necessary to interconnect medical information within a horizontal layer of the health care system may be seen as anticompetitive and subject to antitrust regulation, or it may be hindered by organizations that regard their internal information systems as competitive advantages and accumulated patient records as corporate assets.

Information technologies tend to flatten organizations and may not mesh well with the rigidly defined job roles and hierarchical structure of current clinical practice. As an example, a patient records system was installed at the University of Virginia Medical Center that required clinicians to enter medical orders on computers. This had an unexpected effect on the education of fourth-year medical students who are often allowed to place orders for a patient's care with the approval of a resident physician. With paper records, this had been a simple matter that saved time for the resident and gave satisfying responsibility to the students: the student drew up a list of potential orders, consulted the resident, and had the list approved. With computerized order entry, the process was much more cumbersome. Each order was issued separately and needed to be approved separately. This meant either calling a resident multiple times to approve individual orders or placing

⁹⁵ T.L. Lincoln, D.J. Essin, and W.H. Ware, "The Electronic Medical Record: A Challenge for Computer Science To Develop Clinically and Socially Relevant Computer Systems To Coordinate Information for Patient Care and Analysis," *The Information Society*, vol. 9, 1995, pp. 157-158.

orders in suspension one by one and then finding ways to reassemble them for a single consultation with the resident.⁹⁶

It might be argued that changes to the design of the system, or implementation of a records system more carefully tailored to support desired work patterns, could alleviate this specific problem. Nonetheless, the deeper issue is that completion of every detail of order entry is a new and perhaps unwelcome task for physicians. To some extent, all information systems that deliver information to a clinician at the point of care also require simultaneous collection of information by the clinician at the point of care. Job descriptions will change as decisionmaking, authorizing actions, and entering data become more tightly linked:

In contradistinction to the retail sector, which can assign relatively inexperienced employees to data-entry positions [and create competitive advantages by capturing data at the point of sale], the health care sector places the most highly trained professional personnel with the greatest opportunity cost in the data-entry role.⁹⁷

Changes in job roles will occur throughout the health care system, should information technologies be widely adopted. These changes will be accompanied by redistributions in health professionals' time and by shifts in the responsibilities and status associated with the various health disciplines.

Information technologies may have more subtle ramifications as well. *The widespread adoption of integrated information systems will challenge the legal system.* Patients are the consumers of health services, and their traditional protection against poor-quality care has been the ability to file lawsuits against their providers. Information technologies are tools for providing health care, but they are maintained and employed by a variety of people who may be geographically

separated. Who is responsible if a treatment protocol recommended by a decision support system turns out to be injurious? Is it the academician who designed the protocol, the reviewers who approved its publication, the insurance company that insisted it be implemented, the hospital board that approved its use, the interface designer who failed to provide contextual information that could have contraindicated its use, or the primary physician who employed the protocol, but may have had no knowledge of its deficiencies? And if no one can be held directly accountable, what alternative system of quality control must be designed to replace the current legal remedies? Information technologies diffuse responsibility, and changes in the hierarchical way that medical care is practiced may be necessary before they are fully embraced.

Finally, *information technologies are expensive to implement and their benefits may be difficult to measure directly*, even when all parties are happy with the results. This may help delay their deployment in an industry whose sophisticated technological base is seen by some to be a driving force in making health care more expensive.

■ Opportunities and Challenges

Given these obstacles, installation and efficient utilization of information technologies in health care will continue to be incremental and difficult. However, there are a number of reasons why Congress may wish to actively support this process.

First, *implementation of information technologies could lead to reductions in federal health care expenditures.* The federal government is a major purchaser of health care through Medicare and Medicaid, and a major integrated provider and payer through its health care programs for military personnel, veterans, and Native Americans. While individual private sector organizations par-

⁹⁶ T.A. Massaro, "Introducing Physician Order Entry at a Major Academic Medical Center: II. Impact on Medical Education," *Academic Medicine*, vol. 68, No. 1, 1993, pp. 25-30.

⁹⁷ T.A. Massaro, "Introducing Physician Order Entry at a Major Academic Medical Center: I. Impact on Organizational Culture and Behavior," *Academic Medicine*, vol. 68, No. 1, 1993, pp. 20-25.

ticipating in health care delivery may find it difficult to realize financial benefits from systemic changes, the federal government is ideally situated to recoup whatever costs might be incurred in encouraging adoption of information technologies at all levels of health care delivery by substantially reducing its own health care costs. Researchers and others have suggested that multi-billion-dollar annual savings might be possible with increased use of information technologies in health care. Chapter 3 discusses these projections for administrative savings.

Information technologies may also foster competition in the health care industry. Chapter 4 discusses ways that advanced information technologies can be used to evaluate the effectiveness of health care procedures and the efficiency of health care organizations. Although these techniques for quality assessment are highly problematic, they may represent an unprecedented metric by which organizations and practices can be compared and contrasted, thereby enabling consumers and managers to make more informed choices concerning their health care.

Implementation of information technologies may help increase access to health care through private sector activities. Chapter 5 discusses ways that information technologies may allow health care providers to extend their reach in the communities they serve through telemedicine or other means for electronic delivery of services. In addition, new technologies may help decentralize health care by increasing the flow of useful information to primary care doctors so that more people can have access to state-of-the-art health care without resorting to hospital or emergency room care. This consideration is especially important in rural communities and inner-city communities where the viability of large health care institutions is uncertain.

Finally, *information technologies could lead to systemic changes and opportunities that will en-*

able the American health care system to better serve its citizens through more convenient and perhaps less expensive delivery of health services. Some of the benefits and conveniences (as well as some of the drawbacks) of health care enhanced by information technology were envisioned in the fictional scenario at the beginning of this chapter. Many others will only become apparent once a broad information infrastructure is in place. Every new tool contains embedded ideas that go beyond the function of the tool itself.⁹⁸ When personal computers were developed, there was little indication or intention that they would rapidly develop into tools for individuals to publish and access information across the globe; the federal government played an important role in that development through its support of the development of the Internet's predecessors.

There are indications that similar dynamics will emerge as the health information infrastructure continues to evolve. One example of this appears in the area of pharmaceuticals. The volume of pharmacy claims is much greater than the number of claims for clinical procedures, and pharmacy claims are also much simpler to process than other claims. Two crucial enabling standards exist: the National Council of Prescription Drug Pharmacies (NCPDP) has developed a widely accepted standard for communication between community pharmacies and claims processors, and the FDA has defined the National Drug Code that specifies a unique code for each drug. As a result, pharmacy claims were one of the earliest areas to be computerized. Today, over 90 percent of community pharmacies are connected online to at least one third-party pharmaceutical claims processor.⁹⁹ This connectivity led to the expected administrative savings due to elimination of paperwork and automation of eligibility verification and inventory replenishment, but it also had the relatively unforeseen benefit of making avail-

⁹⁸ N. Postman, *Amusing Ourselves to Death: Public Discourse in the Age of Show Business* (New York, NY: Viking Press, 1985), p. 30.

⁹⁹ C.J. McDonald, "News on U.S. Health Informatics Standards" (letter), *M.D. Computing*, vol. 12, No. 3, 1995, pp. 180-186.

to savings in pharmacy expenditures for many providers using PBMs, although some studies have shown that savings are sometimes offset by increased use of other, more expensive services such as hospital outpatient, inpatient, or emergency services.¹⁰⁰ Information technologies have led to significant changes in the distribution and purchasing of pharmaceuticals, such as the development of formularies, or lists of preferred drugs, and the widespread use of generic drugs and drugs discounted by manufacturers. The implementation of information systems has had a broad impact even on pharmaceutical research and development because it has encouraged development of novel drugs and generic drugs, but made it less attractive to develop new entries for drug categories with numerous existing products.¹⁰¹ Computerization of pharmacy transactions presents an opportunity for addressing more comprehensive health maintenance issues, such as patient compliance with drug therapies, because physicians could be informed when their patients fail to renew prescriptions or when they obtain additional drugs prescribed by other caregivers. Freely flowing health information may have large implications for both the creativity and the competitiveness of the health care industry.

■ Policy Options

If Congress wishes to support and affect the diffusion of information technology in health care settings, it could consider a number of options.

OPTION 1: *Support standards-setting activities*

Congress may wish to participate in or monitor efforts to set standards for implementation of information technologies in the health care system. Congress could:

- support the development and adoption of consensus standards for electronic messaging and clinical coding. This could be achieved by directing agencies to supply personnel to actively participate in standards-setting meetings and to develop aggressive timetables for government implementations of consensus standards. Tax credits could also be extended to encourage the purchase of information systems that implement consensus standards.
- support the development of coding systems and nomenclatures necessary for communicating the content of patient records. This could be done by continuing to fund the development of the Unified Medical Language System and related efforts at the National Library of Medicine.
- ensure that technical standards for the content of patient records and for minimum levels of privacy and confidentiality meet privacy policy goals. This mission could be delegated to: 1) a special task force made up of technology, privacy, and health information experts; 2) a committee charged with an ongoing review of health information privacy issues; or 3) an existing committee, such as the Health Information and Applications Working Group of the Information Infrastructure Task Force (IITF).

OPTION 2: *Fund and coordinate research efforts to overcome specific technological barriers.*

Most of the technologies discussed in this chapter have been developed through corporate or academic research that was not connected directly to health applications. As a result, some areas, such as human-computer interface design for use in medical contexts, are not well developed and

¹⁰⁰ C.M. Kozma et al., *PharmacoEconomics*, vol. 4, 1993, pp. 92-103, 187-202.

¹⁰¹ Judith L. Wagner, Senior Associate, Health Program, Office of Technology Assessment, testimony presented before the Committee on Finance, U.S. Senate, hearing on Long-Term Care and Drug Benefits Under Health Care Reform, Apr. 19, 1994.

¹⁰² U.S. Congress, Office of Technology Assessment, op. cit., footnote 43, p. 20.

may pose difficult problems in the implementation of integrated systems. Congress could encourage research into these areas by creating focused programs administered by the National Science Foundation, the National Institutes of Health, or other agencies providing traditional peer-reviewed research grants. In addition, Congress could support research into large-scale implementation of information technologies in health care settings through pilot programs and testing centers.

OPTION 3: *Coordinate federal efforts to implement health care information technologies.*

This coordination could be achieved through existing agencies and committees or through the establishment of a special committee or commission. In particular, the relevant bodies might be charged to:

- establish procedures for expediting approval and distribution of medical software. Faulty software is as dangerous and worthy of regulation as poorly designed medical hardware, but software has the unique feature that it can be developed incrementally and distributed electronically.
- establish mechanisms (or support similar private sector efforts) for reviewing and disseminating clinical protocols.¹⁰³
- advise Congress on specific needs of the clinical community with respect to legislation establishing regulations and policies pertinent to information technologies. Current issues that fall under this rubric are liability reform and telecommunications deregulation legislation.
- establish policies consistent with privacy policy goals for implementation of uniform patient and provider identifiers for use in federal agencies.

¹⁰³ For further discussion, see chapter 4.